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Dottorato in Studi Giuridici  
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XXV cycle

Ph.D. thesis

**“Synthetic biology, concerns and risks:  
looking for a (constitutionally oriented)  
regulatory framework and a system of  
governance for a new emerging technology”**

*Thesis supervisor:*  
*Prof. Carlo Casonato*

*Ph.D. Candidate:*  
*Ilaria Anna Colussi*

Academic Year 2011-2012





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**Examination Board:**

Prof. Lorenzo Chieffi, University of Naples

Prof. Aitziber Emaldi Ciri3n, University of Deusto/Bilbao

Prof. Alessandra Magliaro, University of Trento

Prof. Federico Gustavo Pizzetti, University of Milan



“When you set out on your journey to Ithaca,  
pray that the road is long,  
full of adventure, full of knowledge.  
The Lestrygonians and the Cyclops,  
the angry Poseidon - do not fear them:  
You will never find such as these on your path,  
if your thoughts remain lofty, if a fine  
emotion touches your spirit and your body.  
The Lestrygonians and the Cyclops,  
the fierce Poseidon you will never encounter,  
if you do not carry them within your soul,  
if your soul does not set them up before you.

Pray that the road is long.  
That the summer mornings are many, when,  
with such pleasure, with such joy  
you will enter ports seen for the first time;  
stop at Phoenician markets,  
and purchase fine merchandise,  
mother-of-pearl and coral, amber and ebony,  
and sensual perfumes of all kinds,  
as many sensual perfumes as you can;  
visit many Egyptian cities,  
to learn and learn from scholars.

Always keep Ithaca in your mind.  
To arrive there is your ultimate goal.  
But do not hurry the voyage at all.  
It is better to let it last for many years;  
and to anchor at the island when you are old,  
rich with all you have gained on the way,  
not expecting that Ithaca will offer you riches.

Ithaca has given you the beautiful voyage.  
Without her you would have never set out on the road.  
She has nothing more to give you.

And if you find her poor, Ithaca has not deceived you.  
Wise as you have become, with so much experience,  
you must already have understood what Ithaca means”.

(C. Kavafis)

*Dedicated to this Ph.D.:*  
*a hard, but in the end rewarding journey,*  
*that gave me the opportunity to travel around the world,*  
*meet brilliant people, experience life in many of its facets,*  
*including pain, discouragement, hope, persistence, satisfaction,*  
*and let me taste a bit of the anxiety, the thirst and beauty of research.*





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## ABSTRACT

Synthetic biology occupies a relevant position among the new emerging technologies. The potential applications of this field of research, characterized by the adoption of an engineering approach to life, together with a trend to converge between different technologies, span several fields. However, it could also generate numerous risks.

This thesis aims at individuating a regulatory framework and a model of governance for addressing the risks and concerns arising within synthetic biology area. This is to ensure that the progress is not hindered but, at the same time, the problematic issues are not neglected or under evaluated. The suggested model is named “*prudent vigilance*” (inspired by the report about synthetic biology, drafted by the U.S. Presidential Commission on Bioethics, 2010), and it entails an ongoing and periodically revised process of assessment and management of all the risks and concerns, taking into account the interests of all the stakeholders in a dynamic, cooperative, democratic, open and transparent manner. Furthermore, it suggests the adoption of policies that are based on the principle of proportionality (among benefits and risks) and on a reasonable balancing between different interests and rights at stake. These policies should be taken through “hard law” and “soft law” sources, thus involving “actors” at all levels (governments, institutions, the scientific community and general public), and the enforcement and control of those policies should be exercised by judges coupled with independent professional bodies, where all the stakeholders are represented. The policies should also be oriented by a constitutional frame, that is represented by the protection of fundamental human rights emerging in the field of synthetic biology (right to life, right to health, dignity, freedom of scientific research, right to environment).

After the theoretical explanation of the chosen model, the operability of it is “checked”, by considering, as a case study, its application with reference to a specific risk brought up by synthetic biology – biosecurity risk, i.e. the risk of bioterrorism.



## INTRODUCTION

*“The technology does not keep the man away from big problems of nature,  
but it obliges him to study them more deeply”*

*(A. de Saint-Exupéry)*

Science and technology are continuously evolving and the progress made by research in the recent decades has allowed for a significant improvement of one's living conditions. The scientific results obtained at theoretical level, far from remaining confined to a purely abstract level, have “entered” different spheres of reality and had found practical applications in several fields. This situation rouses the interest of society and of the law. The latter is an integral part of society and lives in the dynamism of it. The purpose of the law in this context is to regulate the innovations that science brings each day and to deal with the underlying cultural changes that science produces. It is at these crossroads that the innovative feature of science and technology meets the “tidy” character of law which, by its intrinsic nature, has the tendency of settling the world. Indeed, science and technology challenge the law and the law cannot avoid facing the new issues that emerge as a result of - or thanks to - theoretical insights and practical “translations” that science brings to the table. For this reason, the law is called upon to look for legal solutions and legal principles, so as to provide adequate protection to the various stakeholders. Hence, the relationship between science, technology, law, society and the individual should be one of synergy.

Among the latest developments of science and technology, there is an emerging field that has opened the doors of the 21<sup>st</sup> Century, «*a game changing*

*scientific development that transcends all in human history. It is already underway and it even has a name: synthetic biology»<sup>1</sup>.*

With Watson's and Crick's discovery of double-helix structure of DNA<sup>2</sup>, together with the studies of genetic engineering (focused on isolating a single gene and manipulating it), and the analysis of short and long pieces of DNA of many organisms (object of attention by molecular biology), the field of science has entered into a new era. It starts from the idea of looking at the whole genome of organisms and takes it a step further, going beyond the trying to understand and know the genome to the idea of manipulating it by the writing and re-writing the genome. Such a new "revolution" is known as synthetic biology, a discipline that – to put it provocatively - seems to be capable of realizing the ancient human dream of being able to create life and finding the answer to the mystery that is life.

The term "synthetic biology" was used for the first time, over a hundred years ago, by Stéphane Leduc<sup>3</sup>. However, the field of synthetic biology is still at the infant stage and its definition is far from simple and far from definite. This notion is captured rather eloquently by Kristala Prather, who affirms that: «*If you ask five people to define synthetic biology, you will get six answers*»<sup>4</sup>. Being an emerging science and technology, it is understood that there are many attempts, and thus many different formulations of its definition. However, in trying to explain what it is, it can be observed that the purposes of synthetic biology are to redesign existing biological systems, improving their properties and making them more advantageous than what they are in a "natural" state, and, most of all, to design completely new parts and devices, that are artificial and non existing in nature as such.

In its attempt to reach these targets, synthetic biology assimilates the knowledge coming from different fields, such as biology, genetics, engineering, nanotechnology, computer sciences, biotechnology, and chemistry. The main characteristic of synthetic biology is its adoption of an engineering approach to life.

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<sup>1</sup> D. SASSELOV, *What will change everything?*, 2009, at <http://www.edge.org/response-detail/11143> (last visited 28th January 2013).

<sup>2</sup> It can be noted that currently DNA double helix is challenged by the finding in human cells even a quadruple structure. See G. BIFFI, D. TANNAHILL, J. MCCAFFERTY, S. BALASUBRAMANIAN, *Quantitative visualization of DNA G-quadruplex structures in human cells*, in *Nature Chemistry*, 20<sup>th</sup> January 2013.

<sup>3</sup> S. LEDUC, *La biologie synthétique*, Paris, 1912.

<sup>4</sup> K. Prather, quoted in EDITORIAL, *What's in a Name?*, in *Nature Biotechnology*, 27, 12, 2009, p. 1071-1073.

With such a converging and multidisciplinary approach, synthetic biology lies at the intersection of different areas of research. It is, on the one hand, a biology that turns into technology where living organisms are designed as “machines” to manipulate, miniaturize, study, simplify and transform. While simultaneously, on the other hand, it is also a technology that turns into a form of biology, where technological structures are increasingly acquiring some characteristics referred to living beings.

Synthetic biology first captured a global attention in May 2010, when Craig Venter<sup>5</sup> announced the birth of “Synthia”, the first synthetic cell. It is a synthetic cell, because (a) its genetic material is a result of the computer generated chemical synthesis of a bacterium genome, and (b) this genetic material is subsequently transplanted into a living cell, so as to have a cell with a self-replicating chromosome which can replicate this artificial genetic material. After Venter’s “Synthia”, this new and emerging field of synthetic biology rises rapidly to the forefront of the cutting edge of science and technology.

The applications of synthetic biology are vast and numerous. There are research groups working on finding reprogrammed bacteria, which might be capable of fighting cancer and other diseases, and producing new therapeutic devices or new drugs. There are others focusing on the creation of microorganisms for “eating” pollution from palaces and monuments. Others have thought of using it to produce new types of energy, as an alternative to the “traditional” forms, and for removing parasites in environment, or for creating more nutritional food. As with all things new, it raises the question of ethics and government.

Alongside the potential benefits, synthetic biology also brings with it its own set of risks and concerns, especially in the case of malevolent use. Firstly and most importantly, there are safety and security concerns regarding the accidental release of these synthetic organisms (biosafety), and the risk of a voluntary creation of pathogens that could be able to spread diseases and become weapons for bioterrorist purposes and within biowarfare programmes (biosecurity risk). Then there are the

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<sup>5</sup> As known, Craig Venter is an American scientist who is famous for travelling around the world since 2003 with his boat in search of fragments of DNA from sea beds, and for contributing to the sequencing of human genome in competition with a parallel public project (see J. VENTER ET AL., *The Sequence of the Human Genome*, in *Science*, 291, 5507, 2001, p. 1304-1351. About the “competition” between Venter (with private funding) and Collins (with public funding) for the sequencing human genome, see M.A. SHAMPO, R.A. KYLE, *J. Craig Venter—The Human Genome Project*, in *Mayo Clinic Proceedings*, 86, 4, 2001, p. e26-e27).

ethical concerns regarding the idea of scientists “playing God” by crossing the limits of human manipulation of life and thus altering the notion of life. Finally, there are also the issues regarding intellectual property rights, the economic exploitation of inventions and discoveries coming from synthetic biology, and the possibility of an ever widening the gap among rich and poor countries with respect to the access to synthetic biology applications.

So, in view of these problematic issues regarding safety, security, environmental, social, economic, ethical nature, the intervention of the law is deemed to be useful and necessary. Within the existing legal and governance frameworks, it is of utmost importance to understand how the use and impact of synthetic biology can be accommodated. It is also necessary to determine which framework is the most suitable in order to ensure the proper development of synthetic biology and, at the same time, assess its potential risks.

The world is at the cusp of a new breakthrough in science and technology. In the light of precedent experiences (such as the case of genetic modified organisms), it would be prudent at this current moment to begin the discussion of the governance and legislation of this new and emerging field. This would effectively reduce the time gap between scientific discoveries and legal, socio-economic, and ethical reflection.

In contribution to the current debates on synthetic biology, this thesis aims to (1) look at synthetic biology from the perspective of comparative constitutional law, without neglecting to give some attention to the contribution of other discourses, such as from ethics, sociology, and economics, that play a meaningful role in an interdisciplinary debate, which is required by the unique nature of synthetic biology, (2) delineate a system of regulation and governance, with special consideration for the relevance of Constitutional principles and fundamental human rights, of the risks and concerns posed by synthetic biology.

This thesis adopts the structure in accordance to a “Russian Matrioška model” by presenting and analysing the law within the field of synthetic biology in its broadest and most general sense and work towards a thorough discussion, in the form of a case study, of a particular aspect of the law as applied to a specific concern in the field.

This thesis will be structured as follows:

1. *Synthetic biology between evolution and revolution*. The first chapter concentrates on the description of synthetic biology, focusing on its (a) definition, (b) approaches and methods, (c) potentialities, benefits, and applications, (d) risks, of which the problems related to biosafety, biosecurity, intellectual property rights, and the socio-economic and ethical issues will be established in greater detail.

2. *The Governance of Concerns and Risks Arising in the Context of Synthetic Biology*. The second chapter aims to look for a model of governance for addressing risks and concerns of synthetic biology.

The chapter is subdivided in two parts:

a) an evaluation of the current approaches of the law in the management of the risks and concerns of synthetic biology. This section begins with a reframing of risks and concerns within synthetic biology and while keeping in mind that those risks are difficult to be determined with sufficient certainty. It is followed by an analysis of the “traditional” model of addressing risks which is applied in literature for any kind of risk in the fields of industrial, banks and environmental. This model consists of different phases, that are “risk assessment, risk management and risk communication”. This analysis will check its applicability to synthetic biology by looking in detail at the workings of this model in its different phases. In particular, I will examine the phase of “risk management”, i.e. the phase of policy, where my preference is given to the pattern of “*prudent vigilance*” (inspired by the report about synthetic biology, drafted by the U.S. Presidential Commission on Bioethics, 2010). In order to demonstrate its content, validity and applicability, I will compare it with other principles, i.e. the precautionary principle, the proactionary one and the cost-benefit or risk-benefit analysis, that are usually invoked in similar contexts. With this description of the theoretical features of each of these other approaches, an overview of their employment at the legislative and judicial level will be offered with a specific attention to international law, European Union law and some meaningful national cases (the U.S., the U.K. and Italian legal systems, which are chosen for their relevance for the purpose of the chapter). This comparison is aimed at showing the approaches that have been adopted so far at different levels and at understanding the context where “*prudent vigilance*” model ought to be inserted.

b) an evaluation of who should be responsible for applying the chosen model of governance and of the manner in which the model of governance is adopted. I will deal with the issues regarding the actors that should give application to the model of “*prudent vigilance*” and the sources of law, that are the most suitable to be adopted. With regards to the decision-making process, the preference goes for a mixed model of “hard law” and “soft law”, and for a hybrid approach of “top down” and “bottom up”. It is an approach in which the actors at stake are the legislator, the scientific community and the public. The statutory source is activated but at the same time a regulative space for codes of conduct, guidelines and other self-regulatory sources is granted. As for the phase of enforcement, oversight and control, the role of judges together with government bodies, independent professional bodies and multi-stakeholders ones in which the different components of society are represented is preferred.

3. *The Landscape of Fundamental Human Rights in their Relationship with Synthetic Biology.* In the third chapter I aim to show which fundamental human rights are at stake in the context of synthetic biology and how they could respond to the challenges posed by this new emerging technology, in the belief that «*giving a major protection to human rights is connected with the global development of the human society*»<sup>6</sup>.

The idea proposed here is that any regulation and policy that could be chosen for dealing with risks of synthetic biology should not only take into account the fundamental rights, but it should be based on the respect of these fundamental rights, which ultimately represent the constitutional frame<sup>7</sup> needed to mould any (constitutionally oriented) regulation of the topic. As synthetic biology evokes the “involvement” of many constitutional rights and principles, in this chapter I will discuss in greater detail the role of five rights that are, in my opinion, the most significant in the field of synthetic biology, i.e. (a) the right to life (when talking about the possible alteration of the notion of life or the protection of human life in case of biosafety and biosecurity risks), (b) the notion of dignity (that, with its

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<sup>6</sup> N. BOBBIO, *L'età dei diritti*, Torino, 1997, p. 43.

<sup>7</sup> In this context, I mean “Constitution” as any catalogue of human rights, at the international, European and national level, regardless of the effective level that those bills of rights have in the internal hierarchy of sources of law. I also mean “Constitution” as the set of human rights that are part of the constitutional - even non written - tradition, such as in the U.K. legal system.



problematic feature of being a right, a value, a principle, or a meta-principle, comes at stake in considering the non alteration of human genetic heritage, in reference to the issue of enhancement through synthetic biology, the issue of the moral status of synthetic organisms, the limits to patentability, etc.), (c) the right to health (and its connection with the rights to life, environment, development and with dignity, with regards to the access to benefits of synthetic biology that could ameliorate health or in its public facet, as a good to be protected by States), (d) the freedom of scientific research and its limits (meant from the point of view of researchers, of the States and of the single beneficiaries of the results of research), and (e) the right to environment (with its connections to the sustainability and the rights of future generations). It must be specified that most of the times these rights relate one to each other and thus it is difficult to consider them separately.

For each of these rights, a general frame is offered. This is done in a comparative perspective, in consideration of their formulation, features, facets and judicial application within the international law, European Union law and some constitutional law experiences at national level. Following a case by case analysis, different legal systems are taken into consideration in reference to each right. The attention is neither limited to only one national experience, nor to the same legal systems for all the rights. The choice has been to put the focus on the constitutional frames that, from time to time, could be more meaningful in offering elements for reflecting about some relevant and “hot” issues connected with synthetic biology. A particular preference will be given to international law, E.U. law, and Italian, U.K. and U.S. legal systems, but the focus will not be exclusively on these legal systems.

With this general presentation of the content of each right in a comparative perspective and with the conclusion that the rights are nowadays not confined to national systems, but circulate, producing that phenomenon of «*multilevel protection of human rights*»<sup>8</sup> and the «*transnational flow of legal standards*»<sup>9</sup>, I will consider the applicability of each of them to synthetic biology. The relevance of the technique of balancing rights, on the basis of the principles of proportionality and

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<sup>8</sup> M. CARTABIA, *The multilevel protection of fundamental rights in Europe: the European Pluralism and the need for a judicial dialogue*, in C. CASONATO (ED.), *The protection of fundamental rights in Europe: lessons from Canada*, Trento, 2003, p. 99.

<sup>9</sup> A. SANTOSUOSSO, *The Worldwide Law-Making Process in the Field of Science and Law: A Laboratory Bench (IBLARC)*, in *Journal of International Biotechnology Law*, 6, 1, 2009, p. 1.

reasonableness, is particularly stressed. It is described as the most proper solution for reaching rational and sustainable choices in a context that is full of conflicting rights.

4. *A case study: synthetic biology, biosecurity and bioterrorism.* This final chapter focuses on a specific case study, with the purpose of verifying whether and how the suggested model of “*prudent vigilance*” and the balancing of rights could work effectively in reference to the risk of biosecurity (bioterrorism). This chapter will provide a clear discussion about the concepts of biosecurity, the “dual use” dilemma, and a brief history of biological warfare and bioterrorism from the origins until the current use of synthetic biology as a means for building weapons. After this, I will focus the analysis on the existing regulatory framework in the field of biosecurity and on the fight against bioterrorism, although such framework does not address precisely synthetic biology. In my analysis I will consider the rules adopted at the international, the E.U., the U.S., the U.K. and Italian level. The attempt consists of evaluating them on the basis of the constitutional frame and of checking whether the existing regulatory framework could also address synthetic biology. Then, the proposals that have been drafted so far precisely for the governance of biosecurity risk of synthetic biology are taken into exam. In the last section of the chapter I propose the application of the model of “*prudent vigilance*” and of the constitutionally oriented regulatory framework for dealing with the biosecurity risks posed by synthetic biology.

# CHAPTER I

## SYNTHETIC BIOLOGY BETWEEN EVOLUTION AND REVOLUTION

*“Science may set limits to knowledge, but should not set limits to imagination”*  
(B. Russell)

*Introduction: Science and Technology, a Rich and Complex Scenery.*

Scientific and technological progress has shaped the world in the last 50 years. Important theoretical discoveries have been made within different fields of research, such as medicine, life sciences - biology, biotechnology, genetics, neurosciences and cognitive science. At the same time, the practical applications of the discoveries have been elaborated, and thus bringing forth to the birth and growth of robotics, artificial intelligence, information and communication technologies, computer science.

As a result, the notion of purely theoretical and scientific knowledge has progressively emerged from the borders of purely intellectual thought to find a “translation” in technological products. The co-presence of these two interconnected and complementary dimensions has given rise to a rich and complex scenery.

One of the emerging fields is the so-called “synthetic biology”, which is in its nascent state, but is evolving very rapidly. It demonstrates a lot of potential for public benefit, but at the same time it puts forth a number of risks and harms from a social, ethical, economic and legal perspective. It is these risks and harms which must be carefully evaluated.

The aim of this first chapter is to examine in greater detail the field of synthetic biology, focusing on its definition, approaches, results, applications,

benefits and risks. In this chapter, I offer a general framework for evaluating this emerging field of science and technology.

### 1. *What is Synthetic Biology? Historical Steps in Search for a Definition.*

«At the beginning, the Word (Ἐν ἀρχῇ ὁ λόγος)»<sup>10</sup>. Under the auspices of the law, it is necessary to define and set a premise for the meaning of “synthetic biology”. In general terms, indeed, it is the definition which determines whether entity falls or does not fall under the application of a fixed regulation. The importance of definitional issues and of the epistemology of synthetic biology is evident in the fact that different people may have a different comprehension of the risks, and of the social, economic, ethical, legal aspects connected with this emerging science/technology. However, it should be noted at this moment that, «as synthetic biology is being defined and developed by researchers spanning several fields, it is hardly surprising that a unified definition of synthetic biology is lacking»<sup>11</sup>. As such, «there is no common understanding of synthetic biology, no clear description of its status quo and no comprehensive assessment of its potential»<sup>12</sup>. Hence, the following historical *excursus*<sup>13</sup> cannot offer a definitive and incontrovertible solution to the definition of synthetic biology. It remains, at the current point of discussion, an open area<sup>14</sup>.

The question of whether synthetic biology should be classified as a completely new field of science is addressed in a brief analysis of its evolution. It is established that a good part of it was «implicit in other already existing fields that, with different name, sought for the same things as synthetic biology did»<sup>15</sup>. However,

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<sup>10</sup> Prologue of St. John’s Gospel Book.

<sup>11</sup> J. ANDERSON, N. STRELKOWA, G-B. STAN, T. DOUGLAS, J. SAVULESCU, M. BARAHONA, A. PAPACHRISTODOULOU, *Engineering and ethical perspectives in synthetic biology*, in *European Molecular Biology Organization Reports*, 13, 7, 2012, p. 584.

<sup>12</sup> S. GAISSER, T. REISS, A. LUNKES, K.M. MÜLLER, H. BERNAUER, *Making the most of synthetic biology. Strategies for synthetic biology development in Europe*, in *European Molecular Biology Organization Reports*, 10, 2009, p. S5.

<sup>13</sup> See M. MORANGE, *A Critical Perspective on Synthetic Biology*, in *International Journal for Philosophy of Chemistry*, 15, 1, 2009, p. 21-30.

<sup>14</sup> EDITORIAL, *What’s in a Name?*, cit.

<sup>15</sup> Translation from A. MOYÁ SIMARRO, *Biología Sintética*, in C.M. ROMEO CASABONA (ED.), *Enciclopedia de Bioderecho y Bioética*, tomo I, Cátedra Interuniversitaria Fundación BBVA-

we are now witnessing «*a sort of renaissance of this subject*»<sup>16</sup>. In fact, despite the term as such was being used from the beginning of the 20<sup>th</sup> Century, currently it is meant to be adopted with different meanings, and many diverse definitions of what synthetic biology is have been given.

The main underlying purpose of synthetic biology is to create and manipulate life. Indeed, the dream of creating life and having control over it has always been part of humanity and the goal of scientists. This theme has often been dealt with in literature and mythology as well, as exemplified in the myth of Prometheus, in the fiction of Shelley's *Frankenstein*, and the folklore of the Jewish Golem show. At this point, human's desire of tackling with nature and playing God look like a universal archetype.

Despite the fantastical nature of narratives, the notion of humans playing God can be seen in the main historical steps of the field of synthetic biology. Its history can be traced from 1904 when the Carnegie Institution's Station for Experimental Evolution at Cold Spring Harbour was inaugurated with the purpose to study living things for the greater service of humanity<sup>17</sup>. Thus, it opens the story of life by design and introduces the first experiments on (Darwinian) evolution, which in essence was the beginning of man's first efforts in trying to make the be the very creator of life and nature.

In 1908, Jacques Loeb (1859-1924), one of the founders of the chemistry of proteins, famous for the invention of artificial parthenogenesis, was the first to state that the very purpose of biology was to produce life in a lab. His belief was that things could be understood only if they could be fabricated<sup>18</sup>. At about the same time, the French biologist Stéphane Leduc (1853–1939) wrote a book in 1912 entitled "*La biologie synthétique*"<sup>19</sup>. In it, he discussed the chemical synthesis of molecules, but the main point was the proposal of whether a similar approach could be applied, in future, to cells. His focus was on the osmosis and diffusion of

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Diputación Foral de Bizkaia de Derecho y Genoma Humano, Universidad de Deusto, Granada, 2011, p. 255 ff.

<sup>16</sup> J. PERETÒ, J. CATALÁ, *The Renaissance of synthetic biology*, in *Biological Theory*, n. 2, 2007, p. 128.

<sup>17</sup> See *Scientists Assembled at Cold Spring Harbour: Formal Opening of the Carnegie Station for Experimental Biology*, in *Brooklyn Daily Eagle*, 12<sup>th</sup> June 1904.

<sup>18</sup> J. LOEB, *Dynamics of the living matter*, Ney York, 1906.

<sup>19</sup> S. LEDUC, *op.cit.*

crystalline solutions, in order to check whether they could produce new “organic” forms. Thus, postulating that biology is not only as a matter of observation, but rather as a form of manipulation.

In the same years, parallel to studies about the modification of life and attempts of creating artificial life, genetic studies developed. The discovery of DNA double helix by Watson and Crick opened the doors to the first cases of genetic manipulations. The emergence of DNA studies in biology brought forth a new era for synthetic biology and influenced the way of conceiving it: in fact, in 1974 Waclaw Szybalski defined synthetic biology as molecular biology’s promise to evolve from description to manipulation of genetic systems<sup>20</sup>. As synthesis has been very useful to chemistry in order to understand the chemical behaviour of enzymes, metabolisms, and even diseases, the same could be said for biology. Since the 1970s, biology started to complement its observation of living things with “synthesis”, through the advent of recombinant DNA technology. At first, biologists used biotechnology to cut and paste single genes, but by the 1980s they progressed to synthesize «*entire genes encoding proteins, generating new artificial genetic systems with extra nucleotide letters, and engineering the expression of proteins with more than 20 different kinds of amino acids*»<sup>21</sup>. During this period, the notion of “synthetic biology” was chosen to describe bacteria that had been genetically engineered using recombinant DNA technology<sup>22</sup>. In this sense, the notion of “synthetic biology” during the 20<sup>th</sup> Century was synonymous with the notion of “genetic engineering” or “bioengineering”, but at this point in history, the notion of “synthetic biology” was preferred to the latter, because “genetic engineering” held a eugenic connotation. However, over the years the term disappeared, being supplanted by the more familiar “genetic engineering”, that had meanwhile lost the negative background that it carried on with itself.

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<sup>20</sup> W. SZYBALSKI, *In Vivo and in vitro initiation of transcription*, in A. KOHN, A. SHATKAY (EDS.), *In Control of Gene Expression*, New York, 1974, p. 405. Furthermore, Szybalski in the journal *Gene* in response to the 1978 Nobel Prize being awarded for the discovery of restriction endonucleases said: «*The work on restriction endonucleases not only permits us easily to construct recombinant DNA molecules and to analyze individual genes but also has led us into the new era of synthetic biology where not only existing genes are described and analyzed but also new gene arrangements can be constructed and evaluated*».

<sup>21</sup> S.A. BENNER, *Q&A: Life, synthetic biology and risk*, in *BioMed Central Biology*, 8, 2010, p. 77 ff.

<sup>22</sup> B. HOBOM, *Surgery of genes. At the doorstep of synthetic biology*, in *Medizinische Klinik*, 75, 1980, p. 14-21.

The disappearance of the term “synthetic biology” is short-lived. In the beginning of the 21<sup>st</sup> Century, «*with the re-emergence of contemporary synthetic biology, efforts were made to distinguish this new engineered-based approach to life from earlier genetic engineering*»<sup>23</sup>. Indeed, the expression was re-introduced by Eric Kool and other speakers at the annual meeting of the American Chemical Society in San Francisco<sup>24</sup>, referring to description of the synthesis of unnatural organic molecules that function in living systems. Thus begins a new era of synthetic biology.

The first “Synthetic Biology conference”, later known as “Synthetic Biology 1.0” (in 2004 at the Massachusetts Institute of Technology), was the first of its genre, and it stressed upon the idea of synthetic biology as a link among biology and engineering. It was aimed at applying engineering tools in the writing of DNA and in the creation of new biological structures.

The subsequent “Synthetic Biology Conferences”, 2.0 (at the University of California, Berkeley 2006), 3.0 (Zurich, 2007), 4.0 (Hong Kong, 2008), 5.0 (Stanford University, 2011)<sup>25</sup> showed how the notion of synthetic biology was progressively broadening. In fact, synthetic biology was developing new fields and sectors of research from within. European and international conferences are a clear indication of its growth<sup>26</sup>.

From the brief discussion of its historical evolution<sup>27</sup> in the previous paragraphs, it is possible at this point to offer a tentative definition of synthetic biology<sup>28</sup>:

- «*a) the design and construction of new biological parts (called “building blocks”), scratched and put together in novel circuits, networks and systems (that are synthetic because they do not exist in the natural world), and b) the re-design of*

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<sup>23</sup> L. CAMPOS, *That Was the Synthetic Biology That Was*, in M. SCHMIDT (ED.), *Synthetic Biology. The technoscience and its societal consequences*, Dordrecht, Heidelberg, London, New York, 2009, p. 15.

<sup>24</sup> This news can be found in R. RAWLS, ‘*Synthetic Biology*’ makes its debut, in *Chemical English News*, 24<sup>th</sup> April 2000, p. 49-53.

<sup>25</sup> The next one (6.0) is supposed to be taken in June 2013 at Imperial College, London.

<sup>26</sup> Beyond the Synthetic Biology Conferences on the model S.0, all the meetings that have been taken until now at the international and European level can be found in <http://syntheticbiology.org/Conferences.html> (last visited 28<sup>th</sup> January 2013).

<sup>27</sup> For a further analysis of historical steps, see E.F. KELLER, *Making Sense of Life: Explaining Biological Development with Models, Metaphors, and Machines*, Cambridge, M.A., 2002.

<sup>28</sup> See A. DEPLAZES ZEMP, *Piecing together a puzzle. An exposition of synthetic biology*, in *European Molecular Biology Organization Reports*, 10, 2009, p. 428-432.

*existing, natural biological systems for useful purposes»<sup>29</sup>, focusing for the former on «extract[ing] from living systems interchangeable parts that might be tested, validated as construction units and reassembled to build artificial biological systems»<sup>30</sup>, and for the latter<sup>31</sup> on «the attempt to recreate in unnatural chemical systems the emergent properties of living systems, including inheritance, genetics and evolution, and the practice to assemble components that are not natural (therefore synthetic) to generate chemical systems that support Darwinian evolution (therefore biological)»<sup>32</sup>;*

- the research interested in the synthesis of parts of biological parts of biological systems, or in the construction of models of biological systems. Synthetic biology comprises and is somehow an extension of biomimetic chemistry, with the additional issue of «systems thinking»<sup>33</sup>;

- the area of research encompassing three broad approaches towards the synthesis of living systems: DNA-based device construction, genome-driven cell engineering and protocell creation;

- the use of unnatural molecules to reproduce emergent behaviours from natural biology, with the goal of creating artificial life, and assembling of

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<sup>29</sup> For this definition, see <http://www.syntheticbiology.org> (last visited 28<sup>th</sup> January 2013). This website welcomes the activities of the synthetic biology community, set up by researchers from the Synthetic Biology Department and individuals from research laboratories at other institutions in the U.S.A., among which the Massachusetts Institute of Technology (M.I.T.) and Harvard University. The definition given by the mentioned community reflects the one given in 2003 by the Physical Biosciences Division at Lawrence Berkeley National Laboratory (L.B.N.L. or the Berkeley Lab), which established a Synthetic Biology Department with the claim that this was the world's first research facility in synthetic biology (2006, at <http://www.lbl.gov/pbd/synthbio/default.htm>, last visited 28<sup>th</sup> January 2013). For a similar definition, see also the High-level Expert Group of European Commission, that labels synthetic biology as «*the engineering of biological components and systems that do not exist in nature and the re-engineering of existing biological elements*» (HIGH-LEVEL EXPERT GROUP OF EUROPEAN COMMISSION, *SYNBIOLOGY. An Analysis of Synthetic Biology Research in Europe and North America Final Report on Analysis of Synthetic Biology Sector*, September 2006, at <http://www2.spi.pt/synbiology/documents/news/D11%20-%20Final%20Report.pdf>, last visited 28<sup>th</sup> January 2013).

<sup>30</sup> W.W. GIBBS, *Synthetic life*, in *Scientific American*, 290, 2004, p. 74-81.

<sup>31</sup> See S.A. BENNER, *Redesigning life. Organic chemistry and the evolution of protein*, in *Chimia*, 41, 1987, p. 142-148; J.W. SZOSTAK, D.P. BARTEL, P.L. LUISI, *Synthesizing life*, in *Nature*, 409, 2001, p. 387-390; S.A. BENNER, *Act natural*, in *Nature*, 421, 2003, p. 118.

<sup>32</sup> G.W. SALT, *Use of the term 'emergent properties'*. *Comment*, in *American Naturalist*, 113, 1979, p. 145-148, as mentioned by S.A. BENNER, A.M. SISMOUR, *Synthetic Biology*, in *Nature Reviews, Genetics*, 6, July 2005, p. 533.

<sup>33</sup> P.L. LUISI, C. CHIARABELLI, P. STANO, *From never born proteins to minimal living cells: two projects in synthetic biology*, in *Origins of Life and Evolution of the Biosphere*, 36, 2006, p. 605-616.



interchangeable parts from natural biology to create systems that function unnaturally.

From this review of possible definitions, it is plain that, common to all of them, is the idea that synthetic biology aims at designing novel artificial cellular or non cellular components with new functions, or to redesign cells and properties via a different architecture. However, some of them<sup>34</sup> consider synthetic biology simply as an “evolution” of genetic engineering or biochemistry or biotechnology, while for others<sup>35</sup> it represents a “revolution”, because it is more than a “meeting” between biology and engineering. In a sense, it shapes as a “converging science”, having a cross-disciplinary feature that makes it encompass a wide range of knowledge, such as that coming from molecular biology, engineering, mathematics, physics, chemistry, information technology, computing, biochemistry, nanotechnology and biotechnology (especially adopting computational simulations and quantitative modelling for developing genetic algorithms in computer codes, for the construction of genetic circuits and biological systems from a digitized parts-based approach<sup>36</sup>).

In a nutshell, for the purposes of this thesis, the definition that we opt for is the one that tries to be as broad as possible, meaning synthetic biology as a converging science and technology<sup>37</sup>, that assembles knowledge from three “pillars” that are:

- Engineering, Computing and Modelling;
- Biology (Origin of life, Artificial life, Orthogonal life);
- Molecular biology, Evolutionary genomics, Biotechnology<sup>38</sup>,

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<sup>34</sup> For example, see B. ERICKSON, R. SINGH, P. WINTERS, *Synthetic Biology: Regulating Industry Uses of New Biotechnologies*, in *Science*, 333, 2<sup>nd</sup> September 2011, p. 1254-1256.

<sup>35</sup> For example, the Rathenau Institute in the Netherlands stresses the interdisciplinary feature of synthetic biology, considering it as a synergistic “*new trend in science and technology and a clear example of converging technologies, i.e. nanotechnology, biotechnology [and molecular biology], information technology and cognitive sciences*” (H. DE VRIEND, *Constructing Life. Early social reflections on the emerging field of synthetic biology*. Working Document 97, The Hague, 2006, p. 9).

<sup>36</sup> Software programmes thought for synthetic biology are numerous. For example, platforms and operating systems that are adopted are: Windows, Mac, Linux systems. A great number of open source projects are being developed (such as Open Bioinformatics Foundation, see <http://open-bio.org/>, last visited 28<sup>th</sup> January 2013). For further details see M. SUAREZ, G. RODRIGO, J. CARRERA, A. JARAMILLO, *Computational Design in Synthetic Biology*, in M. SCHMIDT (ED.), *The Technoscience*, cit., p. 49-63.

<sup>37</sup> About the impossibility of considering synthetic biology as a circumscribed discipline, being it the result of the “merging” of different science and technologies, see A.M. CALLADINE, R.T. MEULEN, *Defining Synthetic Biology. Encyclopaedia of Applied Ethics*, Amsterdam, 2012, p. 281-288.

<sup>38</sup> P.L. LUISI, *The Emergence of Life. From Chemical Origins to Synthetic Biology*, Cambridge, 2006.

in order to re-design existing living forms, and design *de novo* artificial parts or systems in the biological world<sup>39</sup>.

## 2. Sub-fields of Synthetic Biology.

Synthetic biology in itself is a big field and it subdivides into numerous branches of research. In this section, I am going to examine a set of approaches to the notion of synthetic biology.

Thomas Murray identifies four of them: synthetic biology as (1) advanced genetic engineering, (2) as DNA-based device construction, (3) as the creation of the minimal cell (protocell), and (4) as the design of new biological entities<sup>40</sup>.

Another view proposes five subfields<sup>41</sup>: bioengineering, synthetic genomics, protocell synthetic biology, unnatural molecular biology, and *in silico* approach.

Others suggest a subdivision among DNA-based device construction, genome-driven cell engineering and protocell creation<sup>42</sup>.

The diversity of the field of synthetic biology is exemplified by the different views of its proponents. According to Benner and Sismour, the dichotomy in unnatural molecular biology and bioengineering is sufficient<sup>43</sup>. Van Martins dos Santos et al. propose DNA-based device construction (which includes engineering biocircuits, biosystems, and synthetic metabolic pathways), genome-driven cell engineering (also known as “genome minimization”), protocell construction, design of unnatural components and synthetic microbial consortia<sup>44</sup>. On the other hand,

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<sup>39</sup> See D. ENDY, *Engineering Biology; A Talk with Drew Endy*, in *Edge* 237, 2008, at <http://www.edge.org/documents/archive/edge237.html> (last visited 28th January 2013). See also R. CARLSON, *Biological Technology in 2050*, published as “Open Source Biology and Its Impact on Industry,” *IEEE Spectrum*, 2001. Moreover, it should be underlined that “synthetic biology” differs from “systems biology”, in the sense that the latter encompasses an integrated approach of studying biological systems at the genomic, transcriptomic, proteomic, and metabolomic levels.

<sup>40</sup> See T.H. MURRAY, *What Synthetic Genomes Mean For Our Future: Technology, Ethics, And Law, Interests And Identities*, in *Valparaiso University Law Review*, 45, 2011, p. 1315-1342. See in particular, p. 1319-1322.

<sup>41</sup> A. DEPLAZES ZEMP, *Piecing together a puzzle*, cit.

<sup>42</sup> M.A. O’MALLEY, A. POWELL, J.F. DAVIES, J. CALVERT, *Knowledge-making distinctions in synthetic biology*, in *Bioessays*, 30, 2008, p. 57-65.

<sup>43</sup> S.A. BENNER, A.M. SISMOUR, *Synthetic Biology*, cit., p. 533.

<sup>44</sup> V.A.P. MARTINS DOS SANTOS ET AL., *An Introduction to Synthetic Biology*, in M. SCHMIDT (ED.), *The Technoscience*, cit., p. 26 ff.

Schmidt proposes engineering DNA based biological circuits by using e.g. standard biological parts; finding the minimal genome and constructing protocells<sup>45</sup>.

The following subsections aim to describe the subfields of synthetic biology by giving a brief overview of each of them, so as to show the variety and complexity of this emerging field of research.

### *2.1. Advanced Genetic Engineering.*

If it is considered as an advanced step in genetic engineering field, synthetic biology demonstrates the ambition of intervening upon genetic networks rather than upon single genes. It represents the evolution of the Recombinant DNA techniques, born in the 1970s, roughly at the time of the achievement of metabolic engineering of bacteria for natural product synthesis. So, adopting the tools that were used for developing engineered bacterial plasmids for biotechnology and for producing genetically modified organisms, synthetic biology continues on the path in line with genome sequencing, but enlarging the view to genetic systems and networks.

### *2.2. DNA-based Device Construction.*

The research area of DNA-based device construction, also defined as “bioengineering”, is the association between biotechnology and engineering. It aims at engineering parts of DNA using abstract and simplified metabolic and regulatory modules and other standardized components, in order to create circuits, systems and pathways with pre-defined functions. With such definition, synthetic biology is compared to electronics or to computer engineering, because the organisation and complexity of biological cells is associated to the one of computational devices, which *«are both made up of sophisticated subunits being evolved/designed to adapt*

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<sup>45</sup> M. SCHMIDT, *Do I Understand What I Can Create? Biosafety Issues in Synthetic Biology*, in M. SCHMIDT (ED.), *The Technoscience*, cit., p. 81-100.

to the living environment or to serve as physical functional tools»<sup>46</sup>. The idea is to put together different pieces with different functions, as assembling a car<sup>47</sup>, and the basic concepts of this perspective are the ones of “standardization”, “modularization” and “catalogue” of living components. At this regard, it is worth mentioning the initiative developed by the synthetic biologist Drew Endy from Stanford, and others, that - never forgetting the secret of Legos – in 2005 started in the U.S.A. the BioBricks Foundation<sup>48</sup>, a non-profit organization formed to register and develop standard parts for assembling DNA. The purpose of the foundation is to develop a (physical and also online) registry or catalogue of *Standard Biological Parts*<sup>49</sup>. The registry includes lists of formatted components and interchangeable parts, such as protein coding sequences, ribosome binding sites and cell strains. These components and interchangeable parts could then be combined to design new genetic and metabolic circuits, representing new entities to be inserted in recipient cells and producing new functions.

Beyond the realization of DNA circuits, the production of synthetic metabolic pathways is also relevant. It consists in the construction of new metabolic pathways, either borrowed from another organism (through the modification of properties of organisms, by inserting genes from foreign species or synthetic sequences<sup>50</sup>), or entirely artificial (synthetic)<sup>51</sup>, through altering cellular metabolisms by adding or removing elements in the metabolic pathways. Some examples are the synthesis of poliovirus complementary DNA<sup>52</sup>, the bacteriophage whole-genome synthesis<sup>53</sup>, the

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<sup>46</sup> E. ANDRIANANTOANDRO, S. BASU, D.K. KRIG, R. WEISS, *Synthetic biology: New engineering rules for an emerging discipline*, in *Molecular Systems Biology*, 2, 2006.

<sup>47</sup> G.N. MANDEL, *Regulating Emerging Technologies*, in *Law, Innovation and Technology*, 1, 2009, p. 77. See also R.H. CARLSON, *Biology Is Technology. The Promise, Peril, and New Business of Engineering Life*, Cambridge, M.A., London, 2010.

<sup>48</sup> See <http://biobricks.org/> (last visited 28<sup>th</sup> January 2013).

<sup>49</sup> See [http://partsregistry.org/Main\\_Page](http://partsregistry.org/Main_Page) (last visited 28<sup>th</sup> January 2013).

<sup>50</sup> M. ITAYA, K. TSUGE, M. KOIZUMI, M. FUJITA, *Combining two genomes in one cell: Stable cloning of the *Synechocystis* PCC6803 genome in the *Bacillus subtilis* 168 genome*, in *Proceedings of the National Academy of Sciences of the U.S.A.*, 102, 2005, p. 15,971-15,976. See also Y. LIAN, Z. JIA, K. HE, Y. LIU, F. SONG, B. WANG, G. WANG, *Transgenic tobacco plants expressing synthetic *CryIAc* and *CryIIe* genes are more toxic to cotton bollworm than those containing one gene*, in *Chinese Sciences Bulletin*, 53, 2008, p. 1381–1387.

<sup>51</sup> A. MEYER, R. PELLAUX, S. PANKE, *Bioengineering novel in vitro metabolic pathways using synthetic biology*, in *Current Opinion Microbiology*, 10, 2007, p. 246–253.

<sup>52</sup> J. CELLO, A.V. PAUL, E. WIMMER, *Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template*, in *Science*, 297, 2002, p. 1016 ff.

chemical construction of the whole genome of *Mycoplasma genitalium*<sup>54</sup>, and the synthesis of mouse mitochondrion and rice chloroplast genomes in *Bacillus subtilis*<sup>55</sup>.

This perspective focuses the attention upon the distinction of synthetic biology with genetic engineering, since the aim is to «*create a programmable microorganism from scratch, as opposed to modifying components of living cells to achieve desired functionality*»<sup>56</sup>. So, «*rather than splicing in a gene from one organism to another, or forcing a mutation in a genome for a specific purpose, synthetic biology is concerned with designing and building artificial regulatory elements into genomes or constructing a complete genome from scratch*»<sup>57</sup>.

The main differences among synthetic biology and genetic engineering are summarised in the following table by the Rathenau Institute<sup>58</sup>:

	<b>GENETIC ENGINEERING</b>	<b>SYNTHETIC BIOLOGY</b>
<b>TECHNOLOGY</b>	Reading/analysing DNA	Writing DNA
	Trial and error	Software programming
<b>APPLICATION</b>	Adaption / modification of existing biological systems	Design and construction / modulation of new biological systems

### 2.3. Synthetic Genomics or Genome-driven Cell Engineering (Construction of Minimal Genome).

This area of research is based on biology and chemistry, and focuses on the creation of organisms with a chemically synthesized (minimal) genome. It aims to develop chassis genomes based on essential genes and other DNA sequences, which

<sup>53</sup> H. SMITH, C.A. HUTCHISON, C. PFANNKOCH ET AL., *Generating a synthetic genome by whole genome assembly: φX174 bacteriophage from synthetic oligonucleotides*, in *Proceedings of the National Academy of Sciences of the U.S.A.*, 100, 2003, p. 15440.

<sup>54</sup> D.G. GIBSON, G.A. BENDERS, C. ANDREWS-PFANNKOCH ET AL., *Complete chemical synthesis, assembly and cloning of a Mycoplasma genitalium genome*, in *Science*, 319, 2008, p. 1215.

<sup>55</sup> M. ITAYA, K. FUJITA, A. KUROKI, K. TSUGE, *Bottom-up genome assembly using the Bacillus subtilis genome vector*, in *Nature Methods*, 5, 2008, p. 41–43.

<sup>56</sup> A. BHUTKAR, *Synthetic Biology: Navigating the Challenges Ahead*, in *The Journal of Biolaw & Business*, 8, 2, 2005, p. 20.

<sup>57</sup> Ibid.

<sup>58</sup> RATHENAU INSTITUTE, *Constructing Life: the World of Synthetic Biology*, November 2007, p. 2.

are able to house various genetic circuits, metabolic pathways, or protein synthesis mechanisms<sup>59</sup>. Such structure made of chassis genomes hosting other molecules is then transplanted into living cells, thereby replacing the genome of the host cell and reprogramming its metabolism to undertake new tasks. Tom Knight from M.I.T. has started working on this with the view of using a very simple bacterium and making it even simpler, by deleting all the genes not needed for basic metabolism and growth. Knight's chassis of choice is an innocuous bacterium named *Mesoplasma florum*, which is non-pathogenic to any known organism, and contains only a few hundred genes. Furthermore, it grows very quickly in the laboratory. In a few words, the purpose is to «*redesign the genome of the species from the ground up, with the goal of creating a very well understood, carefully crafted organism suitable as a simple living substrate for the nascent engineering discipline of synthetic biology*»<sup>60</sup>.

The first experiments in order to create a minimal genome organism focused on *Mycoplasma genitalium* and a big step was made when in 1999 Craig Venter from Celera Genomics (that was pursuing the so-called “Minimal Genome Project”) suggested that 265 to 350 of the 482 protein-coding genes<sup>61</sup> of *M. Genitalium* were essential under laboratory growth conditions, included about 100 genes of unknown function.

#### 2.4. Protocell Creation or In Vitro Synthetic Biology (Creation of the Minimal Cell).

By associating biochemistry and chemistry, this subfield aims to find the synthetic minimal cell which has the simplest possible components to sustain reproduction, self-maintenance, and evolution<sup>62</sup>. It attempts to understand the origin of life and identify new biotech production systems.

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<sup>59</sup> J.I. GLASS, N. ASSAD-GARCIA, N. ALPEROVICH, S. YOOSEPH, M.R. LEWIS, M. MARUF, C.A. HUTCHISON III, HAMILTON O. SMITH, J. CRAIG VENTER, *Essential genes of a minimal bacterium*, in *Proceedings of the National Academy of Science of the U.S.A.*, 103, 2006, p. 425-430.

<sup>60</sup> T. KNIGHT, *Thoughts on the biology/EECS relationship*, 23<sup>th</sup> January 2003, additions 26<sup>th</sup> May 2005, at [http://www.eecs.mit.edu/bioeecs/Knight\\_essay.html](http://www.eecs.mit.edu/bioeecs/Knight_essay.html) (last visited 28<sup>th</sup> January 2013).

<sup>61</sup> Just to have a comparison it should be noted that humans have about 23.000 genes.

<sup>62</sup> P.L. LUISI, C. CHIARABELLI, P. STANO, *op.cit.* The idea of minimal cell was firstly introduced by H. J. MOROWITZ, *Beginnings of Cellular life*, New Haven, 1992.

The methods for doing so are: (a) building a cell from scratch using biophysical, biochemical, and biological components, or (b) simplifying an existing micro-organism, until it contains only essential and characterized genes and functional elements.

The first method (“bottom up”) tries to build artificial cells *in vitro*, and then a fully artificial organism, so that eventually not only the genome, but all the components of the cell would be synthesized *in vitro*. The second method (“top down”), like in the case of the construction of the minimal genome, looks for the minimal cell, giving up genetic elements progressively, until the point when the cell is able to “survive”.

### 2.5. Unnatural Molecular Biology (*Design of New Biological Entities*).

This is the most innovative, revolutionary and visionary area of synthetic biology. It aspires to realize the dreams of creation of novel life forms, by using unnatural molecules (such as unnatural base pairs and aminoacids), with the purpose of reproducing emergent behaviours from natural biology. This is exemplified by the introduction of artificial properties to proteins. The synthetic biologists in this sector are usually inspired by Richard Feynman’s quotation, used as a “mantra”: «*What I cannot create, I cannot understand*»<sup>63</sup>, and by Tom Knight’s words: «*the genetic code is 3.6 billion years old. It’s time for a rewrite*»<sup>64</sup>.

Some experiments, trying to replace or enlarge the genetic alphabet of DNA with unnatural base pairs, have led for instance to a genetic code that instead of four bases ATGC had six bases ATGCPZ<sup>65</sup>. Moreover, the attention is focused on the design of synthetic proteins where enzymes are used to catabolise an unnatural

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<sup>63</sup> Quoted by H. VAN DEN BELT, *Philosophy of Biotechnology*, in A. MEIJERS (ED.), *Philosophy of Technology and Engineering Sciences*, Amsterdam, 2009, p. 1301-1340.

<sup>64</sup> L.M. SILVER, *Life 2.0 Newsweek International*, 4<sup>th</sup> June 2007, at <http://wwsilvermacg4.princeton.edu/challenging/articles/2007Newsweek/Scientists.html> (last visited 28<sup>th</sup> January 2013).

<sup>65</sup> Z. YANG, A.M. SISMOUR, P. SHENG, ET AL., *Enzymatic incorporation of a third nucleobase pair*, in *Nucleic Acids Research*, 35, 2007, p. 4238–4249; A.M. SISMOUR, S. LUTZ, J.H. PARK, ET AL., *PCR amplification of DNA containing non-standard base pairs by variants of reverse transcriptase from Human Immunodeficiency Virus-1*, in *Nucleic Acids Research*, 32, 2004, p. 728-735.

substrate<sup>66</sup>. Indeed, the possible combination of the 20 canonical aminoacids that are present in virtually all known organisms is explored by computer programs, so as to generate new genetic chains<sup>67</sup>. A development towards the creation of new entities and living beings could come from the artificial self-replicating ribosomes, designed by George Church: these organisms are useful for the protein synthesis and they can work to produce a complex protein. The next step could be the one of elaborating a ribosome able to create itself.

### 2.7. *In Silico Approach.*

Putting biology together with computer sciences constitutes the basis of a research area that seeks to establish computational models for the design of standard biological components or synthetic circuits. This is to enable natural genetic rules, responsible for natural evolution, to be substituted by artificial design. Computer algorithms are used for the analysis of biomolecule sequence and structure related problems, and some of them are adopted not only for defining the structure of the biomolecular components or for the analysis of their behaviour, but also for designing artificial regulatory systems, circuits, pathways, and for simulations<sup>68</sup>.

At present, the most advanced technology is a software package, named “*BioJADE: A design and Simulation Tool for Synthetic Biological Systems, for programming of algorithms for BioBrics*”, made available by C.S.A.I.L. (M.I.T. Computer Science and Artificial Intelligence Laboratory)<sup>69</sup>.

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<sup>66</sup> L. JIANG, E.A. ALTHOFF, ET AL., *De novo computational design of retro-aldol enzymes*, in *Science*, 319, 2008, p. 1387–1391.

<sup>67</sup> See, for example, M.C. HARTMAN, K. JOSEPHSON, C.W. LIN, W. SZOSTAK, *An expanded set of amino acid analogs for the ribosomal translation of unnatural peptides*, in *PLoS ONE*, 2, 2007, p. e972.

<sup>68</sup> J. HASTY, *Computational studies of gene regulatory networks: in numero molecular biology*, in *Nature Review Genetics*, 2, 4, 2001, p. 268-279; P. FRANCOIS, V. HAKIM, *Design of genetic networks with specified functions by evolution in silico*, in *Proceedings of the national Academy of Science of the U.S.A.*, 2, 101, 2004, p. 580-585.

<sup>69</sup> J.A. GOLER, *BioJADE: A Design and Simulation Tool for Synthetic Biological Systems*, Cambridge, M.A., 2004.



## 2.8. Xenobiology.

Xenobiology aims at creating biological systems that are based on biochemistry, and are not found in nature. The scientists try to construct molecules that are different from the normal DNA, but having similar functions (so-called “xeno-nucleic acid”, XNA), in order to build living systems that have never existed before, at the point that it is thinkable to arrive at the creation of «*orthogonal xenobiological systems that act as genetic firewalls to natural life forms*»<sup>70</sup>. Life forms that are based on XNAs, in fact, are orthogonal to natural ones, in the sense that they are context independent and have its own properties that can facilitate the feasibility and simplicity of complex designs.

## 2.9. Synthetic Microbial Consortia.

This field of synthetic biology focuses on the design of cell-to-cell communication across different microbial species<sup>71</sup>. It aims to design synthetic ecosystem communication, such as between mammalian and bacterial cells mimicking symbiosis, parasitism, and oscillating predator-prey relationships, by changing the signalling mechanism between two species<sup>72</sup>. Another example is the inducement of metabolic co-dependence or cooperative enzyme complex production between two microbial organisms<sup>73</sup>.

In conclusion, from the examination of these nine different subfields of synthetic biology, its feature of aiming at designing and redesigning life could be

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<sup>70</sup> M. SCHMIDT, *Xenobiology. A new form of life as the ultimate biosafety tool*, in *BioEssays*, 32, 2010, p. 330.

<sup>71</sup> K. BRENNER, L. YOU, F.H. ARNOLD, *Engineering microbial consortia: A new frontier in synthetic biology*, in *Trends Biotechnology*, 26, 2008, p. 483–489.

<sup>72</sup> W. WEBER, M. DAOUD-EL BABA, M. FUSSENEGGER, *Synthetic ecosystems based on airborne inter- and intrakingdom communication*, in *Proceedings of the National Academy of Science of the U.S.A.*, 104, 2007, p. 10,435–10,440.

<sup>73</sup> T. ARAI, S. MATSUOKA, H-Y. CHO, H. YUKAWA, M. INUI, S-L.WONG, R.H. DOI, *Synthesis of Clostridium cellulovorans minicellulosomes by intercellular complementation*, in *Proceedings of the National Academy of Science of the U.S.A.*, 104, 2007, p. 1456–1460.

perceived. Each of the subfields tries to achieve those targets from a different perspective and with diverse instruments.

### *3. Classification of Synthetic Products, Approaches and Achieved Results.*

Deepening the world of synthetic biology, it is worth focusing now on what products are obtained from research in synthetic biology and what approaches synthetic biology mainly follows in its investigation.

#### *3.1. Products.*

A proposed classification of synthetic products<sup>74</sup> subdivides them into four categories:

- *Synthetic Elements* are the fundamental building blocks providing primitive functionality. They are produced in the lab and they are not a part of the natural cellular process, i.e. they have no identical copy in natural cells, and they are controllable with an external stimulus;

- *Synthetic Networks* are composed of interacting components that are individual synthetic elements;

- *Synthetic Organisms* are the result of the synthetic assembly of complete or minimal genomes, i.e. the set of genes critical for survival of an organism. These genomes would most likely be substituted in place of an existing genome in a favourable cellular environment. In addition to the artificial genome, synthetic organism could contain synthetic networks and synthetic elements.

- *Synthetic Systems* represent the ultimate goal of synthetic biology, i.e. the aim to design synthetic systems composed of multiple synthetic organisms working synchronously to achieve a complex objective.

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<sup>74</sup> See A. BHUTKAR, *op.cit.*, p. 22.

### 3.2. Approaches.

The main approaches that the aforementioned subfields of synthetic biology usually follow are:

- the *top-down approach (Deconstructing life)*, which is considered to be an extension of the current methods of genetic modification. It refers to the dissection of biological systems in the search for simplified and minimal forms that will help understand the adaptation and evolution of natural processes. It aims to redesign existing organisms or gene sequences with the goal of stripping out unnecessary parts, or replacing or adding specific parts to achieve new or amplified characteristics and functions; or

- the *bottom-up approach (Constructing life)*, that aims at building systems inspired by general biological principles. It uses biological or chemical components to reproduce the behaviour of living systems. It means that scientists take raw materials starting with non-living components, assembled them like Legos, hoping to create synthetic systems that mimic the functions of living cells.

#### 3.2.1. Top-down Approach.

From the results achieved within the field of synthetic biology, the examples taken from the “top-down” approach can be found in its aims to create a “minimal genome organism”, containing the smallest set of genes an organism needs to live in a particular environment, or at realising the “minimal cell”.

The idea is to simplify biological structures, and a meaningful metaphor of this research area is given by Robert Carlson, who states that: «*Aeronautical engineering, in particular, serves as an excellent metaphor when considering the project of building novel biological systems. Successful aeronautical engineers do not attempt to build aircraft with the complexity of a hawk, a hummingbird, or even a moth; they succeed by first reducing complexity to eliminate all the mechanisms they are unable to understand and reproduce. In comparison, even the simplest cell contains far more knobs, bells, and whistles than we can presently understand. No*

*biological engineer will succeed in building a system de novo until most of that complexity is stripped away, leaving only the barest essentials»<sup>75</sup>.*

### 3.2.2. Bottom-up Approach.

With regard to the second approach, it is mainly adopted by bioengineering subfield, by the protocell creation (in vitro synthesis) and by *in silico* approach.

Some relevant works can be mentioned as examples of this approach: the research conducted by Eckard Wimmer, who in 2002 synthesised the poliovirus genome<sup>76</sup>; Craig Venter's group who in 2003 successfully synthesized the  $\phi X174$  bacteriophage virus<sup>77</sup>; U.S. scientists who in 2005 recreated the 1918 "Spanish Flu" virus<sup>78</sup>. The most notable experiment was in 2008 where the scientist Venter succeeded in synthesising a full bacterial genome<sup>79</sup> and in May 2010 it announced the creation of the first living and replicating bacterium with a synthetic genome (called "Synthia")<sup>80</sup>. Although scientists have used recombinant DNA techniques to engineer pieces of the genetic code for many years, Venter's achievement with "Synthia" marked the first time that all of the natural genetic material in a bacterial cell was replaced with a synthetic copy of the genes necessary for that organism to function. The contents of this genetic information mostly come from nature. Nevertheless, it is a digitized information, because genes were reproduced on a computer, and then converted into synthetic DNA and transplanted into a bacterium. The series of actions consisted in «*a chain of computer information to genome information and then to the life information*»<sup>81</sup>, thus producing the result of a cell as «*a universal programmable biomachine*»<sup>82</sup>. Therefore, life looks like an electrical circuit or computer software. More specifically, Venter took a bacterium present in

<sup>75</sup> R.H. CARLSON, *Biology is Technology*, cit., p. 6.

<sup>76</sup> J. CELLO, A.V. PAUL, E. WIMMER, *op.cit.*, p. 1016.

<sup>77</sup> H. SMITH, C.A. HUTCHISON, C. PFANNKOCHE ET AL., *op. cit.*

<sup>78</sup> T.M. TUMPEY ET AL., *Characterization of the reconstructed 1918 Spanish influenza pandemic virus*, in *Science*, 310, 2005, p. 77–80.

<sup>79</sup> D.G. GIBSON, G.A. BENDERS, C. ANDREWS-PFANNKOCHE ET AL., *op. cit.*

<sup>80</sup> D.G. GIBSON, J.I. GLASS, C. LARTIGUE ET AL., *Creation of a Bacterial cell controlled by a chemically synthesized genome*, in *Science*, 329, 2010, p. 52.

<sup>81</sup> C. REHMANN-SUTTER, *Synthetische Biologie. Wenn das Leben zur Tupperware wird*, in *Frankfurter Allgemeine Zeitung*, 18<sup>th</sup> August 2010, 190, p. 3.

<sup>82</sup> *Ibid.*

goats, called *Mycoplasma mycoides*, he synthesized its chromosome and inserted the synthesized one into another bacterium (*Mycoplasma capricolum*), thus generating a new bacterium having a synthesized chromosome (and thus called *Mycoplasma laboratorium*). This announcement made headlines around the globe<sup>83</sup>. Even though Venter has stated that it is the first case of a cell whose parent is a computer, some scientists such as Benner stressed that «*Venter's bug is essentially the same as a bacterium that came to us through Darwinian evolution, which provided all of its genetic information. Venter's bug is alive and is life, but it is not particularly new in either of these features. Its DNA is fully synthetic, but the information within its sequence is natural. Likewise, the casing - the cell in which it replicates and instructs protein synthesis - was taken preassembled from an existing cell*»<sup>84</sup>.

Another example of a successful and noteworthy experiment to exemplify the notion of synthetic biology is the significant re-designing of life by Floyd Romesberg and colleagues. They have successfully developed two new bases which (1) can be incorporated into DNA alongside the existing four bases, and (2) can be replicated by naturally occurring enzymes<sup>85</sup>. Meanwhile, members of the *PACE (Programmable Artificial Cell Evolution) consortium* have taken the first steps towards developing life-like “protocells” that use peptide nucleic acid rather than DNA as the information-storing molecule<sup>86</sup>. It is also important to note the successful production of engineered bacteria to synthesize drug precursors or other complex chemicals. In particular, Jay Keasling’s group at the University of California, Berkeley, U.S.A., who has created a bacteria which produces a precursor of the anti-malarial drug artemisinin<sup>87</sup> and synthetic biofuels<sup>88</sup>.

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<sup>83</sup> For example, see F. MACRAE, *Scientist accused of playing God after creating artificial life by making designer microbe from scratch-but could it wipe out humanity?*, in *Daily Mail*, 3<sup>rd</sup> June 2010, at <http://www.dailymail.co.uk/sciencetech/article-1279988/Artificial-life-created-Craig-Venter--wipe-humanity.html> (last visited 28<sup>th</sup> January 2013).

<sup>84</sup> S.A. BENNER, *Q&A: Life, synthetic biology and risk*, cit., p. 2.

<sup>85</sup> A.M. LECONTE, G.T. HWANG, S. MATSUDA ET AL., *Discovery, characterization, and optimization of an unnatural base pair for expansion of the genetic alphabet*, in *Journal of American Chemical Society*, 130, 2008, p. 2336.

<sup>86</sup> PACE CONSORTIUM, *PACE Report*, 2009, at <http://www.istpace.org//index.html> (last visited 28<sup>th</sup> January 2013).

<sup>87</sup> D.K. RO ET AL., *Production of the antimalarial drug precursor artemisinic acid in engineered yeast*, in *Nature*, 440, 2006, p. 940–943.

<sup>88</sup> J.R. KIRBY, J.D. KEASLING, *Metabolic engineering of microorganisms for isoprenoid production*, in *Natural Product Reports*, 25, 2008, p. 656–661.

The *bottom-up approach* has also inspired the birth of the mentioned “*catalogue of BioBricks*”. As they comply with international standards, these components can easily be distributed and shared. There are currently over 3000 modules, available as an open source resource. Such “*BioBricks*” have been used within the *iGEM competition* (International Genetically-Engineered Machine)<sup>89</sup>, a competition established for the first time in 2005, in which students and lecturers from universities across the world - instructed by synthetic biologists - engineer new metabolic pathways in bacteria or eukaryotic cells, based on those standardized DNA elements that are combined into well-specified working devices, which can then be applied in biological systems.

#### 4. Potential and Effective Benefits from the Applications of Synthetic Biology.

Synthetic biology is a field with enormous potential. In many ways its current situation can be compared with the very early days in the development of the computer industry. It has the capacity to change quite fundamentally the way we approach certain key technologies, such as medicine and manufacturing, but «*at this very early stage it is hard even to guess where the most important applications will turn out to lie*»<sup>90</sup>.

The current known positive applications fall into several different areas of technology<sup>91</sup>. In this section I offer a brief analysis in the areas of (1) environment, (2) energy, (3) biomedicine, (4) agriculture and food, and (5) industries. I aim to demonstrate the potential and effective benefits from the applications derived from synthetic biology.

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<sup>89</sup> See iGEM (2005), *Project summaries*, at [http://parts.mit.edu/wiki/index.php/Igem\\_2005](http://parts.mit.edu/wiki/index.php/Igem_2005); the registry of BioBricks in [http://parts.mit.edu/registry/index.php/Main\\_Page](http://parts.mit.edu/registry/index.php/Main_Page) and BIOBRICKS FOUNDATION (2006), *Our Goals*, in [http://openwetware.org/wiki/The\\_BioBricks\\_Foundation:Our\\_Goals](http://openwetware.org/wiki/The_BioBricks_Foundation:Our_Goals) (last visited 28<sup>th</sup> January 2013).

<sup>90</sup> N.E.S.T., *Synthetic Biology: Applying Engineering to Biology*. Report of a N.E.S.T. High-Level Expert Group, Luxembourg, 2005, p. 5, at [ftp://ftp.cordis.europa.eu/pub/nest/docs/syntheticbiology\\_b5\\_eur21796\\_en.pdf](ftp://ftp.cordis.europa.eu/pub/nest/docs/syntheticbiology_b5_eur21796_en.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>91</sup> See L. SERRANO, Y. BENENSON ET AL., *Synthetic Biology. Applying Engineering to Biology*, Brussels, 2005. See also A.S. KHALIL, J.J. COLLINS, *Synthetic biology: applications come of age*, in *Nature Reviews Genetics*, 11, May 2010, p. 367-379.

#### 4.1. In the Environment, for Agriculture and Food.

In the field of “*bioremediation*”, microorganisms and plants could be engineered to degrade pesticides, detect and remove pollutants, i.e. these organisms are designed to emit a signal like fluorescence in the presence of certain environmental toxins<sup>92</sup>. Synthetic biologists are also experimenting with high-yield and disease-resistant plant feed stocks that can be supplemented with efficient and environmentally friendly microorganisms to minimize water use and replace chemical fertilizers<sup>93</sup>. There are also concurrent research into the notion of altering the properties of plants in order to gain nutritional benefits, such as higher levels of food-grade protein<sup>94</sup>, and studies aimed at implementing the successful results of GMOs (genetic modified organisms). The creation of “*biosensors*” is also important as the ability to monitor soil for nutrient quality or signs of environmental degradation<sup>95</sup> is extremely valuable to the agricultural industry.

Moreover, synthetic biology allows for the development of new seed products with multiple genetic traits<sup>96</sup>. This enables the generation of new engineered and optimised crops that can feed biofuel applications and optimise food production.

One of the most likely developments in agriculture may also be the mentioned production of new types of pesticides which are environmentally friendly.

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<sup>92</sup> V. DE LORENZO, *Systems biology approaches to bioremediation*, in *Current Opinion in Biotechnology*, 19, 6, 2008, p. 579-589; J.R. KIRBY, *Synthetic biology: Designer bacteria degrades toxin*, in *Nature Chemical Biology*, 6, 2010, p. 398-399.

<sup>93</sup> THE JOINT BIOENERGY INSTITUTE, *About JBEI*, at <http://www.jbei.org>; SYNTHETIC GENOMICS, INC., *Agricultural Products*, at <http://www.syntheticgenomics.com/what/agriculture.html> (last visited 28<sup>th</sup> January 2013).

<sup>94</sup> G. SCRINIS, K. LYONS, *Nanotechnology and the Techno-Corporate Agri-Food Paradigm*, in G. LAWRENCE, K. LYONS, T. WALLINGTON (EDS.), *Food Security, Nutrition and Sustainability: New Challenges, Future Options*, London, 2010, p. 252-270.

<sup>95</sup> A.A. SNOW ET AL., *Genetically engineered organisms and the environment: current status and recommendations*, in *Ecological Applications*, 15, 2005, p. 377-404.

<sup>96</sup> Synthetic biology applications in food remind of the similar applications promoted by genetic engineers with regards to genetic modified food (the case of “Golden Rice” that was hyped as a way for solving the food in the world is a meaningful one).

#### 4.2. In Energy, Industrial and Chemical Field.

Thanks to synthetic biology, it is possible to generate hydrogen as a source of fuel, via breakdown of water using sunlight as the energy source. Moreover, the field of synthetic biology could be used to develop more efficient methods in utilising biomass for developing biofuels that, at the moment, are the result from either the production of ethanol from sugars or biodiesel from vegetable oils. The aim is to avoid the waste of organic matter or biomass, and reduce global dependence on fossil fuel, cutting harmful emissions and minimizing the appeal of fossil fuel reserves<sup>97</sup>. New studies are also looking for the optimisation of similar chemical processes to produce ethanol from sugar, but with the input being various types of perennial crops such as grasses. Aviation fuels are now being developed on the basis of synthetic biology techniques too.

In future, it is likely that more advanced biofuels will be created from renewable resources, such as branch-chain higher alcohols. It is also possible that new types of the bacterium *E. coli* and other laboratory based micro-organisms such as yeast to be engineered to produce biofuels<sup>98</sup>.

As Craig Venter said, «*Over the next 20 years, synthetic genomics is going to become the standard for making anything. The chemical industry will depend on it. Hopefully, a large part of the energy industry will depend on it*»<sup>99</sup>.

The relevance of synthetic biology for industries could be visible in reference to the mentioned production of energy through biofuels obtained through synthetic material. In addition, thanks to the expansion of the molecular basis of living systems and the broadening the genetic alphabet, it is likely to modify nucleic acids that could be easier to transport across membranes or to create novel proteins: this target could lead to many interesting industrial applications and within the cosmetic production.

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<sup>97</sup> D.F. SAVAGE, J. WAY, P.A. SILVER, *Defossilizing fuel: How synthetic biology can transform biofuel production*, in *American Chemical Society Chemical Biology*, 3,1, 2008, p. 13-16.

<sup>98</sup> THE U.K. ROYAL ACADEMY OF ENGINEERING, *Synthetic Biology: scope, applications and implications*, London, 2009, p. 39-40.

<sup>99</sup> P. ALDHOUS, *Interview: Sleep when you are dead*, in *New Scientists*, 2626, 2007.



#### 4.3. In Biomedical Sector.

Bio-synthetic products could be used in order to produce medicines (“*biopharmaceuticals*”), such as engineering bacteria to produce commercially relevant molecules like insulin, and vaccines (in the case of hepatitis B virus and human papillomavirus)<sup>100</sup>. Already in place are “*in vivo applications*”, such as the regulatory circuits designed to trigger insulin production in diabetes<sup>101</sup> or the bacteria or viruses programmed to identify malignant cancer cells and deliver therapeutic agents, in order to implement personalized medicine and the fight against cancers<sup>102</sup>. The field of “*biomedicine*” is of particular interest here as synthetic biology could be applied to develop complex molecular devices composed of sensors and enzymes, which could be used for tissue repair or regeneration, or as vectors for therapy. Then, these “*new drug development pathways*”, i.e. alternative production routes for useful compounds, could be produced. This is exemplified by the construction of an artificial metabolic pathway in the bacteria *Escherichia coli* and the micro-organism yeast to produce a precursor (*artemisinin*) for an antimalarial drug<sup>103</sup>, which is currently extracted from plants. Furthermore, synthetic biology allows the production of “*new synthetic vaccines*” from scratch, in response to viruses that themselves evolve rapidly, such as those that cause severe acute respiratory syndrome (SARS) and hepatitis C<sup>104</sup>.

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<sup>100</sup> D.V. GOEDEL ET AL., *Expression in Escherichia coli of chemically synthesized genes for human insulin*, in *Proceedings of the National Academy of Sciences of the U.S.A.*, 76, 1, 1979, p. 106–110; E.E. MAST, J.W. WARD, *Hepatitis B vaccines*, in S. PLOTKIN, W. ORENSTEIN, P. OFFIT (EDS.), *Vaccines*, Philadelphia, 2008, p. 205-242; J.T. SCHILLER, I.H. FRAZER, D.R. LOWY, *Human papillomavirus vaccines*, in S. PLOTKIN, W. ORENSTEIN, P. OFFIT (EDS.), *op. cit.*, p. 243-258.

<sup>101</sup> ITI LIFE SCIENCES, *Synthetic Biology Foresighting: Technologies and Markets*, Dundee, 2007.

<sup>102</sup> L. SERRANO, *Synthetic biology: promises and challenges*, in *Molecular Systems Biology*, 3, 158, 2007, p. 1-5.

<sup>103</sup> V.J. MARTIN ET AL., *Engineering a mevalonate pathway in Escherichia coli for production of terpenoids*, in *Nature Biotechnology*, 21, 2003, p. 796-802.

<sup>104</sup> M.S. GARFINKEL, D. ENDY, G.L. EPSTEIN, R.M. FRIEDMAN, *Synthetic Genomics: Options for Governance*, Rockville, M.D., Washington, D.C., Cambridge, M.A., 2007.

## 5. Challenges and Concerns of Synthetic Biology.

From the discussion in the previous sections, it is clear that synthetic biology provides enormous possibilities to humanity in different fields, but at the same time it poses a number of risks and problems<sup>105</sup>. Indeed, «*synthetic biology can no longer be ignored. It is therefore imperative that while the science of synthetic biology is in its infancy, we should begin to consider its possible ethical and societal implications, the deep questions it raises and the impact it could have both on our lives and the lives of future generations before it leaves the confines of the laboratory*»<sup>106</sup>.

Borrowing the Rathenau's<sup>107</sup> classification and completing it, the following summary is presented:

<i>Theme</i>	<i>Genetic modification</i>	<i>Synthetic biology</i>	<i>Significance for debate</i>
<i>Biosafety</i>	Original host organism as reference	No more natural reference	New questions and uncertainties about risk analysis
<i>Biosecurity</i>	Known, risky viruses and bacteria	Difficult to establish what short DNA fragments will be used for	Monitoring misuse of potentially risky organisms and research becomes more difficult
<i>Intellectual property</i>	Limited number of genes	Number of genes virtually unlimited	Research & innovation impeded
<i>International justice concerns</i>	Gaps in access to new technologies among rich and poor countries	Gaps in access to new technologies among rich and poor countries	Effects on third world
<i>(Other) Ethical issues</i>	The alteration of existing organisms	The creation of (partially) artificial life	Morality of creating life, human self-conception, boundary between life and machine blurs

<sup>105</sup> For deepening the subject, see INTERNATIONAL RISK GOVERNANCE COUNCIL, *Synthetic Biology. Risks and opportunities of an emerging field*, Geneva, 2008.

<sup>106</sup> R.T. MEULEN, A.M. CALLADINE, *Synthetic Biology and Human Health: some initial thoughts on the questions and how we ought to approach them*, in *Law and the Human Genome Review*, 32, January-June 2010, p. 121.

<sup>107</sup> RATHENAU INSTITUTE, *op. cit.*, p. 9.

It must be specified that, however, this subdivision among the concerns is not so strict and they can overlap. For example, the «*ethical issues are embedded in environmental risk assessment*<sup>108</sup> [...] ; *intellectual property regime [...] can affect biosecurity and economic development, as well as pose difficult ethical dilemmas about owning life*»<sup>109</sup>.

A short analysis of the main concerns concerning synthetic biology in this section will be provided to illustrate its existing problematic aspects. The possible options or ways of tackling will be postponed to the later chapters where they will be addressed in greater detail<sup>110</sup>.

### 5.1. Biosafety Risks.

The World Health Organisation (W.H.O.) defines biosafety as «*the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release*»<sup>111</sup>. The Organization for Economic Cooperation and Development (O.E.C.D.) refers to «*the safe handling practices, procedures and proper use of containment facilities to prevent accidental harm caused by living organisms either directly or indirectly to individuals within laboratories or to the environment*»<sup>112</sup>.

This category of risks relates to environmental, agricultural, food, industrial, chemical and health applications of synthetic products. Its main feature is the “chance, accidental nature”, which does not depend on human’s will.

The concerns here are similar to those raised, in the past, with regards to genetic engineering and recombinant DNA research (involving the cutting and splicing of genes from different species), as they discuss the potential harms to

<sup>108</sup> J. KUZMA, J.C. BESLEY, *Ethics of Risk Analysis and Regulatory Review: From Bio- to Nanotechnology*, in *Nanoethics*, 2, 2008, p. 149–162.

<sup>109</sup> J. KUTZMA, T. TANJI, *Unpackaging synthetic biology: Identification of oversight policy problems and options*, in *Regulation & Governance*, 4, 2010, p. 99.

<sup>110</sup> It is important to specify here that the terms “concerns” and “risks” are used interchangeably in the current context, but they will be distinguished in the II chapter.

<sup>111</sup> WORLD HEALTH ORGANIZATION (W.H.O.), *Biorisk Management: Laboratory Biosecurity Guidance*, Geneva, 2006, p. 1-41.

<sup>112</sup> ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (O.E.C.D.), *Best Practice Guidelines on Biosecurity for Biological Research Centers*, Paris, 2007, at <http://www.oecd.org/science/biotechnologypolicies/38778261.pdf> (last visited 28<sup>th</sup> January 2013).

humans, plants, or animals, due to the accidental release of synthetic organisms that are difficult to control and can replicate<sup>113</sup>.

In the environment, synthetically created microorganisms could interact with another environmental substance and impact the overall environment negatively. There could also be the possibility of a “genome contamination”, when a genetic exchange between a synthetic biological entity and a naturally-occurring biological entity occurs<sup>114</sup>. Moreover, synthetic organisms could increase pesticide resistance and growth of invasive species and can have detrimental effects on human health, ecosystems and biodiversity, affecting mutation and evolution as well.

As for food, the consumption of synthetic food derived from engineered crops could potentially cause damages to human and animal health, such as the introduction of a new gene in a food could provoke allergies or negative changes in nutritional values<sup>115</sup>.

With regards to industrial and chemical application, the dangers lie in the harm to ecosystems during energy production. For example, if large areas of land were to be dedicated to biofuel development, this could put new and intense pressures on land, potentially affecting food production and current ecosystems. Because these applications of synthetic biology are still young, the impact of biofuel production on land use remains unknown.

In the area of health applications, the perils of synthetic biology are linked to the unknown consequences that it can potentially have. There can be adverse effects due to the inadvertent release of the organisms engineered using synthetic biology or the unintentional exposure to toxins, pathogens and so on. Infectious diseases may be accidentally transmitted to laboratory workers or to family members following airborne transmission of disease agents, manipulated using synthetic biology techniques. These risks may also potentially spread to the wider human community or the environment, when organisms are allowed proliferate without adequate means

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<sup>113</sup> J. EGGERS ET AL., *Is biofuel policy harming biodiversity in Europe?*, in *Global Change Biology Bioenergy*, 1, 1, 2009, p. 18-34.

<sup>114</sup> A. BHUTKAR, *op.cit.*

<sup>115</sup> B.M. CHASSY, *Food safety evaluation of crops produced through biotechnology*, in *Journal of the American College of Nutrition*, 21, 3, 2002, p. 166S–173S.

to limit reproduction. In patients, the use of cell therapies of bacterial, or potentially, mixed microbial origin may cause infections or unexpected immune responses<sup>116</sup>.

## 5.2. Biosecurity Risks.

This subfield of risks refers to misuse and mishandling of synthetic products and knowledge by unauthorized people. Biosecurity must be interpreted in this case in a laboratory context, as «*control and accountability for valuable biological materials [...] within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release*»<sup>117</sup> or as the set of «*measures to protect against the malicious use of pathogens, parts of them, or their toxins in direct or indirect acts against humans, livestock or crops*»<sup>118</sup>. In short, measures and efforts must be taken and are needed to prevent the creation of deadly pathogens for the purposes of bioterrorism, of which the threat has since begun to manifest itself following the events of the 11<sup>th</sup> September 2001<sup>119</sup>. Researchers have shown that it is possible to create or recreate deadly viruses such as polio<sup>120</sup> and the 1918 Spanish flu<sup>121</sup> which will provide a viable threat to humanity. The N.E.S.T. High-Level Expert Group study commissioned by the European Commission, for example, has acknowledged that «*genetic manipulation of organisms can be used or can result by chance in potentially dangerous modifications of human health or the environment. The possibility of designing a new virus or bacterium à la carte could be used by*

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<sup>116</sup> Both in the US and in the EU several forums for discussion and documents regarding biosafety have appeared (for example, see [http://www.etcgroup.org/upload/publication/602/01/synthetic\\_biologyreportweb.pdf](http://www.etcgroup.org/upload/publication/602/01/synthetic_biologyreportweb.pdf); <http://www.jcvi.org/research/synthetic-genomics-report/>; <http://www.rathenau.nl/>; [http://openwetware.org/wiki/Synthetic\\_Society/Community\\_Organization\\_and\\_Culture](http://openwetware.org/wiki/Synthetic_Society/Community_Organization_and_Culture), last visited 28<sup>th</sup> January 2013). In the case of the EU, some research projects have been funded to analyze the impact and safety problems of Synthetic Biology in Europe (SYNTHETIC BIOLOGYSAFE, at [http://www.synthetic\\_biologysafe.eu](http://www.synthetic_biologysafe.eu); SYNTHETIC BIOLOGYLOGY, 2005, at [http://www2.spi.pt/synthetic\\_biologylogy/](http://www2.spi.pt/synthetic_biologylogy/), last visited 28<sup>th</sup> January 2013).

<sup>117</sup> WORLD HEALTH ORGANIZATION, *op.cit.*

<sup>118</sup> ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, *op.cit.*

<sup>119</sup> An early Central Intelligence Agency (CIA) report (2001) warned that synthetic biology could produce engineered agents worse than any disease known to man and proposed that a qualitatively different working relationship was now required between the intelligence and biological sciences communities (see <https://www.cia.gov/index.html>, last visited 28<sup>th</sup> January 2013).

<sup>120</sup> J. CELLO, A.V. PAUL, E. WIMMER, *op. cit.*

<sup>121</sup> T.M. TUMPEY ET AL., *op. cit.*

*bioterrorists to create new resistant pathogenic strains or organisms, perhaps even engineered to attack genetically specific sub-populations»<sup>122</sup>.*

The hypothesis that someone could potentially spread all over the world these organisms to contaminate the environment and to harm humans' health is not so abstract and distant in practice, even with the caveat that only the presence of an infectious virus is not sufficient to produce a "biological weapon". In fact, as Tucker and Zilinskas argue, «*a biological weapon is [...] a complex system consisting of (1) a supply of pathogen [...]; (2) a complex "formulation" of chemical additives that is mixed to stabilize it and preserve its infectivity and virulence during storage; (3) a container to store and transport the formulated agent and (4) an efficient dispersal mechanism»<sup>123</sup>.*

Linked to misuse and mishandling of synthetic products, fit for terrorism, are the risky notions of the "lone operator" (who is a highly trained synthetic biologist with a grudge against someone or an organisation, like the "Unabomber". This individual could be a professional researcher who has access to lab equipments or a "garage biologist"<sup>124</sup>).

There is also the notion of "biohacker". He is similar to computer hacker, wherein he tries to create a virus «*out of curiosity or to show his technical prowess»<sup>125</sup>. Indeed, the worry that synthetic biology could be used for creating new pathogens and viruses is amplified by information technology, which provides open access to such information on the Internet, and by the lowering of prices for obtaining technological equipment. It is apparent that «*the development of the internet and the routinization of many biotechnological procedures have made the field more easily accessible»<sup>126</sup>.**

In addition, it cannot be forgotten that, beside the risk of malevolent use of biological knowledge by bioterrorists, there is «*the concern that the knowledge*

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<sup>122</sup> N.E.S.T., *op.cit.*

<sup>123</sup> J.B. TUCKER, R.A. ZILINSKAS, *The promise and perils of synthetic biology*, in *New Atlantis*, 12, 2006, p. 25-45.

<sup>124</sup> See H. WHITTALL, *The Ethics of Synthetic Biology*, in EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EDS.), *Ethical Aspects of Synthetic Biology*, Proceedings of the Round Table, 19<sup>th</sup> May 2009, p. 27, at [http://ec.europa.eu/bepa/european-group-ethics/docs/publications/round\\_table\\_ethical\\_aspects\\_of\\_synthetic\\_biology.pdf](http://ec.europa.eu/bepa/european-group-ethics/docs/publications/round_table_ethical_aspects_of_synthetic_biology.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>125</sup> The matter of "biohacker" was deeply discussed at the 2004 International Meeting on Synthetic Biology in Boston, referring to those who create computer viruses.

<sup>126</sup> M.S. GARFINKEL, D. ENDY, G.L. EPSTEIN, R.M. FRIEDMAN, *op.cit.*

*output of synthetic biological research and development could be incorporated into the offensive bioweapons programs of developed states»*<sup>127</sup>. Both these aspects give origin to the so-called “dual use dilemma”<sup>128</sup>, i.e. the dilemma which arises when scientific knowledge could be used in both good and harmful ways. The same dilemma occurred within nuclear fission technology regarding the ethics in usage of that technology). According to Michael Selgelid<sup>129</sup>, though, the threat posed by the misuse of knowledge from synthetic biology will ultimately be greater than that posed by nuclear technology: firstly, nuclear technology was and is too expensive for common people, while the technologies required to produce bioweapons may become quite portable and cheap; secondly, in contrast to nuclear technology, which was kept confidential, the biological field has a long tradition of openness in its access to knowledge and sharing of resources.

As exemplified in this section, biosecurity issues are thus strictly linked to (1) the ethics of knowledge and responsibility, (2) the limits of freedom of research, (3) the open or confidential access and publication of synthetic biology information.

### 5.3. Challenges upon Intellectual Property Rights.

Synthetic biology, being at the intersection of engineering, biology, software, electronics, challenges the field of intellectual property rights (I.P.Rs) as well. Indeed, «*intellectual property law has already had some difficulty incorporating two of the technologies from which synthetic biology draws inspiration - biotechnology and software»*<sup>130</sup>.

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<sup>127</sup> A. BUCHANAN, R. POWELL, *The Ethics of Synthetic Biology: Suggestions for a Comprehensive Approach* (to the U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, P.C.S.B.I.), at <http://bioethics.gov/cms/sites/default/files/The-Ethics-of-Synthetic-Biology-Suggestions-for-a-Comprehensive-Approach.pdf> (last visited 28<sup>th</sup> January 2013).

<sup>128</sup> See, for example, U.K. PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY. *The dual-use dilemma*, London, 2009.

<sup>129</sup> M.J. SELGELID, *A tale of two studies: ethics, bioterrorism, and the censorship of science*, in *Hastings Center Reports*, 37, 2007, p. 35-43.

<sup>130</sup> S. KUMAR, A. RAI, *Synthetic Biology: The Intellectual Property Puzzle*, in *Texas Law Review*, 85, 2007, p. 1748.

The issue of I.P.Rs, mainly identified with patents although patents are only one of the different types of I.P.Rs<sup>131</sup>, has already been dealt with in the field of genes and human embryonic stem cells.

As is well known, patents are legal titles granting its holder (i.e. in most of the cases, it is the inventor, but in pharmaceutical and biotech companies is often not) the right to prevent third parties from using an invention without authorisation and the right to obtain financial gains from the application. The diffusion of the invention for a period is generally twenty years. IPRs are believed to be an important instrument for encouraging investment in technological innovation, but at the same time they can inhibit the progress of research in synthetic biology, especially when the field is monopolised by large companies. The notion of IPRs is particularly relevant in the field of synthetic biology as a patent on the designs of new biological systems can be seen as a patent on the «*essence of life*»<sup>132</sup>. A symptomatic example is given by the patent on the smallest genome needed for a living organism (*Mycoplasma laboratorium*) obtained by Craig Venter's team in 2007. This patent received considerable media attention because it was felt as if it was a patent on life<sup>133</sup>. Another company, Scarab Genomics, has a patent on a minimised *E. coli* genome<sup>134</sup>.

Stepping aside from the patent system and its notion of a “patent on life”, another model has been suggested for synthetic biology, that of the notion of open source which is based on a similarity between synthetic biology and software.

Such model is formed on the grounds of the observation that synthetic biology is modular and information based. Thus it should be based on copyrights and

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<sup>131</sup> Intellectual property rights are usually divided into two main areas: (a) copyright and rights related to copyright (the rights of authors of literary and artistic works and the rights of performers, producers of phonograms (and broadcasting organizations) and (b) industrial property rights, assembling rights for the protection of distinctive signs, in particular trademarks and geographical indications; and rights aimed at stimulating innovation, design and the creation of technology, such as inventions (patents), industrial designs and trade secrets.

<sup>132</sup> E.T.C., *Extreme Genetic Engineering: An Introduction to Synthetic Biology*, 2007, at [http://www.etcgroup.org/en/materials/publications.html?pub\\_id=602](http://www.etcgroup.org/en/materials/publications.html?pub_id=602) (last visited 28<sup>th</sup> January 2013).

<sup>133</sup> J.I. GLASS, H.O. SMITH, C.A. HUTCHINSON III, N.Y. ALPEROVICH, N. ASSAD-GARCIA, *Minimal bacterial genome. United States patent application 20070122826*, Rockville, M.D., 2007.

<sup>134</sup> F.R. BLATTNER, C.D. HERRING, G. PLUNKETT, G. GLASNER, Wisconsin Alumni Research Foundation (Assignee), *Bacteria with reduced genome*, United States patent, 26<sup>th</sup> January 2006. For other patents in synthetic biology field, granted by the US Patent and Trademark Office and classified in the classes of Chemistry and Data Processing, see V.S. MOHAN-RAM, J.M. WAXMAN, *Synthetic Biology Patent Applications Expected to Present New Challenges*, in *Life Sciences Law & Industry Report*, 2, 12, 6<sup>th</sup> June 2008.



“copyleft” licenses, exactly as in open software systems, in which open-source software producers make their source code available to others, thereby establishing “copyleft licenses” and require those who are given those licenses to distribute improvements to the source code. So, in essence, if strings of DNA bases are compared to source code and are covered by copyright laws, then the licenses could be established on them<sup>135</sup>. This entails that, first of all, a property right is conferred upon the source code (strings of DNA bases) and then the licenses are given from it.

A third model would be to put synthetic products directly and immediately in public domain (treating them as “commons”). Such a solution has been adopted, for example, by the BioBricks Foundation (in the registry of *Standard Biological Parts*), that has preferred to leave the registry freely available to the public<sup>136</sup>.

The choice of openness raises questions of ownership too, as currently a lot of DNA sequences have already been patented and the openness could limit competition or could diminish the value of the elements at stake.

In summary, currently the main proposals for the protection of inventions in the field of synthetic biology are patents, copyrights and commons. Some synthetic biologists agree that the infrastructure (protocols, standards, registries, design methods, and testing methods) should be located in the commons, as this perspective promotes synergism and sharing, thus encouraging public investment in research<sup>137</sup>. Others, instead, believe that the devices composed of biological parts should be located in the private enclosures, thus fostering innovation through private

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<sup>135</sup> In October 2009 the so-called *BioBrick™ Public Agreement* (BPA) was proposed as a new legal framework for regulating the rights and duties of the contributors and users of the parts collection (see <http://bbf.openwetware.org/BPA>, last visited 28<sup>th</sup> January 2013).

<sup>136</sup> Besides BioBricks example, there are other emerging phenomena, such as: BiOS (Biological Open Source), which is a group that wants to promote the use of agricultural biotech patents as a kind of freeware, comparable to what has been done with Linux in the field of software development, and to do so, it offers a legally enforceable framework to enable the sharing of the capability to use patented and non-patented technology (see <http://www.bios.net>, last visited 28<sup>th</sup> January 2013); Public-Sector Intellectual Property Resource for Agriculture (P.I.P.R.A.), that is an initiative of US-based public research institutes involved in agrobiotech research that wants to map the patenting and licensing practices of the public sector and create a common patent database, aiming to develop “shared technology packages” of key technologies for agrobiotech research too (see R. ATKINSON ET AL., *Intellectual Property Rights: Public Sector Collaboration for Agricultural IP Management*, in *Science*, 301, 11<sup>th</sup> July 2003, p. 174–175).

<sup>137</sup> E.T.C., *Extreme Genetic Engineering*, cit.

ownership<sup>138</sup>. Some of the minority perspectives suggest the introduction of “design rights”, often used in Europe and Asia but hardly in the U.S., that could potentially be utilised as a form of I.P. protection for synthetic biology inventions<sup>139</sup>. Moreover, a framework of the “semi commons”<sup>140</sup> has been suggested as a lens with which to view synthetic biology, in order to solve the ambiguities of patents and commons. This concept captures the dynamic interaction between private and shared uses of the same resources at different scales, and the potential for shifting demarcations over time<sup>141</sup>.

However, the most suitable system to be adopted by the field of synthetic biology - schematically, whether a proprietary system or an open one or a mixture of the two and complementary one - remains questionable.

#### 5.4. *International Justice Concerns.*

Synthetic biology, as any new emerging technology, brings with it the risk of widening the gap between rich and poor countries. This is visible, for example, in the production of the precursor for the anti-malarial drug, artemisinin<sup>142</sup>, which has currently received a grant from the Bill and Melinda Gates Foundation to further develop the technology<sup>143</sup>. The concerns are (1) this useful product that could save a lot of people affected by malaria will not be exported in poor countries, or (2) it will be monopolised by the company, which means that every nation will be obliged to

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<sup>138</sup> See A. RAI, J. BOYLE, *Synthetic biology: caught between property rights, the public domain, and the commons*, in *PLoS Biology*, 5, 3, March 2007, p. 389-393; J. HENKEL, S.M. MAURER, *The economics of synthetic biology*, in *Molecular Systems Biology*, 3, 2007, p. 117.

<sup>139</sup> See C. EDWARDS, *Will IP choke synthetic biology work?* (6 June 2010) *The Biomachine*. 6<sup>th</sup> June 2010, at <http://blog.thebiomachine.com/2010/06/james-boyle-synthetic-biology-patent-fears.html> (last visited 28<sup>th</sup> January 2013).

<sup>140</sup> H.E. SMITH, *Semicommon Property Rights and Scattering in the Open Fields*, in *Journal of Legal Studies* 29, 2000, p. 131-169.

<sup>141</sup> L.A. FENNELL, *Commons, Anticommons, Semicommons*, John M. Olin Law and Economics Working Paper n. 457, 2009, at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1348267](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1348267) (last visited 28<sup>th</sup> January 2013).

<sup>142</sup> See J. KEASLING, *Synthetic Biology in Pursuit of Inexpensive, Effective, Anti-Malarial Drugs*, in *BioSocieties*, 4, 2009, p. 275–282.

<sup>143</sup> See <http://www.gatesfoundation.org/global-health/Pages/global-health-strategies.aspx> (last visited 28<sup>th</sup> January 2013).

buy it from a unique supplier<sup>144</sup> or (3) the poor country could not support the expenses to stock it up, and (4) the fear that the costs of research in the field of synthetic biology will prevent developing countries from achieving such a technological progress, as they lack the background knowledge, the money, the means to access and, if necessary, to obtain patentability of achieved discoveries.

Thus, the differences in progress and technology transfer among developed and developing countries would increase because of synthetic biology as well.

For this reason, the considerations about justice and globally equitable distribution of resources have to be centrally considered with regards synthetic biology.

### 5.5. *Ethical Concerns of a Different Nature.*

Synthetic biology also raises ethical questions. All the previously mentioned issues can be, in reality, considered as ethical ones. For example, the biosafety issue opens the ethical questions about (1) the dealing with the environment, (2) leaving nature be exposed to uncertain risks or (3) the intervention with the composition of the ecosystem in a direct manner. There is an ethical side to the issue of biosecurity under the auspices of the issues of knowledge ethics and responsibility ethics. Ethical issues emerge in the field of I.P.Rs as well, where the “moral clause” and the challenging idea of “owning life” and patenting “the essence of life” come at stake. With regards to the international the international justice concerns, ethics emerges in the reference to the ethical problem of equitable distribution of resources among States. Beyond the previous concerns, there are other topics that challenge synthetic biology from the ethical viewpoint, such as (1) the issue of “playing God”, (2) the issue of drawing a line between what is “natural” and what is artificial, and (3) the questions about the notion of “life”<sup>145</sup>.

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<sup>144</sup> W. HEEMSKERK, H. SCHALLIG, B. DE STEENHUISEN PITERS, *The World of Artemisia in 44 questions*, Amsterdam, 2006.

<sup>145</sup> According to Thomas Douglas and Julian Savulescu, there are three main ethical problems to focus on: «(1) concerns about «playing God», which have been prominent in closely related areas of science; (2) concerns about undermining the distinction between living things and machines [...] and (3) concerns about the deliberate misuse of knowledge from synthetic biology» (See T. DOUGLAS, J.

The first concern addresses the limits of science, which is connected to the idea of usurping the role of God in designing and creating life, i.e. man's *hubris*. Indeed, nature is perceived as what man did not make, but in synthetic biology man intervenes in the structure of life. He not only aims at understanding it, but rather he creates and changes it, through "infiltrating" in the notion of evolution. The fabricating or manufacturing life is at stake. Some have advocated it as a legitimate practice<sup>146</sup>, while others have expressed serious concerns about the radical nature of this intervention, as it would contrast with the role attributed to God by religious people or to human limitation by secular beliefs<sup>147</sup>. So, synthetic biology would be able to supplant the world created by Darwinian evolution with one created by human beings, and in doing so, it would open a Pandora's Box or make Frankenstein's dream possible<sup>148</sup>, which in itself is a "slippery slope" perspective<sup>149</sup>.

The second fear is tied to the difficulty of conferring a clear moral status to the "objects" of synthetic biology. This is because they are neither machines which are without any moral status and totally instrumental to mankind, nor are they organisms that have intrinsic moral value and must be treated as valuable ends, and never as a means, in Kantian terms. They blur the distinction among "natural" and "artificial". They seem to have a "hybrid status" that is difficult to settle, but is important to be understood, because from their *status*, the issue of how to treat them derives. The physiocentric or anthropocentric (bioethical) conceptions compete here, because the first approach assigns nature an absolute intrinsic value and a moral

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SAVULESCU, *Synthetic biology and the ethics of knowledge*, in *Journal of Medical Ethics*, 36, 2010, p. 688).

<sup>146</sup> J. HARRIS, *Who's Afraid of a Synthetic Human?*, in *The Times*, 17<sup>th</sup> May 2008; C. NICKERSON, *A Quest to Create Life Out of Synthetics*, in *Boston Globe*, 2<sup>nd</sup> April 2008; E. PARENS, *Making Cells Like Computers*, in *Boston Globe*, 18<sup>th</sup> February 2008; N. ANGIER, *Pursuing Synthetic Life, Dazzled by Reality*, in *New York Times*, 5<sup>th</sup> February 2008.

<sup>147</sup> See P. DABROCK, *Playing God? Synthetic biology as a theological and ethical challenge*, in *Systems Synthetic Biology*, 3, 2009, p. 47–54.

<sup>148</sup> See H. VAN DER BELT, *Playing God in Frankenstein's Footsteps: Synthetic Biology and the Meaning of Life*, in *Nanoethics*, 3, 2009, p. 257–268. J.D. MORENO, *The First Scientist to "Play God" Was Not Craig Venter. Biology Blurred the Line Between Natural and Synthetic Long Ago*, 25<sup>th</sup> May 2010, at <http://scienceprogress.org/author/jmoreno/feed/> (last visited 28<sup>th</sup> January 2013).

<sup>149</sup> H. JURGEN-LINK, *In-Depth analysis of outstanding philosophical issues*, in FP 7, *SYNTH-ETHICS, Report WP1 (deliverable 1), Identification of ethical issues and analysis of public discourse*, 2009, p. 46 ff., at <http://www.synthethics.eu/documents/REPORT%20WP1%20synthethics%20-%20ethics+public%20discourse.pdf> (last visited 28<sup>th</sup> January 2013).

value to be respected in general, the second one makes the man prevail over nature in moral terms and duties<sup>150</sup>.

The main point here is the concept of “*life*”: indeed, synthetic biology opens the doors to (1) a rethinking of the notion (and of the beginning<sup>151</sup>) of life, (2) the assignment of a moral value to it, and (3) the reconsideration of the role and shape of (human and not human) dignity.

As exemplified John Evans’s warning, if within synthetic biology, DNA can be manipulated and human life is essentially DNA, then it derives that each being (human or not) should be treated in the same way, i.e. as an object of manipulation. Therefore, synthetic biology would bring forth a reductionist view of life, alter the way we conceive ourselves (from “*homo faber*” to “*homo creator*”<sup>152</sup>), and thus changing the meaning of life and the treatment of it<sup>153</sup>. Although Evans thinks that there is a degradation of life if it becomes an object of manipulation, Ter Meulen and Calladine stress that this is a merely speculative question, since it does not imply a normative statement, i.e. the fact that people *will* think of life in those terms does not imply they *should*<sup>154</sup>.

Moreover, with an Aristotelian syllogism, if life is tied with morality with the *major premise* that life has a moral status in itself, and the *minor premise* that microorganisms synthetically created are living, thus we will arrive at the *conclusion* that synthetic microorganisms have moral status, just because they have life. Therefore, according to this line of argument, the mere owning life confers morality to the being. However, for avoiding such conclusion, the concept of life should be taken to mean that life cannot be only “biology”, but a sum of other elements, such as cultural and environmental background. In this perspective, only the beings having not simply an intrinsic value, but also an external conferring of qualities would be considered as moral ones. As it is evident, the issue remains questionable.

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<sup>150</sup> For further details of these positions, see J. MITTELSTRASS, *The Impact of the New Biology on Ethics*, in *Law and Human Genome Review*, n. 16, January-June 2002, p. 25-34.

<sup>151</sup> This issue could reopen the debates about abortion, about whether stem cells, early embryos, or hybrid embryos combining human DNA with the cellular components of other species are human (see H. DE VRIEND, *op.cit.*).

<sup>152</sup> See J. BOLDT, ET AL., *Synthetische Biologie. Eine ethisch- philosophische Analyse*, Bern, 2009.

<sup>153</sup> J.H. EVANS, *Will Synthetic Biology Change How We Value Human Life?*, in *Economic and Social Research Council Genomics Network Newsletter*, 11, 2010, p. 26-27.

<sup>154</sup> R.T. MEULEN, A.M. CALLADINE, *op.cit.*, p. 132.

In addition to the aforementioned ethical problems, other questions can be added, such as the case of using synthetic biology for altering the biological design and features of existent people or of those coming to existence (issue of design and enhancement).

*Conclusion.*

This chapter aims at giving a definition of synthetic biology by (1) examining its historical development, (2) analysing its various subfields and the work that is being done in each of these subfields, (3) reviewing the current extant problems that synthetic biology faces, (4) analysing the possible potentials that the field can contribute to humanity as well as the environment, (5) exploring the legal issues surrounding the field and its applications, and (6) discussing the moral issues that it raises. From this chapter it is evident that the field of synthetic biology presents difficult issues. In the field itself, it looks like a combination of various technologies more than a single technology, but at the same time it appears as an evolution of genetic engineering, biochemistry and molecular biology. Affirming that it is something entirely new, i.e. a revolution or, the opposite, that it is the prosecution of the existing sciences and technologies, i.e. evolution is a normative stance in both cases.

Despite how we interpret it, it is evident that synthetic biology possesses its own potentials as well as inherent risks. The question as to how to manage with them is a central point to consider. Thus, to deal with this question the next chapter explores the issue of governance within the field of synthetic biology.

## CHAPTER II

### THE GOVERNANCE OF CONCERNS AND RISKS ARISING IN THE CONTEXT OF SYNTHETIC BIOLOGY

*“Traveller, your footprints  
are the path, and nothing more;  
traveller, there is no path,  
the path is made by walking”  
(A. Machado)*

New technologies certainly bring enormous benefits to many fields and to humanity. However, at the same time, they raise some relevant concerns that pertain to different areas, as we mentioned in the last part of the previous chapter. Such concerns tend to become bigger, as the consequences of the adoption of emerging technologies are often not entirely known, not governable, difficult to predict, and potentially having catastrophic effects. Synthetic biology constitutes no exception in this regard. From the discussion in the first chapter, the field of synthetic biology possesses some inherent risks. This makes synthetic biology a “inchoate technology”, because of its *«ability to evolve in unpredictable ways and to spawn new chains of technological developments»*<sup>155</sup>. Such inchoateness imply novelty, instability, rapid evolution in independent ways.

The question now lies with the method in which to tackle those concerns and this is a central issue in the context of governance of synthetic biology. Indeed, the current *«challenge is how to simultaneously leverage a promising technology’s anticipated benefits, while guarding against its potential risks, particularly when the*

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<sup>155</sup> D. GERVAIS, *The Regulation of Inchoate Technologies*, in *Houston Law Review*, 47, 3, 2010, p. 669.

*potential risks of the technology cannot be suitably understood until the technology develops further»<sup>156</sup>.*

Thus, the purpose of this chapter is to try to analyse and evaluate the potential solutions, so as to determine which could be the most suitable and rational ones to deal with the concerns that synthetic biology poses.

This chapter is subdivided into two main parts: (1) the looking for answers to the question “*how to manage the concerns and risks of synthetic biology?*”. In this section I will be looking for a model of governance for synthetic biology and the underlying principles for approaching these risks and concerns, and (2) the attempt to find a solution to the issue of “*who should be in charge of adopting and controlling the chosen model of governance, and in which way?*”. That is to say that in this section, the focus is upon the actors and the sources of law for the regulation and governance of synthetic biology.

However, before the discussion of “governance”, a short premise on the concept of “governance” is needed.

#### *A Premise: the Notion of “Governance”.*

The term “*governance*” refers to the issue of how to regulate science and new technologies, which is the essence of the relationship between law and science.

For many years, science has been thought as a “neutral and objective” reality (according to a “positivistic” mentality) that was characterized by an inner sense of democracy (since the scientific community is a community of peers) and that was the exact opposite of the relativism and subjectivism that pervaded the notion of law<sup>157</sup>. On this basis, law was seen just as a corpus of technical norms, that had to acknowledge and “translate” into legal language the scientific understandings. So, the role of the law was simply to operate in a mechanical way, converting in its own categories what the science said, but with no interference or influence from the law to the science.

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<sup>156</sup> G. MANDEL, *op.cit.*, p. 75.

<sup>157</sup> See M. POLANYI, *The Republic of Science*, in *Minerva*, 1962, I, p. 54-73; R.K. MERTON, *Science and Democratic Social Structure*, in *Social Theory and Social Structure*, New York 1968, p. 604-615.



This was the situation up till the spread of new technologies and the almost uncontrollable and dizzying progress of science. The development of technologies and the rise of risks and concerns have brought to a very “contamination” of the law and science, so much so that it is difficult to clearly distinguish the borders between them. The necessity of governing new technologies is, therefore, a urgent one.

The concept of “governance” could be defined as follows and further expounded upon the subsequent subsections:

- (1) the reference to policy dimension, i.e. governance as a «*mode of political steering*»<sup>158</sup>;
  - (2) the reference to actors involved in applying that policy<sup>159</sup>;
  - (3) the reference to the instruments needed to achieve the adopted policy<sup>160</sup>,
- thus the sources of law are meant to “translate” a policy into reality.

### PART I: HOW TO MANAGE THE CONCERNS AND RISKS OF SYNTHETIC BIOLOGY?

In the search for a model of governance to manage the concerns and risks of this emerging technology, it should be premised that the traditional model of risk assessment, management and communication is chosen as a point of reference and a starting point, since it is this model that is usually adopted in a context of risk. So, my attempt consists of checking how and according to which principles it can work for all the concerns that are at stake in the context of synthetic biology.

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<sup>158</sup> A. HÉRITIER, *New Modes of Governance in Europe: Policy-making without Legislating?*, in A. HÉRITIER (ED.), *Common Goods: Reinventing European and International Governance*, Langham, M.D., 2002, p. 185-206.

<sup>159</sup> P. KENIS, V. SCHNEIDER, *Policy Networks and Policy Analysis: Scrutinizing a New Analytical Toolbox*, in B. MARIN, R. MAYNTZ (EDS.), *Policy Networks: Empirical Evidence and Theoretical Considerations*, Frankfurt, 1991, p. 25-59.

<sup>160</sup> A. WINDHOFF-HÉRITIER, *Policy-Analyse: Eine Einführung*, Frankfurt, 1987, p. 27-34. See also [http://www.eu-newgov.org/public/Glossary\\_m.asp#Voluntarism](http://www.eu-newgov.org/public/Glossary_m.asp#Voluntarism) (last visited 28<sup>th</sup> January 2013).

*1. The Traditional Model of Risk Assessment, Risk Management and Risk Communication.*

The traditional model for dealing with risks, not only in the context of new technologies but in any case of risk (in industrials, bank, environmental fields, for instance), is divided into three phases: (1) risk assessment, (2) risk management and (3) risk communication.

It is important to specify that such a model works in cases where the risks could be assessed in a scientific way.

(1) The phase of “risk assessment” is the one in which the scientific element emerges in (a) the identification of potential harmful events that a determinate technology arises, (b) the evaluation of the level of them (according to quantitative data or based on perception of risk or on economic elements or on trade-offs) and (c) the consideration of the probability of the consequences they could provoke<sup>161</sup>. According to the European Commission<sup>162</sup> and the U.S. National Research Council<sup>163</sup>, the phase of risk assessment can be subdivided into: (a) hazard identification, i.e. the determination of whether an agent arises risk and the nature and strength of causation; (b) dose-response assessment, i.e. looking at the relationship between the dose of an agent and the biological response in humans; (c) exposure assessment, i.e. measuring and estimating the intensity, frequency and duration of the human exposure to the agent; (d) risk characterization, i.e. estimating the health effects under the various conditions by combining data from dose-response assessment and exposure, and vulnerability analysis. In a nutshell, it is «*the process of converting uncertainty into risk*»<sup>164</sup>.

(2) The phase of “risk management” is the phase which requires the evaluation of possible actions for regulating a new technology, i.e. the choice of one of possible responses with reference to scientific, economic, political, social aspects

<sup>161</sup> See, U.K. ROYAL SOCIETY, *Risk, Analysis, Perception, Management*, London, 1992, p. 3.

<sup>162</sup> COMMISSION OF EUROPEAN COMMUNITIES, *Communication From The Commission On The Precautionary Principle*, COM (2000) 1, at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF> (last visited 28<sup>th</sup> January 2013), p. 13.

<sup>163</sup> U.S. NATIONAL RESEARCH COUNCIL, *Risk Assessment in the Federal Government: Managing the Process*, Washington, D.C., 1983, p. 17.

<sup>164</sup> J. WINPENNY, *The economic appraisal of environmental projects and policies: A practical guide*, Paris, 1995.

of assumption of risks. In other words, it consists of selecting among different options and choose the one that can ensure the most appropriate level of protection to the interests at stake.

The range of responses can be classified into four categories: «a) *risk avoidance: not performing an activity that would create the risk (proscription, prohibition); b) risk reduction: strategic methods to reduce the probability and severity of the impacts of a risk event (licensing, codes and standards, enforcement and compliance strategies); c) risk retention: accepting the loss arising from the risk event (self insurance, retaining responsibility for functions within government); d) risk transfer: cause another party to accept the risk by contracts (compulsory insurance, privatisation, public private partnerships)*»<sup>165</sup>.

(3) The phase of “risk communication” is needed for reasons of transparency and openness to the public. It should be a duty generally developed by the mass media which influences public opinion, trust, acceptability or refusal of a new technology<sup>166</sup>. This phase helps in identifying the nature and extent of the risks, educating and informing the public about the scale of risks and building trust in the proposed responses and the institutions that administer them.

In a nutshell, the traditional model entails that in the first phase be the comprehension of risks is needed, followed by the phase of management where the moment of policy and decision is essential to decide what to do and how to go about it, and finally the third phase where the requirement to communicate the chosen approach to stakeholders and general public, and receiving their feed-backs is achieved.

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<sup>165</sup> G. BOUNDS, *Challenges to Designing Regulatory Policy Frameworks to Manage Risks*, in O.E.C.D., *Reviews of Regulatory Reform. Risk and Regulatory Policy. Improving The Governance of Risk*, 2010, p. 19, at [http://www.nl.gob.mx/pics/pages/umr\\_documentos\\_base/Risk\\_regulatory.pdf](http://www.nl.gob.mx/pics/pages/umr_documentos_base/Risk_regulatory.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>166</sup> For further details, see P. SLOVIC, *The Perception of Risk*, London, 2000.

## 2. *Reframing Risks and Concerns in Synthetic Biology.*

With the establishment of the traditional model of risk analysis, this begs the question of the possibility of adopting this traditional model to address the concerns arising within the field of synthetic biology.

From the discussion in the previous section it is clear that the traditional model refers to the scientifically assessed risks. However, not all the aforementioned concerns and risks in synthetic biology (biosafety, biosecurity, intellectual property rights, international justice and ethical concerns of a different nature) could be addressed in a scientific way. So, before checking whether the traditional model could be applied for dealing with risks and concerns within the field of synthetic biology, it is preliminarily better to re-categorise the aforementioned risks and concerns inherent in the field.

The following redefinition is proposed:

(1) “*risks and concerns in a broad sense*” are the ones that we mentioned in the first chapter: (a) biosafety; (b) biosecurity; (c) challenges to intellectual property rights; (d) international justice concerns; and (e) ethical concerns of a different nature;

(2) “*concerns in a narrow sense*” are the “non-physical” ones (indicated as (c), (d), and (e)), as they can be framed in social, ethical, moral, legal, and economic terms;

(3) “*risks in a narrow sense*” are the “physical” risks (indicated as (a) and (b)), as they could be framed in a scientific, empirical, technical sense.

So, keeping in mind this re-categorization, I will check the applicability of the aforementioned traditional model of dealing with risks.

## 3. *The “Risk Assessment” within Synthetic Biology.*

Since the traditional model of risk analysis works by taking into consideration risks, it is clear that it can be applied in the area of synthetic biology with reference to what I labelled as “*risks in a narrow sense*” (biosafety and biosecurity).

The first phase, as mentioned, is the one that relates to the comprehension of risks from a scientific point of view (“risk assessment”). This brings us to the point of having the need to deepen the notion of “risk” within synthetic biology. Indeed, the physical concerns could be addressed in a scientific way, so that the risk is meant in a mathematical sense as «*the probability of an adverse event multiplied by the impact of the adverse event*»<sup>167</sup>.

The notion of risk<sup>168</sup> in our perspective refers to a future and uncertain event (“hazard”) that has harmful consequences (“harm or damage”)<sup>169</sup>. So, the components of risk<sup>170</sup> are:

- hazard: it is the unwanted and harmful event that affects people, environment, health, society, interests<sup>171</sup>. Hazards can be natural, human-made, technical, ecological, nuclear and so on, but all of them have in common the capability of producing harms;

- harm: it is the outcome/effect/consequence of the unwanted event (hazard). It is what alters and damages something and what creates a negative variation of the existing reality. Harms can be either non-physical, i.e. the alteration of values, interests, etc., or physical, i.e. the alteration of environment, health, people, animals, world, etc.<sup>172</sup>;

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<sup>167</sup> R.E. KASPERSON ET AL., *The Social Amplification Of Risk: A Conceptual Framework*, in *Risk Analysis*, 1988, p. 177-187.

<sup>168</sup> For different view and meanings of “risk”, see S.O. HANSSON, *Philosophical Perspectives on Risk*, in *Techné* 8, 1, 2004, p. 10, quoted in F. ALLHOFF, *Risk, Precaution, and Emerging Technologies*, in *Studies in Ethics, Law, and Technology*, 3, 2, 2009.

<sup>169</sup> About this particular interpretation of “risk”, see F. DE LEONARDIS, *Il principio di precauzione nell’amministrazione di rischio*, Milano 2005. See also A. BARONE, *Il diritto del rischio*, Milan, 2006.

<sup>170</sup> See K. THYWISSEN, , *Components of Risk. A Comparative Glossary*, Source ‘Studies of the University: Research, Counsel, Education’ Publication Series of UNU-EHS n. 2/2006, at <http://www.ehs.unu.edu/file/get/4042> (last visited 28<sup>th</sup> January 2013).

<sup>171</sup> See S.L. CUTTER, *The Changing Nature of Risks and Hazards*, in S.L. CUTTER, *American Hazardscapes, The Regionalization of Hazards and Disasters*, Washington, D.C., 2001, Chapter 1; W.H. SPERBER, *Hazard identification: from a quantitative to a qualitative approach*, in *Food Control* 12, 2001, p. 223-228; D. ALEXANDER, *Confronting Catastrophe - New Perspectives on Natural Disasters*, Oxford, 2000.

<sup>172</sup> About this distinction among harms within synthetic biology, see E. PARENS, J. JOHNSON, ET AL., *Ethical Issues in Synthetic Biology. An Overview of the Debates*, Washington, D.C., 2009. Some criticism of such vision is explained by Ter Meulen and Calladine, who have asserted that most of the times the non-physical harm of non equitable distribution can prevent the access to a medicine, in absence of which a physical harm is caused (so that non-physical harm in reality consists of a physical one); or, on the other way, it is not demonstrated that a mutation of the fundamental belief of the natural world arises a harm (in a similar way, Darwin’s theory should be proved to have been harmful for humanity, but this is not arguable, at least for people who don’t believe in creationism). In other words, the dichotomy of physical and non-physical harms would be blurring in synthetic biology, and

- uncertainty: it is an intermediate situation between the full knowledge or certainty that the harmful event will occur and the full ignorance of it. Such uncertainty can be of two types: (a) the type of harms that can be produced by the hazard, and/or b) the probability of the likelihood that such harms will occur<sup>173</sup>.

More precisely, the notion of uncertainty means that if we find ourselves in a situation of risk, and there is no 100% certainty that the hazard will occur, then, according to the degree of uncertainty, the risks could be further classified into two subcategories:

a) probable risk: there could be the knowledge of the possible harms it could provoke and the knowledge of the probabilities according to which the harms will happen;

b) uncertain risk: the possible consequences of hazard can be known or not, and to assign a clear level of probabilities to them is surely impossible.

In a sum, the “risks” within synthetic biology according to uncertainty can be subdivided as such<sup>174</sup>:

	<b>100% KNOWLEDGE OF THE OCCURRENCE OF THE HARMFUL EVENT (HAZARD)</b>	<b>KNOWLEDGE OF THE HARMFUL CONSEQUENCES OF THE FUTURE EVENT (HARM)</b>	<b>KNOWLEDGE OF THE LEVEL OF PROBABILITIES OF THE HARMFUL CONSEQUENCES OF THE FUTURE EVENT (HARM)</b>
<b>CERTAINTY</b>	Yes (100% knowledge of occurrence of a damage)	Yes	Yes
<b>PROBABLE RISK</b>	No (1-99% knowledge of occurrence of a damage)	Yes	Yes
<b>UNCERTAIN RISK</b>	No (1-99% knowledge of occurrence of a damage)	Yes/No	No

it would be better not to separate them so strictly but to adopt a mixing view of physical and non-physical ones. For this criticisms, see R.T. MEULEN, A.M. CALLADINE, *op.cit.*

<sup>173</sup> See D. BEYLEVELD, R. BROWNSWORD, *Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning*, in *Law, Innovation and Technology*, 4, 1, 2012, p. 36.

<sup>174</sup> With regards to different views of risk, uncertainty and ignorance, see G. MAJONE, *Working party on regulatory management and reform. Risk and regulation : Issues for discussion. Annex 1: Strategic issues in risk regulation and risk management*, Paris, 2006, OECD, GOV/PGC/REG(2006)1/ANN1. See also UK ROYAL SOCIETY, *Risk, Analysis, Perception, Management*, 1992, p. 2.

<b>IGNORANCE</b>	No (0% knowledge of the occurrence of a damage)	No	No
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Examples of the elaboration of this phase of risk assessment can be obtained from the World Trade Organization (W.T.O.). In particular, the W.T.O. “*Agreement on the Application of Sanitary and Phytosanitary Measures*”<sup>175</sup> provides that any restriction to the commercialization and introduction of insects or organisms that could bring diseases can be done only and on the basis of a proper risk assessment (art. 5.1), as defined in Annex A (paragraph 4)<sup>176</sup>.

Under the European Union (E.U.) Law, beyond the specific subjects in which risk assessment is required<sup>177</sup>, the most recent document that suggests the traditional approach to risks in reference to any kind of physical concerns is the “*Risk Assessment and Mapping Guidelines for Disaster Management*”, enacted by the E.U. Commission<sup>178</sup>. The guidelines aim at creating a platform for national risk assessment in cases of natural and human made risks. They address disaster management authorities, policy-makers, public interest groups, civil society organisations and other public or private stakeholders involved or interested in the management and reduction of disaster risks. With regards to the risk assessment phase, the document makes reference to the hypothesis in which the likelihood of the occurrence of a hazard of a certain intensity can be quantified. This is so that risk is seen to be the «*hazard impact X probability of occurrence*», and it opts for a risk assessment composed of «*scenario building, extent of quantitative analysis, number of risks and risk scenarios considered, temporal horizon*».

<sup>175</sup> The Agreement on the Application of Sanitary and Phytosanitary Measures is also known as the “S.P.S. Agreement”, 1995, at [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm) (last visited 28<sup>th</sup> January 2013).

<sup>176</sup> It must provide «*available scientific evidence, processes and production methods, inspection and sampling methods, relevant existing specific diseases or pests, areas free of diseases or pests, relevant ecological and environmental conditions, quarantines or other treatments*».

<sup>177</sup> See: with regards to food safety area (Regulation 178/2002 of the European Parliament and of the Council of 28<sup>th</sup> January 2002, in *Official Journal of the European Communities, O.J. L 31/2002*), working places (Council Directive 89/391/EEC of 12<sup>th</sup> June 1989 in *O.J. L 183/1989*), GMOs (the European Food Security Agency, E.F.S.A., has enacted several documents about GMOs, see <http://www.efsa.europa.eu/>, last visited 28<sup>th</sup> January 2013).

<sup>178</sup> COMMISSION STAFF WORKING PAPER, *Risk Assessment and Mapping Guidelines for Disaster Management*, 21<sup>st</sup> December 2010, SEC (2010) 1626 final, at [http://ec.europa.eu/echo/files/about/COMM\\_PDF\\_SEC\\_2010\\_1626\\_F\\_staff\\_working\\_document\\_en.pdf](http://ec.europa.eu/echo/files/about/COMM_PDF_SEC_2010_1626_F_staff_working_document_en.pdf) (last visited 28<sup>th</sup> January 2013).

Analogously, in the U.K., the monitor for the most significant emergencies is accomplished through the “National Risk Assessment” (N.R.A.), which is the most important method enacted within the U.K. for dealing with natural events, major accidents and malicious attacks. The national risk assessment has been in force since 2005 as a result of the creation of the Civil Contingencies Act in 2004. The N.R.A. constitutes the basis for the “National Risk Register” (N.R.R) which provides the public with an overview of the emergencies that the government believes might have a major impact on all<sup>179</sup>. The 2004 Civil Contingencies Act<sup>180</sup> mandates the Civil Contingencies Secretariat, an office at the core executive of the Cabinet office, which coordinates and facilitates the emergency preparedness and response in the U.K.. For the assessment of risks, a consultation of a wide range of experts in various government departments is pursued. Reasonable worst case scenarios are developed based on the identified risks, and an assessment of likelihood or plausibility and its impact must be provided.

It is meaningful to consider, then, that in the U.S.A. the introduction of the risk assessment pertaining to scientifically quantified risks, in physical dimensions, such as health and environment, has come from the jurisprudence. Indeed, the case *AFL-CIO v. American Petroleum Institute* (1980)<sup>181</sup>, known as the landmark “benzene case”, has inaugurated the road to the traditional risk model in the U.S.A.<sup>182</sup>, while European regulation has remained more qualitative and informal<sup>183</sup>. However, in the U.S.A., the adoption of the traditional model is still not provided by law, but left to the discretion of the single agencies. The Supreme Court of the U.S.A. confirmed the legitimacy of quantitative risk assessment and stated that such

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<sup>179</sup> U.K. CABINET OFFICE, *National Risk Register of Civil Emergencies*, London, 2010, at <http://www.cabinetoffice.gov.uk/ukresilience>. See also U.K. H.M. TREASURY, *The Green Book. Appraisal and Evaluation in Central government Treasury Guidance*, London, 2003 (reviewed in 2011), at [http://www.hm-treasury.gov.uk/d/green\\_book\\_complete.pdf](http://www.hm-treasury.gov.uk/d/green_book_complete.pdf); U.K. H.M. TREASURY, *Orange Book Management of Risk - Principles and Concepts*, London, 2004, at [http://www.hm-treasury.gov.uk/d/orange\\_book.pdf](http://www.hm-treasury.gov.uk/d/orange_book.pdf) (last visited 28th January 2013).

<sup>180</sup> See U.K. PARLIAMENT, *Civil Contingencies Act*, 2004, at <http://www.legislation.gov.uk/ukpga/2004/36/contents> (last visited 28th January 2013).

<sup>181</sup> Case *Industrial Union Department AFL-CIO v. American Petroleum Institute* (448 U.S. 607 (1980)).

<sup>182</sup> B.D. GOLDSTEIN, *The Interface Between Science and Law*, in *Columbia Journal Environmental Law*, 14, 1989, p. 343-355.

<sup>183</sup> S. JASANOFF, *Contingent knowledge: implications for implementation and compliance*, in E.B. WEISS, H. JACOBSON (EDS.), *Engaging Countries: Strengthening Compliance with International Environmental Accords*, Cambridge MA, 1998, p. 63.



methodology had to be considered as obligatory for all American agencies engaged in health regulation. In order to decide whether the benzene emissions could be taken under the Occupational Health and Safety Act, a certain amount of scientific evidence was needed. Indeed, a «*significant risk*» had to be proved before assuming any measure.

#### 4. *The “Concern Assessment” within Synthetic Biology.*

With regards to the non-physical concerns, in my opinion the traditional model could be applied as well. The first phase can be defined as “concern assessment”, which is the phase which corresponds to a general comprehension of the threats that can arise in the field of synthetic biology from the social, ethical, legal, economic point of view.

A meaningful example is provided by the International Risk Governance Council (I.R.G.C.)<sup>184</sup>, which suggests to follow a cyclic sequence for the different stages of risk analysis, and defines the “assessment sphere” as composed of Risk assessment (Hazard identification and estimation; Exposure and vulnerability assessment; Risk estimation), Concern assessment (Risk perceptions; Social concerns; Socio-economic impacts), and Risk characterisation (Risk profile; Judgement of the seriousness of risk; Conclusions and risk reduction options).

#### 5. *The “Risk and Concern Management” within Synthetic Biology.*

Following the assessment of risks and concerns in the previous section, this section discusses in greater detail the phase of management, also known as the phase of “policy”.

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<sup>184</sup> INTERNATIONAL RISK GOVERNANCE COUNCIL, *Risk Governance. Towards An Integrative Approach*, Geneva, 2006, at [http://www.irgc.org/IMG/pdf/IRGC\\_WP\\_No\\_1\\_Risk\\_Governance\\_\\_reprinted\\_version\\_.pdf](http://www.irgc.org/IMG/pdf/IRGC_WP_No_1_Risk_Governance__reprinted_version_.pdf) (last visited 28<sup>th</sup> January 2013). The I.R.G.C. is a Switzerland non-profit and independent organisation whose purpose is to help improve the understanding and governance of systemic risks (for further details, see: <http://www.irgc.org/>, last visited 28<sup>th</sup> January 2013).

In general, the responses to risks and concerns follow – in my opinion – three main patterns:

- (1) precaution, which includes the ban of an action or product, or a moratorium, or a strict regulation and control;
- (2) cost-benefit or risk-benefit decision which is founded on cost-benefit or risk-benefit analysis
- (3) proaction, which is the policy of *laissez-faire*.

The question now is from which of the above responses is the most suitable with regards to risks and concerns of synthetic biology. The answer is: none of those. Better: none of those is completely and entirely likely to be embraced, but in my opinion it is more rational to opt for a “fourth road”. The pattern that works better is the one of “*prudent vigilance*” that entails the adoption of different principles, in particular “*responsible stewardship, public beneficence, intellectual freedom and responsibility, democratic deliberation, justice and fairness*”.

This model is an elaboration and development of the idea proposed by the U.S. Presidential Commission for the Study of Bioethical Issues (P.C.S.B.I.). This is an advisory panel of the nation’s leaders in medicine, science, ethics, religion, law and engineering. In December 2010, the Commission adopted, on request of the President Obama, a report containing 18 Recommendations for a proper governance and regulation of the field<sup>185</sup>. This report finds within itself some references from I.R.G.C. report and its guidelines about synthetic biology<sup>186</sup>, and from Innogen Centre Report<sup>187</sup>. So, the model I am opting for is given by the mixture of the models

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<sup>185</sup> U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), *Report New Directions. The Ethics of Synthetic Biology and Emerging Technologies*, Washington, D.C., December 2010, at <http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12.16.10.pdf> (last visited 28<sup>th</sup> January 2013).

<sup>186</sup> INTERNATIONAL RISK GOVERNANCE COUNCIL, *Concept note: Synthetic Biology: Risk and Opportunities of an emerging field*, Geneva, 2008, at [http://www.irgc.org/IMG/pdf/IRGC\\_Concept\\_Note\\_Synthetic\\_Biology\\_191009\\_FINAL.pdf](http://www.irgc.org/IMG/pdf/IRGC_Concept_Note_Synthetic_Biology_191009_FINAL.pdf). See also INTERNATIONAL RISK GOVERNANCE COUNCIL, *Policy Brief. Guidelines for the Appropriate Risk Governance of Synthetic Biology*, Geneva, 2010, at [http://www.genomicsnetwork.ac.uk/media/irgc\\_SB\\_final\\_07jan\\_web.pdf](http://www.genomicsnetwork.ac.uk/media/irgc_SB_final_07jan_web.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>187</sup> J. TAIT, J. CHATAWAY, D. WIELD, *Appropriate Governance of the Life Sciences – 2: The Case for Smart Regulation*, Innogen Policy Brief, at <http://www.genomicsnetwork.ac.uk/media/AGLS2%20-%20The%20Case%20for%20Smart%20Regulation.pdf> (last visited 28<sup>th</sup> January 2013). The ESRC Centre for Social and Economic Research on Innovation in Genomics is based at the University of Edinburgh, Scotland (for further details, see <http://www.genomicsnetwork.ac.uk/innogen/>, last visited 28<sup>th</sup> January 2013).

suggested in these aforementioned Reports. It must be specified that this model tries to deal with all the criticisms that are raised by the other approaches, in the sense that it shows some elements that are present in cost-benefit and risk-benefit analysis, some elements of precautionary principle and some others which are proactionary, but without fully agreeing with any of them.

### 5.1. The “Prudent Vigilance” Model.

The most suitable model to tackle concerns and risks generated by synthetic biology is, in my opinion, a sort of “middle way” between total openness to new technologies and closure: indeed, it is far away from a Luddite approach towards technologies, which consists in fighting against them<sup>188</sup>, but also apart from letting science proceed uncontrolled and without regulations and/or guidelines.

Starting from the premise that the field of synthetic biology is very young and the uncertainties around it are many (not only about the likelihood of the harms, but also what the possible harms can be), the conclusion states that it is better to adopt a system of ongoing assessments as the risks develop. So, research in synthetic biology should go forward but with safeguards.

In summary, the chosen approach is a balanced one. It evaluates all the terms of the matter and arranges them in a proportioned way. It is meant to be *«a more nuanced decision about the appropriate degree of precaution to take with respect to an emerging technology and the appropriate level and kind of support to offer it»*<sup>189</sup>.

The label “*prudent vigilance*” chosen by the US Presidential Commission is synonymous in its content to the one adopted by International Council of Risk Governance and Innogen Centre. It describes an *«appropriate approach to risk*

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<sup>188</sup> The Luddites were 19th-century English textile artisans who violently protested against the machinery introduced during the Industrial Revolution. The riots protested against machines that left many workers unemployed. The movement took the name by Ned Ludd, a youth who had allegedly smashed two stocking frames and whose name had become emblematic of machine destroyers. This movement has become a symbol of all the movements against innovations and technological progress.

<sup>189</sup> T.H. MURRAY, *What Synthetic Genomes Mean for Our Future: Technology, Ethics, and Law, Interests and Identities*, in *Valparaiso University Law Review*, 45, 4, 2011, p. 1327.

*governance*»<sup>190</sup>, where it «enables innovation, minimises risk to people and the environment, and balances the interests and values of relevant stakeholders»<sup>191</sup>. This is the same view that adopted by the “*prudent vigilance*” approach. However, the expression “*prudent vigilance*” can be seen, at the first sight, as an “empty box”, because what it concretely means in a pragmatic sense seems to be unclear. Therein lies the challenge: the understanding of the concrete application of this expression.

The notion of “*prudence*” brings to mind the definition put forth by Aristotle, which is meant as a practical knowledge: “*phronesis*”. This differs from the theoretical “*sophia*”. It is a capacity of dealing with reality and contingency, keeping distinct the different perspectives and choosing the most preferable one for the benefit of the whole society. In cases of uncertainty, it is a middle way among the irrational fear of novelty, the passive and irresponsible openness to new things, processes, and the products that could be dangerous for health, environment, values, humanity as such.

Such an approach leads to the following principles, which demonstrate its different facets.

1) The principle of “*public beneficence*” means to act in order to maximize current and potential public benefits and to minimize current and potential public harm.

With reference to biosafety and biosecurity risks, the principle operates, first of all, in the assessment phase, as it calls for the importance of collecting knowledge about both risks and benefits. This does not mean the forgetting of one aspect or another, but trying to reach a comprehensive framework such as in the “anti-catastrophe” version of the precautionary principle and the proactionary one. Such knowledge should be obtained through a constant research in risks, which is not limited to the study of possible side effects, but, on the contrary, considers all reasonable alternative actions, and concentrates on both immediate and widely distributed and follow-on effects.

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<sup>190</sup> J. TAIT, J. CHATAWAY, D. WIELD, *Appropriate Governance*, cit. See also J. TAIT, *Systemic Interactions in Life Science Innovation, Technology Analysis and Strategic Management*, 19, 3, 2007, p. 257-277.

<sup>191</sup> Ibid.

Then, after the knowledge assessment, the principle of beneficence works for the management, providing that a research that brings benefits cannot be banned. Even if it poses risks, the policies for progressively managing and minimising those risks should still be pursued, while letting the research go on. In other words, the principle entails that the duty of the society and governments is to balance benefits and risks, through the promotion of intellectual activities and institutional practices, including scientific and biomedical research, that have the great potential to improve the public's wellbeing. At the same time, the society and governments must control the possible emerging concerns in an ongoing way. In this sense, the principle of “*public beneficence*” is in line with cost-benefit analysis, risk-benefit analysis and risk trade-offs analysis.

With reference to non physical concerns, the principle of beneficence calls for the relevance of thinking beyond the individual framework, and for dealing with social, ethical, economic issues by considering their “collective” dimension. In fact, the principle of beneficence finds inspiration from the Belmont Report, a landmark statement of ethical principles for research involving human subjects. The Report cited “*beneficence*” as to requirement that the people «*are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their wellbeing*»<sup>192</sup>. In the context of synthetic biology, though, such “*beneficence*” needs to go beyond the mere individual dimension and be referred «*to the institutional, community, and public levels, while not overlooking possible harms and benefits to individuals. Policy makers should adopt a societal perspective when deciding whether to pursue particular benefits of synthetic biology research in the face of risks and uncertainty*»<sup>193</sup>.

2) The purpose of the principle of “*responsible stewardship*”<sup>194</sup> is to «*demonstrate concern for those who are not in a position to represent themselves (e.g., children and future generations) and for the environment in which future generations will*

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<sup>192</sup> NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIOURAL RESEARCH, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, 1979, at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm> (last visited 28<sup>th</sup> January 2013).

<sup>193</sup> U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), *op.cit.*, p. 25.

<sup>194</sup> The notion of “*responsible stewardship*” in the past was almost exclusively referred to managerial skills relating to property and income; nowadays, it has been applied to environmental field.

*flourish or suffer*»<sup>195</sup>. Indeed, this notion of “*responsible stewardship*” brings to mind Hans Jonas’s concept of “*responsibility*”, and to his imperative to behave in such a way that the effects of our actions cannot destroy the future of life on earth<sup>196</sup>. Furthermore, “*responsible stewardship*” is intended as «*a kind of Aristotelian mean between extreme pro-action and extreme precaution, [and it] is both procedural and substantive. [...It] takes the value of what human innovation and creativity can contribute to saving lives and enhancing lives and also takes seriously the ability of us to think ahead and take precautions against risks. And that will always require something of an assessment and a balancing*»<sup>197</sup>.

With regards to the risks in the field of synthetic biology (that, as I said, are considered as the “physical” risks), the notion of “*responsible stewardship*” reminds us of a risk-benefit analysis. Thus it requires the need for an ongoing evaluation of (biosafety and biosecurity) risks along with the benefits, as well as the establishment of evaluating processes for assessing likely benefits along with assessing risks before and after projects are undertaken.

In particular, pertaining biosafety risks, the principle of “*responsible stewardship*” suggests an iterative process and a cooperative system of information between specialised units, a preventive monitoring and control of labs, a surveillance or containment of synthetic organisms, an interaction with all stakeholders of the field, at international and transnational level too<sup>198</sup>.

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<sup>195</sup> U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), *op.cit.*, p. 4.

<sup>196</sup> H. JONAS, *Das Prinzip Verantwortung: Versuch einer Ethik für die technologische Zivilisation*. Frankfurt, 1979. Max Weber was the first one to talk about an ethics to be oriented to consequences, i.e. when deciding an action, the consequences (real or probable) must be taken into account. Hans Jonas, starting from Weber’s position, proposed the following maxim of conduct: «*Act so that the effects of your actions are compatible with the permanency of a genuine life in the earth*». Jonas adopted a concept of responsibility applied to future generations. Three are the conditions to exercise responsibility: causal power (the action must have a relationship to the world); the action depends from an agent; the consequences of the action are foreseen until a certain point. If these conditions are satisfied, the responsibility shows two facets: responsibility for the individual’s own actions (formal responsibility) and responsibility towards certain subjects with whom the actors relates (substantive responsibility). Echeverría criticized it since it is an imperative duty and an axiological matter rather than an ethical principle (see J. ECHEVERRÍA, *El principio de responsabilidad: ensayo de una axiología para la tecnociencia*, in R.R. ARAMAYO, M.J. GUERRA (EDS.), *Los laberintos de la Responsabilidad*, Madrid, Mexico, 2007, p. 251-270).

<sup>197</sup> A. GUTMANN, *TRANSCRIPT: Meeting 3, Session 3. Emerging Technology Framework & Next Steps for the Commission*, Atlanta, G.A., 16<sup>th</sup> November 2010. See <http://www.bioethics.gov> (last visited 28<sup>th</sup> January 2013).

<sup>198</sup> U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), *op.cit.*, Recommendations nn. 2, 3, 5, 6, 7, 8, 12, 13, 17.

Then, biosecurity and the “dual-use dilemma” of scientific knowledge has the potential to overstate the risks or understate the knowledge. This is done by promoting only security at the expense of other values, such as economic growth, scientific freedom and the intrinsic value of knowledge. As a result, this stifles the progress or, on the contrary, exaggerates the knowledge and exposing people and society to big risks. thus, with regards to biosecurity, the U.S. Report stresses the importance of scientists’ responsibility. Indeed, in the face of situations where there are “amateur” or “do-it-yourself” scientists, *«responsible conduct of synthetic biology research, like all areas of biological research, rests heavily on the behaviour of individual scientists. Creating a culture of responsibility in the synthetic biology community could do more to promote responsible stewardship in synthetic biology than any other single strategy. There are actors in the world of synthetic biology [...] who practice outside of conventional biological or medical research settings. These groups may not be familiar with the standards for ethics and responsible stewardship that are commonplace for those working in biomedical research. This poses a new challenge regarding the need to educate and inform synthetic biologists in all communities about their responsibilities and obligations, particularly with regard to biosafety and biosecurity»*<sup>199</sup>.

However, the notion of “*responsible stewardship*” does not stop at assessing physical concerns. In my opinion, calling upon the development of the U.S. Commission’s approach, the notion of “*responsible stewardship*” could be used to refer to ethical, economic, social concerns too. In fact, it calls for a social involvement of all the components of society in dealing with ethical, economic, and social issues, so as to enact the new model of «*socio-ethics*»<sup>200</sup>. It would imply to involve people (stakeholders and general public) in the study of synthetic biology while it works and develops, instead of waiting for the science to reach some conclusions. This new notion of “*social responsibility*” would prevent the same situation as per the case of GMOs to occur, when the public was only informed at the end of the process, thus generating misunderstandings, incomprehensions, and fears. In other words, the notion of “*responsible stewardship*” calls for a «*transformed*

<sup>199</sup> U.S. PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES (P.C.S.B.I.), *op.cit.*, p. 11.

<sup>200</sup> M.A. O’MALLEY, J. CALVERT, J. DUPRÉ, *The Study of Socioethical Issues in Systems Biology*, in *American Journal of Bioethics*, 7, 4, 2007, p. 67-78.

*notion of responsibility*»<sup>201</sup> that goes beyond the focus on individuals to the focus on «*social institutional spheres*»<sup>202</sup>. In this way, social engagement leads to assemble people from different backgrounds in order to address the issues of “playing God”, the notion of life and nature, and the status of organisms and artifacts. Moreover, it involves people in the decision-making process, where they can decide whether a research must be pursued. It also allows a continuous feedback on applications and research, thus “testing” the products of synthetic biology in an ongoing way. As for the disagreement about the social and moral values, the notion of “responsibility” should be enlarged to include as many stakeholders as possible, in a transparent way. This is to bring the E.L.S.I. issues (i.e., Economic, Legal, Social Issues) from the “top” institutions to the “down” public and society, and thereby improving a social and collective responsibility in dealing with those questions.

3) “*Intellectual freedom and responsibility*”: the notion of responsibility is quoted again in the third principle, but it is now limited to the specific category of scientists. Indeed, the U.S. Presidential Commission underlines the link that should be established between the scientific research and responsibility. In this context, the approach calls for public policies that encourage intellectual exploration and promote progress, but at the same time the Commission put intellectual freedom and (moral) responsibility for scientists under the same umbrella. So, the approach can be considered as an application of the second principle of “*responsible stewardship*”. This principle will be further explained in the second part of the chapter when I discuss the question of “*who*” during the application of the model.

4) The “*democratic deliberation*”. This principle, like the previous, will be expounded upon in the second part of the chapter.

5) The principle of “*justice and fairness*” relates to the distribution of benefits and burdens across society. This principle works in reference with both physical and non physical concerns, as it suggests that all the individuals and institutions should share

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<sup>201</sup> R. VON SCHOMBERG, *From the Ethics of Technology towards an Ethics of Knowledge Policy & Knowledge Assessment*, Luxembourg, 2007.

<sup>202</sup> Ibid.



the same amount of benefits and risks. It means that all of the societies of the world, at the national and international level, must have access to the same benefits of synthetic biology. As for concerns and risks, all of the societies of the world should also be involved in dealing with them. As the field of synthetic biology can have global positive effects and global negativities with the enjoyment of the benefits that it produces, it is only fair that the tackling of the latter should be equally distributed.

In summary, the adopted framework based on the notion of “*prudent vigilance*” proposes a new pattern that aims to solve the limits of the others<sup>203</sup> and is build up on the idea of presenting neither a total closing to new technologies nor a limitless openness. It is a responsible manoeuvre of approach, in which appropriate measures of care should be taken. I believe this framework opens a new road, as it tries to find a compromise among precautionary and proactionary principles, and the schemes connected with cost-benefit analysis. Indeed, this approach takes some elements from all the positions, in its effort to make them coexist. So, the approach, as followed by the U.S. Presidential Commission and others, seems to not be the one that chooses a precautionary approach excluding the others, or a proactionary excluding others or a cost-benefit analysis excluding other approaches. On the contrary, such “*prudent vigilance*” keeps together all the three approaches, “saving” the “best” (i.e. the most rational) parts of each of them, and it makes them coexist.

The following table demonstrates how the notion of “*prudent vigilance*” tackles the other approaches and what it “takes” from the others. It is evident from this table that the “*prudent vigilance*” model keeps some aspects from each of the other models that will be described in a while.

<b>WEAK PRECAUTIONARY PRINCIPLE</b>	Principle of proportionality, cost-effective measures, democratic method and decisions
<b>MODERATE PRECAUTIONARY PRINCIPLE</b>	No
<b>STRONG PRECAUTIONARY PRINCIPLE</b>	No
<b>ANTI-CATASTROPHE PRINCIPLE</b>	Comprehensive view of risks, moderate cost-benefit analysis
<b>PROCEDURAL PRINCIPLE</b>	Democratic method and process
<b>COST-BENEFIT ANALYSIS</b>	Yes when possible (economic values at stake and calculations feasible), but taking into account ethical, environmental, legal, social and political issues as well

<sup>203</sup> The other patterns will be shown in a while under a comparative perspective.

<b>RISK-BENEFIT ANALYSIS</b>	Yes when possible (economic values at stake and calculations feasible), but taking into account ethical, environmental, legal, social and political issues as well
<b>RISK TRADE-OFF ANALYSIS</b>	Yes but comprehensive view of risks and benefits (primary and ancillary)
<b>PROACTIONARY PRINCIPLE</b>	Comprehensive analysis of risks and benefits, transparency of democratic processes, proportionality, review of decisions.

### 5.2. *The Precautionary Principle.*

From the previous section, it has been demonstrated that the approach of “*prudent vigilance*” is, in my opinion, the most suitable for synthetic biology. It does not exclude other approaches that are used in the risk management phase (precautionary, proactionary and cost-benefit analysis). However, it does not entail to prefer entirely one of them, mutually excluding the others, but the “*prudent vigilance*” model, in a sense, “selects” some parts of each of them.

In order to better understand the novelty of the model of “*prudent vigilance*”, it appears important to present the other aforementioned approaches.

The well-known “precautionary principle” (P.P.), according to some, has a millenary tradition<sup>204</sup>, while others are of the opinion that it was born in the late 19<sup>th</sup> Century when a doctor’s recommendation to remove the handle of a water pump to stop a cholera epidemic was enacted (1854)<sup>205</sup>. Despite its historical origins, it is clear that the spread of P.P. happened in Germany during the Seventies, when it first appeared as *Vorsorgeprinzip*<sup>206</sup>. It was embedded in the legislation, and later

<sup>204</sup> P.H. MARTIN, *If you don’t know how to fix it, please stop breaking it!*, in *Foundations of Science* 2, 262, 1997, p. 276.

<sup>205</sup> P. HARREMOES ET AL., *The Precautionary Principle in the 20<sup>th</sup> Century: Late Lessons from Early Warnings*, European Environmental Agency Issue Report, n. 22, Luxembourg, 2001.

<sup>206</sup> *Vorsorge* means “foresight of consequences and taking care of”. The first reference to precautionary policy was made while drafting the new statute about atmosphere pollution in 1970 in Germany, but the first legislation that adopted the principle was the *Bundesimmissionschutzgesetz* (federal law about the protection against emissions) in 1974. Then, the precautionary principle has been mentioned in a lot of German laws about environment, such as the law on chemical products (*Chemikaliengesetz*), 1980; law on the use of atomic energy (*Atomgesetz*), 1985; law on the proof of tolerance on environment (*Umweltverträglichkeitsprüfung*), 1990. For this topic, see A. TROUWBORST, *The Precautionary Principle in General International Law: Combating the Babylonian Confusion*, in *Review of European Community & International Environmental Law*, 16, 2, 2007, p. 185-195.

confirmed by the German Constitutional Court<sup>207</sup>, with the purpose of preventing environmental damages surrounded by uncertainty. P.P. subsequently broadened up to the defence of health risks. The notion of P.P. can be summarized by the old adage, «*it is better to be safe than sorry*». However, its opponents say that P.P. is intrinsically malleable and ambivalent<sup>208</sup>, «*a marvellous piece of rethoric*»<sup>209</sup>, ambiguous and vague<sup>210</sup>.

In general, taking into consideration its numerous versions, P.P. states that if an action like that of scientific research and technological development is suspected to pose a severe harm to the environment or to health or to the public, and a scientific consensus regarding the probability of the harm or even the cause and effect relationship between action and harm is absent, the burden of proof should be shifted to those taking the action. These people must present evidence that the action is not harmful.

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<sup>207</sup> See, for example, *Kalkar*, Decision of the Federal Constitutional Court (49 BVerfGE 89, 1978, at <http://www.iuscomp.org/gla/judgments/tgcm/vkalkar.htm>, last visited 28<sup>th</sup> January 2013). In this case, the Court stated that even a low probability of the harmful event to happen requires the State to intervene for protecting human rights (such as the right to life ex art. 2 of the Basic Law, human dignity in art. 1, the right to health in art. 14). The policy, though, cannot consist in forbidding a new technology, but choosing the best way for reducing risks (such as adopting a system of authorization for the creation and use of power station). The evaluation of risks must follow a criterion of “practical reasonableness” (*practisches Vernunft*), so that a threshold among the acceptable risks and the non acceptable ones should be sketched out. When introducing a new technology, indeed, it is impossible to think to avoid any type of risk: the State must, instead, be careful of allowing the so-called “*Restrsiko*” (“residual risk”) and blocking the other risks. As seen, the Court makes the precautionary principle operate in the context of State policy, in hypothesis of uncertainty that could be low, but never in absence of at least some elements of suspicion of harm. Moreover, the precaution never asks for a “zero risk” situation, but implies a risk-benefit analysis, according to which the least risky situation must be chosen. The “duty” upon the State in adopting those measures lies on art. 20 A of the Basic Law, where there is the reference of the protection of life and animals, towards future generations too, through legislation, the executive power and the judiciary one: so, the State obligation is an all-accomplished one that runs over all the powers of the legal system.

<sup>208</sup> J. SCOTT, E. VOS state: «*few legal concepts have achieved the notoriety of the precautionary principle. Praised by some, disparaged by others, the principle is deeply ambivalent and apparently infinitely malleable*» (J. SCOTT, E. VOS, *The juridification of uncertainty: observations on the ambivalence of the precautionary principle within the E.U. and the W.T.O.*, in C. JOERGES, R. DEHOUSSE (EDS.), *Good governance in Europe's integrated market*, Oxford, 2000, p. 253-286).

<sup>209</sup> A. WILDAVSKY, *But is it true? A Citizen's Guide to Environmental Health and Safety Issues*, Cambridge, M.A., 1995, p. 425. With regards to the criticism to P.P., see also E.C. PARKE, M.A. BEDAU, *The Precautionary Principle and Its Critics*, in M.A. BEDAU, E.C. PARKE (EDS.), *The Ethics of Protocells. Moral and Social Implications of Creating Life in the Laboratory*, Cambridge, M.A., London, 2009, p. 69 ff.

<sup>210</sup> J.D. GRAHAM, *The Role of Precaution in Risk Assessment and Management: An American's View, Remarks at the Conference “The US, Europe, Precaution and Risk Management: A Comparative Case Study Analysis of the Management of Risk in a Complex World”*, January 2002, at [http://www.whitehouse.gov/omb/inforeg\\_eu\\_speech](http://www.whitehouse.gov/omb/inforeg_eu_speech) (last visited 28th January 2013). See also D. BODANSKY, *Scientific uncertainty and the precautionary principle*, in *Environment*, 33, 4, 1991.

It is clear from the current discussion that P.P. applies better “risks” (i.e. physical concerns, according to my definition), rather than to the non-physical ones, since it requires a scientific uncertainty to be at stake. However, an ethical approach founded on P.P. can permeate even the attitude towards economic, social, moral concerns.

In particular, in the case of synthetic biology, with regards to biosafety and biosecurity risks, P.P. would affirm that in case of uncertain risks<sup>211</sup> we should be cautious or even refrain from proceeding until we are completely sure of its status. So, P.P. is *«presumed to provide guidance when our scientific knowledge of the harmful effects of a proposed activity is significantly incomplete and when strict scientific risk assessment cannot be fully completed»*<sup>212</sup>.

As for the social, economic, moral concerns, a precautionary approach means that it is preferable to avoid research in synthetic biology. This is due to the possibility that it can generate some fears. Or, at least, P.P. entails that it is necessary to be extremely cautious in dealing with the matter of our relationship to natural world, playing God, questioning the status of moral beings, and so on. Thus it is better not to act or suspend synthetic biology’s studies and applications. For instance, a precautionary position is the one claimed by Boldt and Müller. They state that, with regards to our tackling of nature, if we begin to create lower forms of life and to think of them as “artifacts” (as researchers in synthetic biology propose), we then *«may in the (very) long run lead to a weakening of society’s respect for higher forms of life»*<sup>213</sup>. Thus undermine our respect for animals and, ultimately, our fellow humans as they naturally occur.

Currently, there are numerous versions and definitions of P.P., thus it is quite hard to conceptualize it. Vanderzwaag and Environ<sup>214</sup> identify fourteen different formulations of P.P. in treaties and non-treaty declarations. Sandin tops that by

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<sup>211</sup> For deepening the notion of “uncertainty”, see also M.B.A. VAN ASSELT, *Perspectives on Uncertainty and Risk: The PRIMA Approach to Decision Support*, Dordrecht, 2000.

<sup>212</sup> M. ATHEENSUU, *The Precautionary Principle in the Risk Management of Modern Biotechnology*, in *Science Studies*, 1, 2004.

<sup>213</sup> J. BOLDT, O. MÜLLER, *Newtons of the Leaves of Grass*, in *Nature Biotechnology* 26, 4, 2008, p. 387-389.

<sup>214</sup> D. VANDERZWAAG, J. ENVIRON, *The Precautionary Principle in Environmental Law and Policy: Exclusive Rhetoric and First Embraces*, in *Journal of Environmental Law and Practice* 8, 355, 1999.

arriving at nineteen possible versions of it<sup>215</sup>. Thus, it seems «*evident that there is no real agreement on what the precautionary principle means and how it should be applied*»<sup>216</sup>.

In the development of this analysis, I will analyse and discuss critically some of the different versions of it<sup>217</sup>. I chose the most meaningful and adopted ones: weak, moderate, strong, anti-catastrophe, and procedural version. However, it should be noted that these versions all refer to physical concerns (as I said, “uncertain risks”), so that the precautionary approach with regards to non-physical concerns is left aside, since it has no different “translations” of itself, despite displaying a general criticism (and fear) of the development of new technologies.

In my attempt to schematise it, any version of the precautionary principle, despite the differences and peculiar features, presents three main conditions:

(1) a potential damage (damage condition);

(2) an uncertain threat (knowledge condition): lack of knowledge, of full certainty about the occurring of the damage and/or about the causal relationship between the action/inaction and the damage; and

(3) a provision of some kind of anticipatory regulation to adopt (action or remedy condition), i.e. before strong scientific proof of harm is developed<sup>218</sup>.

The damage condition uses different qualifications of damage: it could be harmful, serious, catastrophic, irreversible, merely potential and cumulative.

The knowledge condition is usually to be intended as the scientific uncertainty, i.e. uncertainty about causality, magnitude, probability, and nature of harm. Such uncertainty could be found at different degrees, but some of elements to define it are needed, since «*a mere fantasy or crude speculation is not enough to trigger P.P.*»<sup>219</sup>.

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<sup>215</sup> See P. SANDIN, *Dimensions of the Precautionary Principle*, in *Human and Ecological Risk Assessment*, 5, 5, 1999, p. 889-907.

<sup>216</sup> C. MACILWAIN, *Experts Question Precautionary Approach*, in *Nature*, 407, 551, 2000.

<sup>217</sup> See R. COONEY, *From promise to practicalities: The precautionary principle on biodiversity conservation and sustainable use*, in R. COONEY, B. DICKSON (EDS.), *Biodiversity and the precautionary principle: Risk and uncertainty in conservation and sustainable use*, London, 2005; J. WIENER, M. ROGERS, *Comparing precaution in the United States and Europe*, in *Journal of Risk Research*, 5, 4, 2002, p. 317-349.

<sup>218</sup> P. SANDIN, *A Paradox Out of Context: Harris and Holm on the Precautionary Principle*, 15 *Cambridge Quarterly Healthcare Ethics*, 175, 15, 2006.

<sup>219</sup> U.N.E.S.C.O., WORLD COMMISSION ON THE ETHICS OF SCIENTIFIC KNOWLEDGE AND TECHNOLOGY (C.O.M.E.S.T.), *The Precautionary Principle*, March 2005, p. 13.

The action of remedy condition requires that the anticipatory actions chosen include both the notion of whether to act or not, as well as how to act. The types of actions chosen could be either negative (paralysis, prohibitions, moratorium, etc.) or positive (intensification of investigations), but in any case they should be anticipatory<sup>220</sup>.

### 5.2.1. The Weak version and its Limits.

The most well known version of the precautionary principle is the one labelled as “weak”. As embedded in the Principle 15 of the Rio Declaration (1992)<sup>221</sup>, which states that, *«In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats [i.e. hazards] of serious or irreversible damage [i.e. harm], lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation»*.

There are four elements that are relevant here: (1) the presence of a threat, (2) a serious and irreversible damage, (3) a lack of scientific knowledge, and (4) the necessity to opt for an action which must take into consideration cost-effective means<sup>222</sup>. As a result of these elements, the weak version is composed of a triple negation: *«not having evidence about a risk is not a reason for not acting preventively»*<sup>223</sup>. It could work for biosafety and biosecurity risks (where it could be formulated as such: *«When and where serious and credible concern exists that legitimately intended biological material, technology or knowledge in the life sciences pose threats of harm to human health and security, the scientific community*

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<sup>220</sup> With regards to the application of P.P. in the field of biotechnologies, see C.M. ROMEO CASABONA, *Principio de precaución, biotecnología y derecho*, Bilbao-Granada, 2004.

<sup>221</sup> UNITED NATIONS, Report of the United Nations Conference on Environment and Development, Annex I - Rio Declaration On Environment And Development, Rio de Janeiro, U.N. Docs. A/CONF.151/26 (Vol. I), 1992, at [www.un.org/documents/ga/conf151/aconf15126-1annex1.htm](http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm) (last visited 28<sup>th</sup> January 2013).

<sup>222</sup> The action is left to the operators' choice on a case-by-case basis.

<sup>223</sup> See C.D. STONE, *Is There a Precautionary Principle?*, in *Environmental Law Reporter*, 31, 2001, p. 10790-10799.

*is obliged to develop, implement and adhere to precautionary measures to meet the concern»<sup>224</sup>).*

This version is named as an “argumentative” one, since «*it is not a substantial principle for decisions, but a principle for what arguments are valid, i.e. a restriction on dialogue. In essence it says little more than that arguments from ignorance should not be used*»<sup>225</sup>.

Applications of the weak formulations usually include cost-benefit analysis as well. This means that is not the inaction in the face of risks, but rather the choice of the least risky alternative among the possible ones (according to a principle of proportionality) and by taking it before scientific certainty of cause and effect. Moreover, some proof of the likelihood of occurrence of harm and the severity of consequences is needed, and the burden of proof generally falls on those advocating of liability for harm.

According to Edward Soule, the weak version of the precautionary principle has two main features: it is comprehensive, in the sense that it does «*not seriously restrict the factors that decision makers can legitimately take into account*»; and it is optional, in the sense that «*regulators do not receive any specific guidance on the relative weighting of any given factor*»<sup>226</sup>.

There are several limits within the weak version of P.P.. First of all, defining a hazard as “serious” is vague. This quality does not indicate any guidelines about how the different risks should be ranked and how to balance between competing irreversibilities. Furthermore, it is not clear what counts as a threat of harm, whether it includes any potential harm, how to measure this harm, and the level of “uncertainty” that is necessary to take precautionary measures is not easy to identify. Thus, it is hard to distinguish between those risks which are deemed sufficiently probable to justify precautionary action and those which fail to provide sufficient justification. Besides, the model of acceptable risks considers only risks and not the

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<sup>224</sup> F. KUHLAU, A.T. HÖGLUND, K. EVERS, S. ERIKSSON, *A Precautionary Principle For Dual Use Research In The Life Sciences*, in *Bioethics*, 25, 1, 2011, p. 1-8.

<sup>225</sup> P. SANDIN, M. PETERSON, S.O. HANSSON, C. RUDÉN, A. JUTHE, *Five charges against the precautionary principle*, in *Journal of Risk Research*, 5, 4, 2002, p. 289. See also J. MORRIS, *Defining the precautionary principle*, in J. MORRIS (ED.), *Rethinking Risk and the Precautionary Principle*, Oxford, 2000, p. 1-21.

<sup>226</sup> E. SOULE, *Assessing the precautionary principle*, in *Public Affairs Quarterly*, 14, 2000, p. 313.

benefits of technology, being that this version focused only on the risks of damage that a technology can generate.

### 5.2.2. *The Moderate Version and its Limits.*

The moderate version of the principle requires that during the presence of an uncertain and potentially serious threat, an action should be taken. So, a “potential damage” is sufficient for triggering the principle. For example, the 1994 United Kingdom Biodiversity Action Plan states, «*In line with the precautionary principle, where interactions are complex and where the available evidence suggests that there is a significant chance of damage to our biodiversity heritage occurring, conservation measures are appropriate, even in the absence of conclusive scientific evidence that damage will occur*»<sup>227</sup>.

Here, liability is not mentioned and the burden of proof generally remains with those advocating precautionary action.

As for the criticisms, it can be noted that the reference to a “potential damage” is not clear. Indeed, it is not so obvious to understand what the threshold of likelihood is, in order to identify a damage as potential. Furthermore, this version of the precautionary principle would necessitate a hierarchy among insufficient knowledge. Thus, to distinguish between the cases which are urgent to intervene with regulations and with those that are not remains very difficult, as it is «*unclear how to differentiate between situations where there is less than full scientific certainty and situations where there is no evidence of a possible hazard*»<sup>228</sup>.

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<sup>227</sup> U.K. DEPARTMENT OF THE ENVIRONMENT, *United Kingdom Biodiversity Action Plan*, 1994, at <http://jncc.defra.gov.uk/default.aspx?page=5155> (last visited 28<sup>th</sup> January 2013).

<sup>228</sup> S. CLARKE, *Future technologies, dystopic futures and the precautionary principle*, in *Ethics and Information Technology*, 7, 2005, p. 123-124.



### 5.2.3. *The Strong Version and its Limits.*

Strong versions of the principle differ from the weak ones, especially in the area of reversing the burden of proof, which is placed upon innovators or perpetrators, i.e. those who argue that a proposed activity will not cause significant harm. These innovators or perpetrators must prove, beyond any reasonable doubt, that a process, product or technology is sufficiently “safe” before approval is granted.

Strong formulations of P.P. are found in the 1982 World Charter for Nature that affirms that: «*if potential adverse effects are not fully understood, the activities should not proceed*»<sup>229</sup>. It is also found in the 1998 Wingspread Statement, which states that, «*When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically [...]. The proponent of an activity, rather than the public, should bear the burden of proof*»<sup>230</sup>.

The strong version presents four main dimensions: (1) the threat dimension, (2) the uncertainty dimension, (3) the action dimension, and (4) the command dimension<sup>231</sup>. In the cases of potential and uncertain threats, an action is compulsory. For instance, the action could entail bans and prohibitions on entire classes of potentially threatening activities or substances<sup>232</sup>. Thus, it becomes a restraint on the progress, in the absence of firm evidence that the innovative activity will do no harm. The strong version further imposes the need not to use a new technology unless its harmlessness is certain. It also imposes the need to adopt a regulation whenever there is a possible harm, even if the supporting evidence is speculative and even if the economic costs of regulation are high. This version is a “prescriptive” one<sup>233</sup>, since it «*stipulates that once a risk of a certain magnitude is identified, preventive measures*

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<sup>229</sup> UNITED NATIONS, GENERAL ASSEMBLY, World Charter for Nature, A/RES/37/7, 28<sup>th</sup> October 1982, at <http://www.un.org/documents/ga/res/37/a37r007.htm> (last visited 28<sup>th</sup> January 2013). Similarly to the World Charter for Nature, see the Convention on International Trade in Endangered Species of Wild Fauna and Flora (3<sup>rd</sup> March 1973, 27 U.S.T. 1087, 12 I.L.M. 1085) and the Convention on Biological Diversity (5<sup>th</sup> June 1992, S. Treaty Doc. n. 103–20 (1993), 31 I.L.M. 818).

<sup>230</sup> SCIENCE AND ENVIRONMENTAL HEALTH NETWORK, *Wingspread Consensus Statement on the Precautionary Principle*, 26<sup>th</sup> January 1998, at <http://www.sehn.org/wing.html> (last visited 28<sup>th</sup> January 2013).

<sup>231</sup> P. SANDIN, *Dimensions of the Precautionary Principle*, cit., p. 891.

<sup>232</sup> R. COONEY, *op.cit.*

<sup>233</sup> P. SANDIN ET AL., *Five charges against the precautionary principle*, cit., p. 289.

to erase that risk are mandatory»<sup>234</sup>. According to Soule, the strong version is exclusive in scope, in the sense that it considers only the risks posed by the policies at stake and it forgets about the benefits. It does not, for example, weigh these risks against possible economic gains<sup>235</sup>. It is also determinative, i.e. one specific risk is the decisive factor in decision making.

As for the limits, the strong version seems to be irrational, in the sense that it embodies a general form of aversion to any kind of activity that has risks. So, an extreme version of P.P. «will block the development of any technology if there is the slightest theoretical possibility of harm»<sup>236</sup>. This leads P.P. to look like it is an anti-science, anti-technology, and anti-innovation principle, of whose application causes stagnation in society<sup>237</sup>. Indeed, the search for a “zero risk” situation appears to be, in the end, completely impossible and absurd too, because «if only actions that exposed no one to risk were permissible, the result would be a general blockade on action, which would make living together in society impossible»<sup>238</sup>. Since any human action entails risk, the option for a “zero risk” policy does not allow any kind of human action. With this perspective, P.P. in the strong version is not conceivable in a context of human activities.

Furthermore, it should be stressed that even the block of an activity might entail some risks<sup>239</sup> or even the same risks that we wanted to prevent through the banning of research. So, precautionary measures may impose new risks, both directly when precautionary measures themselves generate new threats and indirectly when the precautionary measures are so costly that the resultant loss of wealth imposes risks. In other words, stopping a technology does not coincide with the stopping of

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<sup>234</sup> A. NOLLKAEMPER, *What you risk reveals what you value, and other dilemmas encountered in the legal assaults on risks*, in D. FREESTONE, E. HEY (EDS), *The Precautionary Principle and International Law*, Dordrecht, 1996, p. 73.

<sup>235</sup> E. SOULE, *op.cit.*, p. 317.

<sup>236</sup> S. HOLM, J. HARRIS, *Precautionary Principle Stifles Discovery*, in *Nature*, 29, 400, 1999, p. 398. See also N. MANSON, *The precautionary principle, the catastrophe argument, and Pascal's wager*, in *Ends and Means*, 4, 1999, p. 12-16; W.J. MCKINNEY, *Prediction and Rolston's environmental ethics: lessons from the philosophy of science*, in *Science and Engineering Ethics* 2, 1996, p. 429-440.

<sup>237</sup> J.D. GRAHAM, *The perils of the precautionary principle: Lessons from the American and European experience*, Washington, D.C., 20<sup>th</sup> October 2003, at <http://georgewbush-whitehouse.archives.gov/omb/inforeg/speeches/031020graham.pdf> (last visited 28<sup>th</sup> January 2013).

<sup>238</sup> A. BACHMANN, *Synthetic nanoparticles and the precautionary principle. An ethical analysis*, 2007, at <http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/gutachten/e-Gutachten-Synthetische-Nanopartikel-2007.pdf> (last visited 28<sup>th</sup> January 2013).

<sup>239</sup> See E. STOKES, *Regulating nanotechnologies: sizing up the options*, in *Legal Studies*, 29, 2, 2009, p. 296.

any type of risks associated with it. It seems entirely possible that research which was not possible to conduct under this strong version might very well have led to a solution requires to prevent the risks we wanted to avoid. This, therefore, entails a paradox. As enucleated by Sunstein<sup>240</sup> and Manson<sup>241</sup>, if research brings to dangerous scenarios and at the same time the absence of research could cause the same catastrophes, it means that «*the precautionary principle leads us to conclude both that we should conduct research [...] and that we should not conduct research*»<sup>242</sup>. So, it leads in no direction at all<sup>243</sup>.

With regards to the burden of proof that lies upon the ones who want to introduce a risky technology, it is apparent that such a proof of safety is a *probatio diabolica*. This is because none of the technologies could never be proven safe, and in the meantime second, third, fourth order consequences may arise. It is a fundamental axiom of science that proving a negative is impossible, not just in theory, but in practice. Thus, it cannot be ignored that in reality the claim to prove that something is safe means simply to fail to prove that it is unsafe. This is «*the mathematical way of claiming that absence of evidence is the same as evidence of absence*»<sup>244</sup>.

Moreover, the strong precautionary principle is characterized by high levels of vagueness, as it lacks the consideration of the benefits of a technology and the indication of the level or type of evidence of harm that is sufficient to trigger the principle.

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<sup>240</sup> C.R. SUNSTEIN, *Risk and Reason: Safety, Law and the Environment*, Cambridge, 2002, p. 102-104.

<sup>241</sup> N.A. MANSON, *Formulating the Precautionary Principle*, in *Environmental Ethics*, 24, 2002, p. 270-274.

<sup>242</sup> S. CLARKE, *Future technologies, dystopic futures and the precautionary principle*, cit., p. 123.

<sup>243</sup> C.R. SUNSTEIN, *The paralyzing principle*, in *Regulation*, Winter 2002-2003, p. 32-37.

<sup>244</sup> P. SAUNDERS, *Use and Abuse of the Precautionary Principle*, ISIS submission to the U.S. Advisory Committee on International Economic Policy (A.C.I.E.P.) Biotech Working Group, 13<sup>th</sup> July 2000, at <http://www.i-sis.org.uk/prec.php> (last visited 28<sup>th</sup> January 2013).

#### 5.2.4. The “Anti-Catastrophe” Version and its Limits.

In order to avoid the “strong” version of precautionary principle, some scholars suggest to use it only in reference to catastrophic risks<sup>245</sup>. They start from the consideration that people generally fear risks and have a cognitive attitude to react against any kind of risks. People usually do not think of the effects of introducing a technology nor at the same time in the effects of introducing it. Instead, they are conditioned by their significant cognitive bias, and such emotional fear is at the basis of the precautionary principle. Besides such aversion for risks, there is the misconception that nature is benevolent and human activities are always negative<sup>246</sup>.

So, at the light of these elements, Sunstein supported by Neil Manson<sup>247</sup>, for example, suggests to adopt a narrow “anti-catastrophe principle”. As a principle it is formulated as follows: *«if we can identify an activity and an effect that creates a potentially catastrophic risk, and existing science does not enable to assign probabilities to the worst-case scenarios, thus the imposition of the remedy (more specifically, a ban) is compulsory, regardless of the probability that the activity really causes the catastrophic effect»*<sup>248</sup>.

The main criticism to this version lies in the difficulty in identifying the activities and effects of potential catastrophe and in understanding of the entity and magnitude of catastrophe that an activity could determine. Moreover, understanding what the concepts of “possibility” or “potentiality” and “catastrophe” really mean is not so clearly identifiable. Conceiving “potentiality” as a “logical possibility” is insufficient, as not everything that is logically possible is also empirically possible. This means that “potentiality” as being a “concrete and empirical possibility” is not satisfying, as not everything that is concretely possible is likely to happen<sup>249</sup>. For these reasons, when the proponents of the “anti-catastrophe version” assert that in

<sup>245</sup> See C.R. SUNSTEIN, *Irreversible and Catastrophic*, in *Cornell Law Review*, 91, 841, 2006; F. ALLHOFF, *Risk, Precaution, and Emerging Technologies*, in *Studies in Ethics, Law, & Technology*, 1, 12-13, 2009.

<sup>246</sup> See C.R. SUNSTEIN, *Laws Of Fear: Beyond The Precautionary Principle*, Cambridge, 2005, p. 35.

<sup>247</sup> N.A. MANSON, *Formulating the Precautionary Principle*, cit., p. 270. See also N.A. MANSON, *The Precautionary Principle, The Catastrophe Argument, and Pascal’s Wager*, in *Ends and Means: Journal of the University of Aberdeen Centre for Philosophy, Technology, and Society*, 4, 1, Autumn 1999.

<sup>248</sup> C.R. SUNSTEIN, *Laws Of Fear*, cit.

<sup>249</sup> See F. ALLHOFF, *Risk, Precaution, and Emerging Technologies*, in *Studies in Ethics, Law, & Technology*, 3, 2, 2009, p. 18 ff.

cases of catastrophic damages the probabilities of the event are usually very low, but the magnitude of the disaster is extremely high, and such magnitude justifies precautionary action, they usually link the mere hypothesis of a catastrophe (merely possible at the logical or empirical level, but with a low probability of occurrence) to the enactment of precautionary measures. So, this means that such a version of P.P. requires a very low level of knowledge about the probability of occurrence of the catastrophic outcomes in order to apply precautionary measures. Perhaps it is better that it has nothing to do with a probabilistic (and scientifically founded) framework of data about the occurrence of the catastrophe. So, a lack of probabilistic framework can be individuated here and, in my view, acting regardless of it frankly appears rather weak.

#### 5.2.5. *The Procedural Version and its Limits.*

Jordan and O’Riordan have proposed to read the P.P. as a mere political and procedural principle, appreciating its vagueness and lack of specificity. This is because it is useful for the its application, i.e. *«the application of precaution will remain politically potent so long as it continues to be tantalizingly ill-defined and imperfectly translatable into codes of conduct, while capturing the emotions of misgiving and guilt»*<sup>250</sup>. Jordan and O’Riordan further suggest that P.P. should be procedural, since the very notion of precaution from a substantial point of view is impossible to define and it must be left to the different countries and cultures. The authors claim that “risk perception” is a *«deeply cultural phenomenon, involving entrenched values which have evolved differently in different countries»*<sup>251</sup>, and understanding what P.P. is requires a consultative process, thus the involvement of democratic procedures.

The problems connected with this version of the P.P. lie, as Gardiner says, in the fact that *«the principle plays a very diminished role in decision-making. Its*

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<sup>250</sup> A. JORDAN, T. O’RIORDAN, *The precautionary principle in contemporary environmental policy and politics*, in C. RAFFENBERGER, J.A. TICKNER (EDS.), *Protecting public health and the environment: implementing the Precautionary Principle*, Washington, D.C., 1999, p. 15.

<sup>251</sup> A. JORDAN, T. O’RIORDAN, *op.cit.*, p. 18.

*function seems simply to get parties together and then endorse their agreements. It does not direct decision-making in any substantive way»<sup>252</sup>. So, the principle does not seem to be able to determine a decision, because it only gathers together the people to decide what precaution means. Furthermore, it does not ensure that the effective protection from risks will be given, as it depends upon the democratic decisions of majority.*

The following table results from the summary and comparison of the main elements characteristic of the different versions of P.P.

	<b>Damage condition</b>	<b>Burden of proof</b>	<b>Cost/effective measures or proportionality test</b>	<b>Knowledge condition</b>
<b>WEAK PP</b>	Serious/irreversible	Upon proponents of precautionary measures	Yes	Possible
<b>MODERATE PP</b>	Potential	Upon proponents of precautionary measures	Not mentioned	Low
<b>STRONG PP</b>	Potential	Upon proponents of new technology	Not relevant	Suspected
<b>ANTICATASTROPHIC PP</b>	Potentially catastrophic	Not mentioned	Moderate	Low (mere possibility)
<b>PROCEDURAL</b>	Culturally dependent	Not mentioned	Not mentioned	Culturally dependent

From the extensive discussion of P.P. in this section from the theoretical, i.e. “doctrine” point of view, it is of natural consequence to examine the application of the precautionary principle in the different sources of law, considering the “legislative” source as well as the judicial one in a comparative perspective. The most relevant experiences, crossing the international, European, national areas, have been chosen.

<sup>252</sup> S. GARDINER, *A Core Precautionary Principle*, in *The Journal of Political Philosophy*, 14, 1, 2006, p. 42.

5.2.6. *The Precautionary Principle in International Law.*

5.2.6.1. *“Hard” and “Soft Law”.*

Within the context of International Law, the P.P. appeared primarily in its weak form quoted by international conventions, i.e. hard law, about the protection of the marine environment (first mentioned in the International Convention Relating to Intervention on the High Seas in Cases of Oil Pollution Casualties, 1969<sup>253</sup>).

With regards to non binding texts, i.e. soft law, the main examples of weak P.P. are given by the Declaration of the United Nations Conference on the Human Environment (1972)<sup>254</sup>, Bergen Declaration (1990)<sup>255</sup>, O.E.C.D. Council Recommendations (1991)<sup>256</sup>, Rio Declaration (1992)<sup>257</sup> which constituted a model for the United Nations Framework Convention on Climate Change (1992)<sup>258</sup>, and the Convention on Biological Diversity (1992)<sup>259</sup>.

As for the moderate version, the representative examples can be found in the conventions regarding (a) international fisheries (U.N. Conference on the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, 1995<sup>260</sup>), (b) marine environment (Paris Convention on the Protection of marine environment, 1992<sup>261</sup>; the Baltic Sea Convention, 1994<sup>262</sup>; London Convention on the Prevention of Marine Pollution by Dumping Wastes and Other Matter, 1996<sup>263</sup>), and (c) hazardous wastes (the Basel Convention on the Control of

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<sup>253</sup> International Convention Relating to Intervention on the High Seas in Cases of Oil Pollution Casualties, 29<sup>th</sup> November 1969, art. V (3) (a), 26 U.S.T. 765, 970 U.N.T.S. 211, 212.

<sup>254</sup> Declaration of the United Nations Conference on the Human Environment, Stockholm 1972.

<sup>255</sup> Economic Commission for Europe (E.C.E.), Ministerial Declaration on Sustainable Development in the ECE Region, Bergen, May 1990.

<sup>256</sup> O.E.C.D. Council Recommendation C (90) 164 on Integrated Pollution Prevention and Control, 31<sup>st</sup> January 1991.

<sup>257</sup> See footnote 221.

<sup>258</sup> U.N. Framework Convention On Climate Change, 9<sup>th</sup> May 1992, 21 I.L.M. 849.

<sup>259</sup> See footnote 229.

<sup>260</sup> U.N. Conference on the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, 4<sup>th</sup> August 1995, 34 I.L.M. 1542.

<sup>261</sup> Convention for the Protection of the Marine Environment of the North-East Atlantic, 22<sup>nd</sup> September 1992, 32 I.L.M. 1069.

<sup>262</sup> Helsinki Convention for the Protection of the Marine Environment in the Baltic Sea Area, 1992.

<sup>263</sup> Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 13<sup>th</sup> November 1972.

Transboundary Movements of Hazardous Wastes and their Disposal, 1989<sup>264</sup>; the Bamako Convention on the Ban on Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa, 1991<sup>265</sup>).

The procedural version is chosen by the Cartagena Protocol on Biosafety (2000)<sup>266</sup>, which aims at «ensuring an adequate level of protection» in the safe transfer, handling and use of living modified organisms (LMOs)<sup>267</sup>. Thus, it prescribes a risk evaluation but leaving the States free to implement precaution, or not, depending on the results yielded by the evaluation.

In the context of International Law, P.P. has appeared with different “faces”. It was quoted in conventions and non-binding declarations (which, however, look like a *sui generis* source of law, i.e. «providing an indicator of the law-in-making that has a stronger value than mere political declarations or diplomatic negotiations»<sup>268</sup>).

According to Trouwborst, P.P. is a customary rule<sup>269</sup> and a principle to be integrated with the general legal principles recognized by civilized nations<sup>270</sup>. In Trachtman’s perspective, it belongs to a «non-traditional category of international law», identified as «standard», i.e. «general guidance to both the person governed and the person charged with applying the law, but does not, in advance, specify in precise detail the conduct required or proscribed»<sup>271</sup>.

It is evident that, considering the quantity of conventions and declarations that have been enacted quoting P.P., it is invoked for human-generated activities as well as the preservation of natural resources. It has been «regarded as essential for the achievement of sustainable development, which is commonly defined as

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<sup>264</sup> Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 22<sup>nd</sup> March 1989.

<sup>265</sup> Bamako Convention on the Ban of the Imports Into Africa and the Control of Transboundary Movement and Management of Hazardous Waste Within Africa, 29<sup>th</sup> January 1991, 31 I.L.M. 163.

<sup>266</sup> Cartagena Protocol On Biosafety, 29<sup>th</sup> January 2000, 39 I.L.M. 1027.

<sup>267</sup> See for P.P.: art. 10, par. 6.3.

<sup>268</sup> S. BOUTILLON, *The Precautionary Principle: Development of an International Standard*, in *Michigan Journal of International Law*, 23, 2002, p. 432.

<sup>269</sup> A. TROUWBORST, *The Precautionary Principle in General International Law*, cit.,

<sup>270</sup> According to art. 38, Statute of the International Court of Justice. See J. CAMERON, J. ABOUCHAR, *The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of Global Environment*, in *B.C. International & Comparative Law Review*, 14, 1, 1991, p. 19–20.

<sup>271</sup> J.P. TRACHTMAN, *The Domain of WTO Dispute Resolution*, 40 *Harvard International Law Journal* 333, 40, 1999, p. 334.



*development in a way and at a rate that suits the needs of present generations of human beings without compromising the ability of future generations to meet theirs»<sup>272</sup>.*

The most relevant quotation of P.P. is by the World Trade Organization (W.T.O.), where a minimalist version of P.P. is preferred. In particular, the W.T.O. Agreement on the Application of Sanitary and Phytosanitary Measures (S.P.S.)<sup>273</sup> contains some relevant references P.P., in terms of the measures adopted for the protection of animals, plants, humans. The notion of P.P. here has a residual value, in the sense that only when a risk assessment cannot be done can the precautionary measures be taken in absence of it. These measures can never be arbitrary nor propose unjustifiable different protection levels in different situations. They also cannot be more trade-restrictive than required to achieve the appropriate level of sanitary or phyto-sanitary protection. Art. 5.7 S.P.S. mentions P.P.<sup>274</sup>, but without any reference to cost-efficiency analysis and to the reversal of the burden of proof. It is an exception to the general framework of art. 2.2 and 5.1, and for this reason the burden of proof is exceptionally inverted and it therefore lies upon the party that asks for the introduction of a precautionary measure.

#### 5.2.6.2. *Judicial Cases.*

As for the judicial application of P.P., it turns out that in the decisions made by the International Court of Justice (I.C.J.)<sup>275</sup> there is an attitude of silence and

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<sup>272</sup> A. TROUWBORST, *Prevention, Precaution, Logic And Law. The Relationship Between The Precautionary Principle And The Preventative Principle In International Law And Associated Questions*, in *Erasmus Law Review*, 2, 2, 2009, p.107-108.

<sup>273</sup> See footnote 175.

<sup>274</sup> Art. 5.7 states: «*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time*».

<sup>275</sup> See case *French Nuclear Tests I (New Zealand v. France)*, 20<sup>th</sup> December 197; *Gabcikovo-Nagymaros Project (Hungary/Slovakia)*, 25<sup>th</sup> September 1997. For deepening the topic of P.P. in international courts, see C.E. FOSTER, *Science and the Precautionary Principle in International Courts and Tribunals. Expert Evidence, Burden of Proof and Finality*, Cambridge, 2011. For I.C.J. cases, see <http://www.icj-cij.org> (last visited 28<sup>th</sup> January 2013).

suspicion in the application of the principle. The Tribunal of the Sea<sup>276</sup> has also dealt with P.P., even if it has never been explicitly cited. It has left space for the States' choices on precautionary measures. It suggests a strong interpretation of P.P., entailing that the burden of proof of the safety of products lies on the State wanting to introduce them<sup>277</sup>.

The most relevant application of P.P. in international law appears in the context of the judicial application of the P.P. within the W.T.O.. Among the many delivered cases, the most significant one which best exemplifies the notion of P.P. is the well-known *Beef Hormones* case<sup>278</sup>. The European Communities (E.C.) invoked art. 5 sections 1 and 2 S.P.S. for banning imports of hormone treated beef. The United States and Canada stated that the E.C. had not gathered sufficient proof of the harmfulness of the products to justify the measures taken. Since the first instance decision saw the favour for the U.S.A./Canada's positions, the E.C. appealed the decision, stating that P.P. was not taken into consideration. This is because P.P. should be considered as a norm of customary international law and as a principle to be applied both in the risk assessment and risk management. Furthermore, the E.C. claimed that the mere possibility of risk is sufficient to ban a product, since the risk must be evaluated in qualitative and not quantitative terms. The outcome of thus, i.e. the Appellate Body's decision<sup>279</sup>, is very meaningful here as a means to reflect upon P.P. and about risk assessment and management. Indeed, the Body observed that P.P. was not exhausted in art. 5.7 S.P.S. and it should not be reduced at the mere environmental field<sup>280</sup>, as it is implicit in art. 3.3 and in the Preamble of S.P.S. too. So, in cases of it being impossible to take a traditional risk analysis, the States should found their measures upon scientific opinions, even minority ones, provided they come from reputable sources. Indeed, the States are free to opt for stronger precautionary and trade-restrictive measures. However, these measures must be

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<sup>276</sup> See, for example, the case *Southern Bluefin Tuna Cases (New Zealand v. Japan; Australia v. Japan (Joined Cases))*, 27<sup>th</sup> August 1999.

<sup>277</sup> See case *The MOX Plant (Ireland v. U.K.)*, 3<sup>rd</sup> December 2001. See also *Land Reclamation (Request for Provisional Measures) (Malaysia v. Singapore)*, 8<sup>th</sup> October 2003. For these cases, see <http://www.itlos.org/> (last visited 28<sup>th</sup> January 2013).

<sup>278</sup> For a summary of this case, see [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds26\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm) (last visited 28<sup>th</sup> January 2013).

<sup>279</sup> The Appellate Body's Report was issued on 16<sup>th</sup> January 1998.

<sup>280</sup> This position is shared by the Panel in the case *Biotech products (W.T.O. 29<sup>th</sup> September 2006, EC Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, WT/DS291/R)*.

scientifically grounded, and they should not be based upon mere fear. In the end, the Appellate Body rejected the E.C.'s measures with the view that they were discriminatory and in violation of S.P.S.. It concluded that if a hormone treatment was approved and recognised as a good practice, a ban on the derived products cannot be considered compliant with the conditions established by S.P.S. Agreement.

In conclusion, according to the Appellate Body, the S.P.S. allows the adoption of precautionary measures only for scientifically assessed risks (even potential), provided that the measures are founded on scientific elements (even if it was weak or it referred to a minority position).

#### *5.2.7. The Precautionary Principle in European Union Law.*

The application of the P.P. in the European context is a general one, at the point that P.P. seems to have obtained the value of a general rule having a direct application<sup>281</sup>.

##### *5.2.7.1. Treaties, "Hard Law" and "Soft Law".*

In the context of the E.U. law, the First Environmental Action Programme (1973–1976) called E.A.P. I<sup>282</sup> was the first document to quote the concept underlying P.P., although the expression as such was not explicit.

The very application of the P.P. beyond the environmental sectors started in the 1980s, when the Member States of the E.U. began to invoke public health reasons, under the hypothesis of scientific uncertainty, in order to prohibit specified substance to be contained in foodstuffs. They wanted to stop the importation of these foodstuffs into their territories. The E.U. Member States justified those measures by quoting art. 30 of the Treaty of the European Communities (T.E.C., now art. 36 of

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<sup>281</sup> P. KOURILSKY, G. VINEY, *Le principe de précaution*, Rapport au Premier ministre, Paris, 2000, p. 132.

<sup>282</sup> Declaration of the Council of the European Communities and of the Representatives of the Governments of the Member States, meeting in the Council on the Programme of action of the European Communities on the Environment, in *O.J. C* 112/1973.

the Treaty of the Functioning of European Union, T.F.E.U.<sup>283</sup>), that admits prohibitions or restrictions on imports, exports or goods in transit for reasons of protection of health. From this point onwards, Member States started using P.P. as a means against harmonisation, by appealing to these “safeguarding clauses”.

During the 1980s and before the enactment of Maastricht Treaty (1992), some landmark directives, such as the 1990 directives on genetically modified organisms (where a comprehensive system for the authorisation of GMOs to be released into the environment in the E.U. was established<sup>284</sup>) were enacted.

In the Dublin Declaration on the Environmental Imperative (1990), the E.U. Heads of State for the first time expressed their intention that an action by the European Community as well as by the Member States «*will be developed on a co-ordinated basis and on the principles of sustainable development and preventive and precautionary action*»<sup>285</sup>.

The principle first appeared expressly in the Maastricht Treaty, but only in the Title about environment. In art. 130 R T.E.C. (then art. 174 and now art. 191 of the T.F.E.U.) it was stated that, «*Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle*». As a result, the European Union opted for the conception of P.P. as a “horizontal clause”, i.e. as an element underlining the importance of pursuing environmental and health protection into the definition and implementation of all the Community policies and activities (referred to in art. 3 T.F.U.E. now). However, no definition of it was offered.

After Maastricht Treaty, P.P. was further mentioned in other directives<sup>286</sup>.

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<sup>283</sup> It should be noted that the Lisbon Treaty (2009) determines a consolidated version of the Treaties of the European Communities and European Union. The Treaty of European Communities (T.C.E.) becomes the Treaty on the Functioning of the European Union (T.F.E.U.), while the Treaty of the European Union (T.E.U.) keeps the same name with a different numeration and some modifications to the content. With regards to the Lisbon Treaty, see *O.J. C 306/2007*.

<sup>284</sup> Directive 90/219/EEC, of 23<sup>rd</sup> April 1990, on the contained use of genetically modified micro-organisms, in *O.J. L 117/1990* and Directive 90/220/EEC of 23<sup>rd</sup> April 1990, on the deliberate release into the environment of genetically modified organisms, in *O.J. L 117/1990*.

<sup>285</sup> Bulletin EC 6–1990, Conclusions of the Presidency, Point 1.14 and Annex II.

<sup>286</sup> Directive 94/67/EC of 16<sup>th</sup> December 1994, on the incineration of hazardous waste, in *O.J. L 365/1994*, which aimed, among other things, to regulate dioxin emissions, even though scientific evidence regarding the effects of dioxin was not yet conclusive at the time of adoption, and Directive

The Treaty of Amsterdam (1997) clarified the legal basis and requirements for Member States to derogate from harmonisation measures taken under art. 95 T.E.C. (now art. 114 T.F.E.U.). Indeed, new provisions allowed Member States to maintain or introduce stricter regulation than the harmonisation measure, in order to protect health and environment as fundamental objectives of the E.U.<sup>287</sup>.

As mentioned in the previous sections and reiterated here for emphasis and clarity, some examples of the E.U. legislation show the application of P.P. in its strong version. These are the GMOs Directive 2001/18/EC<sup>288</sup>, the E.U. General Food Law<sup>289</sup>, and the R.E.A.C.H. Regulation which concerns itself with the E.U.'s legislative framework for registration, evaluation, authorisation and restriction of chemicals<sup>290</sup>.

As for “soft law” (non binding), the best example is offered by the Communication on the precautionary principle, enacted by the E.U. Commission in 2000 with the purpose of establishing guidelines for the application of the precautionary principle in the E.U.<sup>291</sup>. The Communication states that the P.P., born in an environmental field, has acquired a broader field of application. This broader field refers to consumers' policies, human health protection, the protection of animals and plants as well as the ambit of biotechnologies and human genome.

The Commission addresses E.U. Institutions and the Member States as well as the trading partners of the E.C., in the choosing of a science-based approach to precaution, in connection with art. 5.7 S.P.S.. The Communication does not provide a definition of P.P., but it indicates that the circumstances in which it should be

96/61, 24<sup>th</sup> September 1996, on integrated pollution prevention and control, in *O.J. C* 137/1996, in which a loose reference to the precautionary principle is made in Annex IV.

<sup>287</sup> The Lisbon Treaty has not changed such framework, only limiting to alter the numeration of articles.

<sup>288</sup> Directive 2001/18/EC of 12<sup>th</sup> March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, in *O.J. L* 106/2001.

<sup>289</sup> Regulation 178/2002 of 28<sup>th</sup> January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in *O.J. L* 31/2002.

<sup>290</sup> Regulation 1907/2006 of 18<sup>th</sup> December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (R.E.A.C.H.), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation 793/93 and Commission Regulation 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 92/67/EEC, 93/105/EC and 2000/21/EC, in *O.J. L* 396/2006.

<sup>291</sup> See footnote 162. See also E.U. COMMISSION, *Guidelines on the application of precautionary principle*, HB/hb d (98), 17<sup>th</sup> October 1998, DG XXIV, offering guidelines for the application of P.P. in cases of risks and scientific uncertainty.

employed should be as follows: *«it covers those specific circumstances where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection»*<sup>292</sup>.

The Commission opts for a traditional model of risk, which is composed of risk assessment, management and communication, and considers P.P. as part of the process for making provisional decisions about risk management under uncertainty. So, the application of P.P. must be science-based, even though the scientific evidence that is needed to apply the principle may be based upon the minority opinion of the scientists active in the field, provided it is a credible one and owns logical reasoning. A zero risk situation is not required. However, it remains unclear for the determination of what levels of risk are to be met.

The appeal to P.P. is allowed when the following three conditions are met:

- (1) the identification of potentially negative effects of an activity;
- (2) the evaluation of scientific available data;
- (3) the broadness of scientific uncertainty.

The measures to adopt after the risk assessment could consist of acting or non acting and such a choice is simply a political one as it opts for the *«acceptable level of risk»* for the society. So, the Commission prefers an “open clause”, leaving Member States to choose for the kind of risk to accept. However, it seems that restrictive measures appear only to be allowed in case of a scientifically ascertained risk, and this is a problematic issue when referring to technologies whose risks are not entirely foreseeable or measurable yet. So, the precautionary measures can be different and no action is admitted as well. Thus, even when the measures have been taken, further scientific research should be conducted with the aim of ending the scientific uncertainty<sup>293</sup>.

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<sup>292</sup> COM (2000) 1, cit. (see footnote 162), p. 10.

<sup>293</sup> It is relevant to underline that the Communication provides five guidelines for using the principle in a politically “transparent” manner. They are: (1) Proportionality: measures must not be disproportionate to the desired level of protection and must not be aimed at zero risk; (2) Non-discrimination: comparable situations should not be treated differently and different situations should not be treated in the same way *«unless there are objective grounds for doing so»*; (3) Consistency: measures should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available; (4) Examination of the benefits and costs of action or lack

With regards to the reversal of the burden of proof in cases of scientific uncertainty, the Commission states that it is applicable not for every case, but only when prior authorization to put a specific product on the market is needed. In all other cases, it is the task of the users and addressees to show the kind and degree of harm and the level of risk that can be associated with them. So, the proof of harmfulness generally lies upon consumers, citizens and users, and no prior authorization of products is necessary before their entrance in the market, except for medicines and food additives in which case the authorization for commercialisation is possible only after the producers has proved their innocuousness.

In conclusion, according to the Commission, the precautionary principle is applicable in those specific circumstances where scientific evidence is insufficient or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environmental, human, animal or plant health may occur.

The Commission's Communication about P.P. is very relevant, as it is the only one explaining the content of P.P. within E.U.. In addition, it represents the Commission's attempt is to find a point of convergence among the traditional risk analysis, the cost-benefit analysis and P.P.. However, some gaps still remain, such as in the lack of clarity with regards to who can use P.P. and how to apply it within E.U. structure.

Subsequently, the European Council has given out specific guidelines in the clarification of the working of the principle<sup>294</sup>. It states that P.P. could be invoked when the possibility of potential negative effects on health or environment is recognised and when a preliminary scientific evaluation, on the basis of available data, does not allow to reach certain conclusion with regard to the level of risks. The E.U. Parliament, then, has confirmed that the P.P. could be adopted when, on the ground of uncertain information, there are reasons for the fear in view of the possible occurrence of potentially dangerous effects on health and environment<sup>295</sup>.

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of action: the cost-benefit analysis should be done when it is appropriate and feasible (with consideration to the economic and non economic values at stake); (5) Examination of scientific developments: the measures must be of a provisional nature and scientific research shall be continued with a view to obtaining more complete data.

<sup>294</sup> E.U. PARLIAMENT, Resolution, 4<sup>th</sup> December 2000, in *Bulletin EU*, 12-2000, par. 1.4.60.

<sup>295</sup> Published in *Bulletin EU*, 12-2000, par. 1.4.75.

5.2.7.2. *Case Law.*

Considering the European Court of Justice (E.C.J.)'s rulings and the ones of the Tribunal of First Instance (T.F.I.)<sup>296</sup>, it emerges that «*the progressive strengthening of the judicial endorsement of the precautionary principle provides evidence of a settled jurisprudence on its nature and implication*»<sup>297</sup>, as the following analysis is going to show.

The first quotations of P.P. can be found in the in *Kaasfabriek Eyssen case*<sup>298</sup>, where the Court grounded the Dutch prohibition on the use of an antibiotic, nisin, as a preservative in processed cheese, on reasons of health protection. Quoting the Food and Agriculture Organization (F.A.O.)'s and W.H.O.'s studies on the risk of the ingestion of nisin, the Court stated that the uncertainty, lack of evidence and doubts about the safety of the substance were sufficient reasons to justify the block of importation, thus embracing a moderate version of P.P.<sup>299</sup>

One of the most important rulings, in which the E.J.C. Court expressed the relevance of P.P. is that of the B.S.E. crisis. In 1996 U.K. authorities discovered that Bovine Spongiform Encephalopathy (B.S.E.) could be transferred to humans and manifest in humans as the Creutzfeldt-Jakob disease. For that reason, the Commission immediately banned the importation of British beef to the rest of the EU<sup>300</sup>. The word “precaution” was not employed, but the measure was clearly a precautionary one during an uncertain situation. The ban on British beef was challenged before the E.C.J., and on that occasion the Court took advantage by

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<sup>296</sup> See E. STOKES, *The E.C. courts' contribution to refining the parameters of precaution*, in *Journal of Risk Research*, 11, 4, June 2008, p. 491–507; A. ALEMANNI, *The Shaping of The Precautionary Principle by European Courts from Scientific Uncertainty to Legal Certainty*, in L. CUOCOLO, L. LUPARIA (EDS), *Valori Costituzionali e Nuove Politiche del Diritto - Scritti raccolti in occasione del decennale della rivista Cahiers Européens*, Matelica, 2007, p. 11 ff.; G.E. MARCHANT, K.L. MOSSMAN, *Arbitrary and capricious: The precautionary principle in the European Courts*. Washington, D.C., 2005, p. 27.

<sup>297</sup> J.L. DA CRUZ VILAÇA, *The precautionary principle in EC law*, in *European Public Law*, 10, 2, 2004, p. 369–406; J. CAZALA, *Food safety and the precautionary principle: The legitimate moderation of community courts*, in *European Law Journal*, 10, 5, 2004, p. 539–554.

<sup>298</sup> Case C-83/80, *Officier van Justitie/Kaasfabriek Eyssen* [1981] ECR 409.

<sup>299</sup> The same ratio was adopted in reference to non-pathogenic micro-organisms in pasteurised milk (Case C-97/83, *Melkunie* [1984] ECR 2367), with regards to the intake of vitamins in Sandoz case (Case C-174/82, *Sandoz BV* [1983] ECR 2445), with regards to pesticides and additives (Case C-94/83, *Heijn* [1984] ECR 3263; Case C-54/85, *Mirepoix* [1986] ECR 1067).

<sup>300</sup> Council Decision 96/239, 27<sup>th</sup> March 1996, on emergency measures to protect against bovine spongiform encephalopathy, in *O.J. L* 78/1996.



broadening P.P. to the protection of human health too. It stated that the ban was a proportionate measure<sup>301</sup>, since it was based on the means of evidence on the causality nexus between the causes and the effects of the introduction of the beef.

In a successive ruling, the E.C.J. affirmed *claris verbis* that: «where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent»<sup>302</sup>.

The Tribunal of First Instance has also dealt with P.P.<sup>303</sup> In 2002, two pharmaceutical companies, *Pfizer and Alparma*, brought an action<sup>304</sup> to ask for the annulment of Regulation 2821/98, on the basis of which the authorization to use certain antibiotics as growth promoters in animal feeding stuff was withdrawn to the two companies. Denmark had adopted a ban on the use of those substances in feeding stuffs in its territory. Despite the Scientific Committee for Animal Nutrition (S.C.A.N.) stating that the use of that antibiotic did not constitute an immediate risk to public health, the E.U. Commission based on uncertainty suggested the issue of the ban. It affirmed that the risk assessment is not compulsory and there exists scientific uncertainty when there is no scientific basis for assigning possibilities to a defined set of outcomes. The T.F.I., trying to follow the vague framework established by the Commission Communication on P.P., highlighted the importance of risk assessment and cost–benefit analysis. However, it specified that, in order to avoid regulation, the challenging party would have to prove the absence of risk. By requiring this, the Tribunal chose a strong version of P.P., raising the level of proof to the impossible.

This attitude has been the most adopted in the following jurisprudence. It is the consolidated E.C.J.'s and T.F.I.'s opinion that, if a situation of scientific uncertainty implies that it is not possible to demonstrate conclusively the existence or nonexistence of a risk, and any situation is surrounded by uncertainty, the E.U.

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<sup>301</sup> Case C-157/96, *National Farmers' Union* [1998] ECR I-2211 and case C-180/96, *United Kingdom v. Commission* [1996] ECR 3903.

<sup>302</sup> Case C-180/96, *UK v. Commission* [1998] ECR 3903, par. 99.

<sup>303</sup> See J.L. DA CRUZ VILAÇA, *op.cit.*, p. 369-406.

<sup>304</sup> Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union* [2002] ECR II-03305; case T-70/99, *Alparma v. Council* [2002] ECR II-3495. About Pfizer case, see I. FORRESTER, J.C. HANEKAMP, *Precaution, Science and Jurisprudence: a Test Case*, in *Journal of Risk Research*, 9, 4, June 2006, p. 297–311.

Institutions can adopt any precautionary measure in the event of scientific uncertainty, as long as they act within the margins of their discretion. In other words, scientific certainty is not required before taking a protective measure, but some scientific basis is necessary to conclude that the substances represent a health risk. Once an authority has decided to take the action, the principle of proportionality is at stake, since it evaluates whether (a) the measure is in line with the level of risk needed for it to tackle, and (b) the measures are legitimate, legal, not onerous, and appropriate.

The most recent and relevant case that confirms such perspective is the one of *Gowan*<sup>305</sup>, where the E.C.J. intervened in a preliminary reference regarding the commercialization of phytosanitary products. The case deals with Gowan, a Portuguese company who triggered the authorization procedure for fenarimol, and who sought the annulment of two Italian decrees complying with Directive 2006/134<sup>306</sup> before the Tribunale Amministrativo del Lazio (T.A.R.). Gowan pleaded the illegality of this Directive (and of the Decrees enacted in execution of it). It complained that the restrictions on the use of this substance were not justified by the scientific studies carried out during the course of the assessment procedure pursued by the U.K.<sup>307</sup>.

The E.C.J.<sup>308</sup> states that the restrictions on the use of fenarimol were based on the assessment criteria, and that the Commission had a wide discretion in the

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<sup>305</sup> Case C-77/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute* [2010] ECR I-13533.

<sup>306</sup> The Directive 2006/134/EC, that modifies Directive 91/414/CEE of the Council, about the conditions and procedures of authorization for the commercialisation of phytosanitary products, and their revision and withdrawal, includes an Annex I, in which the substances that could be authorised are inserted. In the case of fenarimol, the Directive 2006/134 limits the authorization of it only for 18 months and refers it only to some specific cultivations that have a marginal importance compared with the ones that constitute its main market. Such provision was decided in reference of some fears expressed by Member States with regards to the risk of fenarimol to create dangers to human health (endocrine system). It must be underlined that in the risk assessment phase, the State that was entitled to pursue the evaluation of risks (U.K.) had observed the absence of high levels of risks, and concluded for the acceptability of risks in the case of fenarimol, but later on the Commission changed its view and limited the use and commercialization of it. See Commission Directive 2006/134/EC of 11<sup>th</sup> December 2006 amending Council Directive 91/414/EEC to include fenarimol as active substance Text with EEA relevance, in *O.J. L 349/2006*.

<sup>307</sup> The Italian court asked the E.C.J. to ascertain if the Directive was valid, keeping in mind the contradiction among the risk assessment that had been done in the preliminary phase for the elaboration of the proposal of the Directive and the following phase of concrete proposal enacted by the Commission.

<sup>308</sup> The E.C.J. took into consideration: (1) the breach of the principle of legal certainty, (2) the error of risk assessment, (3) the violation of P.P., and (4) the violation of the principle of proportionality. As a

assessment of risks posed by the use of those substances, provided that scientific elements were posed at the basis of the decision. With reference to P.P., the Court underlines that it could be quoted only in the presence of uncertain scientific data, but not for asking the demonstration of absence of risks to those who would like to introduce fenarimol. Indeed, P.P. does not look for “zero risk” situations. However, it should be used as a means for justifying a restriction of measures in a context of scientific uncertainty regarding risks and without waiting for the risks to become real<sup>309</sup>. The risk assessment must be grounded on the most recent and available scientific data, coming from international research, and when those data are lacking in a complete sense, but when the risk is scientifically understandable, P.P. must be applied. Therefore, according to the Court, the Commission has founded its decision making on scientific elements (even if it is not exhaustive) about the risks of fenarimol to human health. Moreover, the Commission has respected the principle of proportionality<sup>310</sup>, in choosing temporally limited measures and referred only to a short set of cultures.

The E.J.C.’s behaviour has been contested by some authors, such as Alemanno, who thinks that the Court has reduced its role of judicial scrutiny, thereby allowing E.U. institutions to hide a public concern «*in the clothing of a science-based concern*»<sup>311</sup>, and thus limiting its judicial role only for the cases of «*manifest mistake*». In other words, the E.C.J. only concentrated on the compliance with the principle of proportionality with respect to the suitability and necessity of measures<sup>312</sup>, thus avoiding the matter of adequateness of them, in order not to invade the sphere of Commission’s discretion<sup>313</sup>.

From this ruling, the relevance of scientific data is evident. Firstly, in the phase of risk assessment as such with a cognitive role for the determination of the type of risk involved in a situation and, secondly, in the phase of risk management, being integrated with economic, social political data and instances. Under this

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result, the E.C.J. concluded in the absence of breach of the principle of legal certainty, of P.P. and the principle of proportionality, and in the absence of manifest error of assessment.

<sup>309</sup> See Par. 74.

<sup>310</sup> See Par. 81.

<sup>311</sup> See A. ALEMANNI, *Annotation of European Court of Justice, Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute (Precautionary Principle)*, in *Common Market Law Review*, 48, 4, 2011, p. 1347.

<sup>312</sup> See Par. 83 e 84.

<sup>313</sup> See Par. 56.

perspective, scientific data ground the political decision of the governance of risks and could be thought of as legalising and legitimising the political and discretionary choices<sup>314</sup>. These data exercise a role of “help” within the decision-making process in balancing some interests and rights such as, on the one hand, the right to life, health and environment and, on the other hand, the needs of commercialisation coming from the market. So, the administrative discretion would be limited by scientific data, or better, it should be grounded on them.

In conclusion, it has been shown that in the course of the years the application of P.P. has become more defined by the E.C.J.<sup>315</sup>, which has specified that P.P. must be anchored on scientific evidence with regards the risks to health and environment. P.P. is linked to risk assessment procedures, being a phase of decision-making process. Therefore, P.P. must imply the least restrictive measures, and it must include the analysis of cost and benefits of any kind of action, inaction or restriction. The result is that between the weak and strong version of P.P., the E.C.J. has chosen a sort of “third way”, founded on proportionality and reasonableness. However, the EU courts’ self restraint in examining scientific evidence in detail and their attitude of leaving the precautionary measures completely at the discretion of the institutions cannot be forgotten.

#### 5.2.8. *The Precautionary Principle in the United States of America.*

The U.S. approach to P.P. is completely different to that of the E.U., since in the U.S. a strong evidence of harm before deciding to regulate a certain technology is required, to the point that it has been affirmed that «*Precaution is for Europeans*»<sup>316</sup>.

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<sup>314</sup> See S. PENASA, *Balancing of Interests, Scientific Knowledge and Health: The Gowan Case*, in S. CASSESE, B. CAROTTI, L. CASINI, E. CAVALIERI, E. MACDONALD (EDS.), *Global Administrative Law: The Case-book*, New York-Roma, 2012, p. 97-104.

<sup>315</sup> With regards to the application of P.P. by E.C.J., see also: Case C-270/02, *Commission of the European community v. Italian Republic* [2004] ECR I-1559; Case C-6/99, *Association Greenpeace France and others v. Ministère de l'Agriculture et de la Pêche and others* [2000] ECR I-1651; Case C-236/01, *Monsanto Agricoltura Italia SpA and others v. Presidenza del Consiglio dei Ministri and others* [2003] ECR I-08105.

<sup>316</sup> S. LOEWENBERG, *Precaution is for Europeans*, in *New York Times*, 18<sup>th</sup> May 2003, Section 4, p. 14.

In reality, the first precautionary approaches to new technologies came from the U.S., even if in successive years its attitude has been very proactive.

As a legal concept, P.P. is quoted neither in the Federal Constitution, nor in the National ones, and neither by doctrine nor by Courts. However, there is no doubt that the concept has been faced several times in the field of criminal punishment, environmental protection, food and safety regulations, and health care regulation. In particular, the 1969 National Environmental Protection Act (N.E.P.A.)<sup>317</sup> has been considered as an embodiment of the P.P. in U.S. legislation, despite there being no specific obligations to Environmental Protection Agency to adopt precautionary measures in respect of possible harms.

In the 1970s<sup>318</sup>, precautionary measures could be taken by agencies without the need of “strong” evidence and the presence of uncertainty pertaining to the risks of a phenomenon was considered as sufficient to justify the measures (as allowed in *Ethyl Corporation* case<sup>319</sup> and *Reverse Mining*<sup>320</sup>). So, «from the 1960s through the mid 1980s, the regulation of health, safety and environmental risks was generally stricter in the United States than Europe. Since the mid 1980s, the obverse has often been the case»<sup>321</sup>.

The agencies’ discretion has been particularly underlined in the course of the years, as *Daubert v. Merrel Dow Pharmaceuticals* decision<sup>322</sup> witnesses. Indeed, in this ruling the U.S. Supreme Court allowed federal judges to reject irrelevant or unreliable scientific evidence, thus indicating the treatment of scientific evidence and the importance of screening it, and thereby stressing the role of judges in evaluating only the «principles and methodology, not [...] the conclusions they generate»<sup>323</sup>. So, since this judgment, the U.S. Courts have expressly restrained themselves and their attention to agency decisions, limiting to analyse the scientific evidence brought before them, so as only to establish whether a plausible risk actually exists, i.e. in accordance to “hard look doctrine” which aims to ensure that agencies had reviewed

<sup>317</sup> The National Environmental Policy Act of 1969 (Pub. L. 91-190, 42 U.S.C. 4321-4347).

<sup>318</sup> Other norms invoking the P.P. are the 1973 Endangered Species Act and 1963 Clean Air Act.

<sup>319</sup> Case *Ethyl Corp. v. EPA*, 598 F.2d 91 (D.C. Cir. 1979).

<sup>320</sup> Case *Reserve Mining Co. v. EPA*, 514 F.2d 492 (8th Cir. 1975), 528.

<sup>321</sup> D. VOGEL, *Ships passing in the night: the changing politics of risk regulation in Europe and the United States*, Working Paper 2001/16, Badia Fiesolana, 2001, at [http://www.eui.eu/RSCAS/WP-Texts/01\\_16.pdf](http://www.eui.eu/RSCAS/WP-Texts/01_16.pdf) (last visited 28<sup>th</sup> January 2013), p. 1.

<sup>322</sup> Case *Daubert v. Merrel Dow Pharmaceuticals*, 509 U.S. 579 (1993).

<sup>323</sup> Par. 595.

the relevant scientific evidence underpinning an issue and had understood it. In the U.S.A., therefore, P.P. does not exist as an independent concept, but the risk analysis is based on risk assessment, strong scientific evidence of risks before regulation, and cost-benefit analysis (so that the benefits of regulating exceed, or justify, the imposition of costs). P.P. here is intended to be adopted only after procedural steps are taken.

It should be noticed, in addition, that U.S. system does not quote the principle of proportionality, since it does not present itself in regulatory law. Furthermore, «*the U.S. Constitution has few or no general 'principles' of affirmative government responsibility to act, but it delegates enumerated powers to the federal government, and then recognizes individual rights against government action*»<sup>324</sup>, while the EU is more comfortable in indicating to the governments, with P.P., as to how they should act.

#### 5.2.9. *The Precautionary Principle in the United Kingdom.*

In the U.K. the precautionary principle is not codified in any norm. However, the reference of it has been given in policy documents and in judgments.

The choice favours a flexible P.P. that looks like an approach to assume in the risk management phase<sup>325</sup>, instead of a principle<sup>326</sup>. Moreover, P.P. is not limited to serious and irreversible damages, but can be adopted when the situation requires, provided that some scientific fundamentals are present (moderate version).

In case-law, P.P. was indicated in its E.U. version (weak), mentioning art. 191 T.F.E.U. In their decisions, the U.K. Courts have usually left to the government and its respective bodies to apply P.P. at their discretion, although it should be noted that the interpretation of it seems to be in line with cost-benefit analysis and risk-trade off

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<sup>324</sup> J.B. WIENER, M.D. ROGERS, *op. cit.*, p. 341.

<sup>325</sup> See also INTERDEPARTMENTAL LIAISON GROUP ON RISK ASSESSMENT, *Report. The Precautionary Principle: Policy and Application*, 2002, at [www.hse.gov.uk/aboutus/meetings/committees/ilgra/minrpt3.pdf](http://www.hse.gov.uk/aboutus/meetings/committees/ilgra/minrpt3.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>326</sup> See U.K. HOUSE OF COMMONS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY, *Scientific Advice, Risk and Evidence Based Policy Making*, 2006, p. 82–83; U.K. HOUSE OF LORDS SELECT COMMITTEE ON ECONOMIC AFFAIRS, *Government Policy on the Management of Risk*, vol. I, 2006, p. 25.

ones. The U.K. Courts limit themselves to only reviewing the formal procedure under which the decisions were taken (according to the principle of reasonableness), and they refrain from analysing the substance of the cases. They underline that P.P. can be quoted only in cases of “significant risk” and only in presence of scientific evidence. However, they do not check if the events at their attention constitute a risk in line with this feature of “significance”.

The first case where P.P. appears is in the *Duddridge* (1994)<sup>327</sup>, where the U.K. Secretary of State for Trade and Industry declined to issue regulations restricting the electromagnetic fields created by electric cables. The judge affirmed that P.P. could work for environmental protection, and since it was clearly affirmed only in EU legislation, the absence of national norm on this issue left the Secretary of State free in his decision to adopt precautionary measures or not<sup>328</sup>.

In the case of *Al Fayed*<sup>329</sup>, it was held that the U.K. Government was obliged to act in a precautionary manner in cases concerning base stations for mobile telephones, but the U.K. Court could not give any clear scientific evidence for sustaining such a claim.

#### 5.2.10. *The Precautionary Principle in Italy.*

In Italian legal system P.P. appeared for the first time in a Decree by the Ministry of Health (22<sup>nd</sup> November 2000), which stated that people who lived in the U.K. between 1980 and 1996 were not allowed donate their blood, for precautionary reasons (due to the fear of B.S.E.)<sup>330</sup>.

P.P. also grounded also the emanation of Legislative Decree n. 212/2001 regarding the commercialization of seeds, the law n. 36/2001 about the exposure to

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<sup>327</sup> Case *R. v. Secretary of State for Trade and Industry ex parte Duddridge and Others*, Queen’s Bench Division (Crown Office List), 4<sup>th</sup> October 1994.

<sup>328</sup> The same attitude is also seen in the *Cullen* case (Queen’s Bench Division, 14<sup>th</sup> February 2005).

<sup>329</sup> Case *R. v. Tandrige D.C. and another, ex parte Al-Fayed*, Queen’s Bench Division Crown Office List), 28<sup>th</sup> January 1999.

<sup>330</sup> “Aggiornamento del protocollo per l’esecuzione della vaccinazione contro l’epatite virale B”, at [http://www.salute.gov.it/imgs/C\\_17\\_normativa\\_1516\\_allegato.pdf](http://www.salute.gov.it/imgs/C_17_normativa_1516_allegato.pdf) (last visited 28<sup>th</sup> January 2013).

electric, magnetic and electromagnetic fields, and the Legislative Decree n. 224/2003 pertaining to GMOs<sup>331</sup>.

Other norms that appear to be “precautionary” are art. 2050 of civil code, where there is an inversion of the burden of proof with regards to the responsibility for dangerous activities, and the norms that are the recipient of European Directives such as the producer’s responsibility for defective products (85/374/CE), that has been adopted in Italian system with D.P.R. 224/1988, abolished and substituted by Consumers’ Code, Legislative Decree n. 206/2005.

A particular importance to precaution as a norm to be legally stated is offered within the Environmental Code (Legislative Decree n. 152/2006): art. 301 states that, in cases of risk even potential to human health and the environment a high level of protection must be ensured, though on the basis of a preliminary scientific evaluation. However it should be noted no reference is done within the Constitution, which is different from that of France and Spain<sup>332</sup>.

The rulings by the Italian Constitutional Court<sup>333</sup> are very meaningful in this regard, as they deal with P.P. in two main senses: first of all, the Court checks the application of P.P. and the compliance with its general requirements in the measures that claim to adopt it (such as the check of the scientific basis for uncertainty); secondly, the Court uses P.P. in developing the well-known technique of “*bilanciamento di diritti*”, i.e. the balancing mechanism for protecting some fundamental rights (right to health, right to environment, right to life, etc.) in front of other rights, such as the freedom of private enterprise (art. 41, Const.)<sup>334</sup>.

Decisions n. 282/2002 and 406/2005 belong to the first approach.

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<sup>331</sup> For Italian legislation, see <http://www.normattiva.it> (last visited 28<sup>th</sup> January 2013).

<sup>332</sup> Spanish Constitution contains in art. 45 an expressed reference to the protection of environment for the adequate development of the person, to be pursued especially through the prevention principle. In 2005, French Constitution has inserted in the Preamble a reference to the *Charte de l’environnement*, stating that in case of event, even if uncertain, which is likely to damage in a serious way the environment, the public authorities are bound – in the name of P.P. - to adopt procedures of evaluation of risks and proportioned measures to tackle the damage. This kind of P.P. limits its efficacy to cases of risks upon environment and the norm creates a duty only to public authorities.

<sup>333</sup> For the rulings of the Italian Constitutional Court, see <http://www.giurcost.org/decisioni/index.html> (last visited 28<sup>th</sup> January 2013).

<sup>334</sup> With regards to the two uses of P.P. by the Italian Constitutional Court, see G. DI COSIMO, *Il principio di precauzione nella recente giurisprudenza costituzionale*, n. 25/2006, at <http://www.federalismi.it> (last visited 28<sup>th</sup> January 2013). See also M.G. STANZIONE, *Principio di Precauzione e Diritto alla Salute. Profili di Diritto Comparato*, 2010, at [http://www.comparazionedirittocivile.it/prova/files/cat\\_stanzione\\_saggio.pdf](http://www.comparazionedirittocivile.it/prova/files/cat_stanzione_saggio.pdf) (last visited 28<sup>th</sup> January 2013).



The first ruling concerns the judgment of the constitutional legitimacy of a law adopted in a Region (Marche) in 2001 (regional law n. 26) that, on the basis of P.P., had suspended the electro convulsive therapy and other therapies along the whole national territory, until the Ministry of Health had proven that those therapies were safe and not productive of damages to health<sup>335</sup>. In such a ruling, the judges declare the unconstitutionality of the law, by stating that fundamental principles such as P.P. cannot be derived from regional laws but only from national ones (in line with art. 117, 3 Const.) and, in any case, P.P. can be applied only on the basis of scientific knowledge and experimental scientific evidence, and not on a mere political will. So, the legislation should respect a “*scientific reasonableness*” principle, not deriving exclusively from political discretionary power, but being grounded on verification of available scientific knowledge and experimental evidence<sup>336</sup>, acquired through institutions and organisms – usually national or supranational – voted to this.

The sentence n. 406/2005 (about the constitutional legitimacy of a regional law – Region Abruzzo, n. 14/2004 - that suspended the prophylactic campaign against the oxen fever, the so-called “blue tongue” and admitted the circulation, commercialisation and slaughtering of not vaccinated animals, only within regional territory<sup>337</sup>) clearly defines P.P. as a «*a directive criterion that must inspire the elaboration, definition and actuation of EC environmental policies on the basis of sufficient scientific data and reliable scientific evaluations about the effects that can*

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<sup>335</sup> More specifically, the Region claimed that those therapies were surrounded by uncertainty with regards to the efficacy and the possible collateral effects.

<sup>336</sup> The Italian Court specifies that the Legislator cannot establish in a direct and specific way what the allowed therapeutic practices are, under which limits, and according to what conditions. The Legislator cannot hinder the doctor’s autonomy that grounds on the scientific and experimental acquisitions that are continuously evolving. These acquisitions found the use of therapeutic means, and an adequate experimentation and clinic-scientific documentation grounds the ban for adopting and spreading not scientifically tested therapies. Yet, it does not mean that the Legislator can never intervene, but he must do it according to the same requirements asked of the doctor, i.e. supported scientific knowledge.

<sup>337</sup> In particular, the case was about Italian Government’s claim that the regional law at stake was in contrast to Directive 2000/75 (which fixed the measures of prophylaxis against blue tongue, thus including the Abruzzo region in the addresses of the rules). The Region, instead, justified the suspension of the campaign without the EU Commission’s consent, by giving voice to the farmers’ and breeders’ fears that the delays in the prophylaxis could make the situation even worse. See Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue, in *O.J. L 327/2000*.

*derive from certain activities»*<sup>338</sup>. It is thus a reminder of art. 174 T.C.E. (weak version). The Italian Court declares the illegitimacy of the law, because it is in contrast with the Directive 2000/75 and it limits the efficacy of the E.U. norms. Moreover, the judges state that the scientific opinions upon which the P.P. must be applied and the evidence of scientific uncertainty are usually the majority ones. Therefore, the Court makes prevail the most quoted scientific opinion to base the adoption of P.P., and this behaviour is more sectarian than the one of W.T.O. Panels, which allows indifferently both the minority or the majority scientific positions to ground uncertainty, provided that the position has scientific elements. The Italian Court specifies that P.P. cannot be used in a misleading sense by the addresses of E.U. rules, i.e. for negating the application of a directive based on P.P. itself. In this view, P.P. would be used for both providing a measure and for negating it.

The second approach by the Constitutional Court, in its use of P.P. for the balance of rights, is visible, for example, in the ruling n. 116/2006, concerning GMOs and a regional law that had prohibited *tout court* the production and commercialization of GMOs, instead of regulating their release and making them coexist with traditional and biological agriculture<sup>339</sup>. The regional law was adopted as a response to a State law which gave application to an E.U. provision (Directive 2001/18), and had opted for a separation of cultures but without impeding GMOs to be produced. In this way, the State law sought to find a proper balance among the freedom of circulation of GMOs and the protection of health. In this case, the Constitutional Court admits the limits to freedom of private enterprise (stated in art. 41 Const.) in order to protect environment and human health, on the basis of P.P.. According to its reasoning, the State law represent a right and rational balance among the economic freedom of circulation of GMOs and the protection of the people's health and environment. It is the State's duty to individuate, for reasons of national uniformity, the limits to the exercise of the freedom of economic initiative at the light of P.P. based on the state of scientific knowledge and evidences acquired at national or supranational level (here the Court quotes its own decision n. 282/2002). So, P.P. is not an element to be balanced, but an instrument to be used in order to find the "key" point where the balance can be reached. The limitations to art. 41 are

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<sup>338</sup> Para. 3.

<sup>339</sup> See G. GALASSO, *Il principio di precauzione nella disciplina degli OGM*, Torino, 2006, p. 178.

admitted on the basis of the verification of the state of scientific knowledge acquired by institutions and bodies deputed for this.

The decision confirms the framework already adopted in the decision n. 185/1998<sup>340</sup>, concerning the constitutional legitimacy of a law (n. 194/1998) that had excluded from the insertion on the list of innovative drugs to be bestowed upon by the State in the cases of no alternative treatment, the drugs that lack results of experimentations of the “second phase”, such as drugs adopted within “Di Bella therapy”, i.e. a new alternative therapy against cancer. The Italian Court affirms that it is not called to pronounce with regards to the effects or the therapeutic efficacy of that treatment, or for the ascertainment of which there is an experimentation in the course of action. Neither is it called to substitute its judgement to evaluations that should be assumed in the competent seats, i.e. technical-scientific bodies. Nor could it express its opinion about the ban of inserting some medicines that lack experimentations (of “second phase”) in the list of innovative drugs. So, the Court opts for a “self-restraint” and “deference” towards scientific data and, in reference to the temporal duration of experimentation, it admits that the situation of scientific uncertainty with reference to the efficacy of the treatment is not sufficient to exclude the adoption of measures in order to protect human health. Such temporal data are based on P.P., even if it is not clearly stated<sup>341</sup>.

Moreover, the Court (n. 399/1996) rejects the claims of constitutional illegitimacy with regards to the law n. 584/1975, in the part in which it does not contain the forbade of smoking in working places. This forbade, indeed, is implicitly provided in other norms, where the onus is on the employer to adopt measures to protecting its employees from passive smoking – on the basis of art. 32 Constitution - is clearly stated. The right to health is respected if the risk of passive smoking is reduced to a low level, to the point that it is reasonable to think that the health cannot be damaged.

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<sup>340</sup> See also ruling n. 351/1999.

<sup>341</sup> Moreover, the Court accepted the claims of illegitimacy of the law for violation of art. 3 (principle of equality), in the part in which the law did not establish that the national sanitary service should supply the necessary medicines that were necessary for such therapy to the subjects being in a situation of economic unavailability. Indeed, the right to health cannot depend on the economic means of people.

From these decisions it emerges that the protection of human health (art. 32 Const.) is central and it must be guaranteed in cases of scientific certainty and uncertainty too, as this solution *«seems to be the only one compatible with the central relevance that the right to health assumes within the constitutional framework as a value per se and as a prerequisite for the exercise of the other constitutional freedoms. Denying the right to health in presence of the risk of a serious and irreversible harm, that is scientifically and rationally hypothesized and that can be proved, would mean to renounce at the possibility of its effective warranty»*<sup>342</sup>.

In summary, the weak version of P.P. seems the most preferable one within Italian system.

### 5.3. Cost-Benefit Analysis.

Another approach used in the risk management phase<sup>343</sup> is based on the Cost-Benefit Analysis, i.e. “C.B.A. *per se*”,. The models of Risk-Benefit analysis and Risk-trade off can also be considered as an application of C.B.A. This is a technique for assessing and comparing options, *«a tool for judging efficiency in the case where the public sectors supply goods, or where the policies executed by the public sectors influence the behaviour of private sectors and change the allocation of resources»*<sup>344</sup>.

C.B.A. has its origins in the water development projects of the U.S. Army Corps of Engineers. In 1879, the U.S. Congress created the Mississippi River Commission to prevent destructive floods, and in 1936 it passed the Flood Control Act which contained these words: *«the Federal Government should improve or participate in the improvement of navigable waters or their tributaries, including watersheds thereof, for flood-control purposes if the benefits to whomsoever they may accrue are in excess of the estimated costs»*. Initially the Corps of Engineers developed *ad hoc* methods for estimating benefits and costs, and economists influenced and improved their methods by extending this analysis to all the policies.

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<sup>342</sup> A. GRAGNANI, *Il Principio di Precauzione come Modello di Tutela dell'ambiente, dell'uomo, delle Generazioni Future*, in *Rivista di diritto civile*, 49, 1, 2003, p. 35.

<sup>343</sup> See G. BOUNDS, *Challenges to Designing Regulatory Policy Frameworks to Manage Risks*, cit.

<sup>344</sup> T. OKA, *Effectiveness and Limitations of Cost-benefit Analysis in Policy Appraisal*, in *Government Auditing Review*, 10, March 2003, p. 17.

Similarly to what has been done with reference to P.P., the next subparagraphs will focus on C.B.A., so as to show its main features and how it and the models linked with it (risk-benefit and risk-trade off analysis) have been adopted as tools for risk management.

### *5.3.1. Cost-Benefit Analysis As Such and its Limits.*

In general, C.B.A. consists of the calculation of the relevant possible benefits and possible costs of particular outcomes of an action or an inaction, and the comparison of results, so that, on the basis of the calculation, the policy in which the benefits are more than costs should be adopted. This model is based on the concept of efficiency as elaborated in the market economy, which consists of the spontaneous transaction of goods and services<sup>345</sup>. It makes use of consequential (and utilitarian) evaluation, because costs and benefits are judged by looking at the consequences of the respective decisions.

With regards to synthetic biology, an application of cost-benefit analysis would mean to calculate the costs and benefits deriving from the pursue of research and from the avoidance of it, and listing all the stakeholders connected with a project or programme<sup>346</sup>. Benefits and costs are obviously expressed in monetary terms and are calculated, keeping in mind the so-called “annualisation”, that is a procedure through which the average cost and the average benefit per year are worked out, and the “discounting”, i.e. a procedure that allows a comparison between the costs and benefits arising from different time periods. As for the latter, in fact, it cannot be forgotten that normally people prefer to receive benefits sooner rather than later, and

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<sup>345</sup> The main concepts within C.B.A. are the W.T.P., “willingness to pay”, i.e. the upper limit to the amount of money a buyer is willing to relinquish in exchange for obtaining the goods (suppose that a buyer of goods, who obtains the goods by paying money, is willing to obtain them because the amount he or she has to relinquish in exchange for obtaining the goods is in a permissible range), and the W.T.A., “willingness to accept”, that is the minimum amount of money needed to make a seller willing to relinquish the goods. Indeed, if the amount to be relinquished is excessive, a person dare not obtain the goods, while if the amount of money is too small, the seller will not be willing to relinquish the goods. Both the values depend on the buyer’s and seller’s subjective appraisal of the goods (utility). Moreover, if a buyer bought at a price lower than W.T.P., he will have the better subjective utility, and if a seller sold at a price greater than W.T.A., he should make a profit from the sale that exceeds the costs.

<sup>346</sup> N.E. BOARDMAN, *Cost-benefit analysis, concepts and practice*, Upper Saddle River, N.J., 2006.

they prefer to incur costs later rather than sooner. So, in the light of this, more weight must be given to earlier costs and benefits than later ones by applying a discount rate.

Since C.B.A. is based on money calculations, its application with reference to risks could work only for cases of physical risks, which are likely to be scientifically assessed. So, in the calculation of cost and benefits with reference to synthetic biology C.B.A. could be used only with respect to one type of risks (the probable and uncertain physical risks).

As for the limits and problematic aspects of C.B.A., it can be said that the model of cost-benefit analysis suffers from the tendency of not taking into sufficient account of how society, industry and technology change over time. It focuses only on monetary elements and does not consider the social and ethical aspects. Some scholars, in particular, have criticized the assignation of monetised value to noneconomic things, such as the environment and human lives, stating that it is immoral or unethical as it entails a commodification of meaningful values and entities that are not marketable by nature<sup>347</sup>, despite the fact that for economists this is not a controversial issue<sup>348</sup>. However, the question lies in whether a monetary value be assigned to these elements, and in the event it could, it would be very difficult to be found and the margin of error would be enormous.

Furthermore, the use of cost-benefit analysis has been contested on the grounds that, with reference to uncertain risks, the cost-benefit analysis is unable to provide a clear answer, as it is not founded on sufficient information<sup>349</sup>. Since the causal link between a harm and an activity may be hidden, and the magnitude of a harm may be impossible to estimate, some variables in the cost-benefit equation might be overlooked, or be assigned the wrong values. Thus, the result of a cost-benefit analysis may not show reality properly<sup>350</sup>. Harrison has also underlined the

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<sup>347</sup> See E. ANDERSON, *Value in Ethics and Economics*, Cambridge, M.A., 1993.

<sup>348</sup> K. VISCUSI, *Monetizing the Benefits of Risk and Environmental Regulation*, in *Fordham Urban Law Journal*, 33, 2006, p. 1003. It must be specified that economists say that they do not assign value to life itself, but to improved safety, health and reduction of risks.

<sup>349</sup> See P. SLOVIC, *op.cit.*, p. 124; D. PEARCE, *Cost-benefit analysis and environmental policy*, in *Oxford Review of Economic Policy*, 14, 4, 1998; J. ADAMS, *Cost-benefit analysis: part of the problem, not the solution*, Oxford, March 1995.

<sup>350</sup> J. ZANDER, *The Application of the Precautionary Principle in Practice*, Cambridge, 2010, p. 23.

peril of the avoidance in addressing important issues such as justice needs and the interests of future generations<sup>351</sup>.

### 5.3.2. Risk-Benefit Analysis and its Limits.

Risk-benefit analysis (or risk-cost-benefit analysis) starts from the same presumption as cost-benefit analysis: all consequences of an action should be identified and evaluated. However, risk-benefit analysis does not aggregate all the consequences<sup>352</sup>, and it specifically concentrates on the risk of a situation to its related benefits. The approach tries to answer to a main question: “How safe is safe enough?” in economic terms. Of course, the analysis does not try to reach a zero risk situation, but to enucleate the level of acceptance of risks which entails that benefits are, however, more than costs.

With regards to synthetic biology, it can work only for (physical) probable risks, where the possible harms are identifiable and quantifiable, according to the measurements of “risk unit”, and “quality-adjusted life year” (to calculate the severity of harm).

After the calculation of the probability of occurrence of a harm, the cost of a decision, a project or an undertaking upon society must be provided. It includes the cost of all resources and a cost assigned to the possibility of harm that the activity involves. The risk is obtained by estimating the cost of harm and by multiplying it by the probability that the harm will occur. The social cost of the risk is included, that is to say that the willingness of people to pay to avoid risks of that type or how much they will demand to accept them is taken into account.

Finally, the risks are compared with benefits, and only if the amount of benefits clearly outweighs the amount of risks, the activity may be considered acceptable. The value of a policy is measured by the amounts that individuals are or not willing to pay for its consequences (less the costs that they would pay to avoid).

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<sup>351</sup> M. HARRISON, *Valuing the Future: the social discount rate in cost-benefit analysis*, Visiting Researcher Paper, Canberra, 2010, p. 18 ff.

<sup>352</sup> R. ZECKHAUSER, *Measuring Risks and Benefits of Food Safety Decisions*, in *Vanderbit Law Review*, 539, 38, 1985, p. 543 ff.

So, the main idea is to maximize “social profit”. An efficient choice is the one that allocates resources so that it maximizes the good (things that people like and are willing to pay for) and minimizes the harms (things that people do not want and would pay to avoid).

The criticism to risk-benefit analysis is similar to the one that has been presented in the previous section for C.B.A.. In particular, the main contestation pertains to the fact of dealing with society as with a firm and a market arena. Policy makers should sometimes make decisions despite economic grounds and take into consideration some values such as safety and health or rights and interests of the society that overcome any calculation of benefits and costs and go beyond individual preferences (such as the protection of human dignity). The approach «*offers guidance for political decisions, but it does not provide an adequate basis for reaching or for justifying those decisions*»<sup>353</sup>, since a lot of political, legal, social values cannot be evaluated in money terms and as a market commodity.

Moreover, risk-benefit analysis allows the evaluation of the actions in terms of maximization of benefits and minimization of harms, despite the action is a safe, healthy, sustainable one. It only takes into account the relative amount that people would pay for the goods and for avoiding the harms. Thus it concentrates only on economic efficiency, not on other moral or ethical values. The utilitarian thought is dominant here<sup>354</sup>. Therefore, the efficiency pursuit corresponds to the happiness one and is meant as a seek for satisfaction of preferences. However, measuring “happiness” or benefits to the society is not a simple endeavour, since there are very subjective “feelings” that seem too complex to calculate in a scientific way.

Economists have struggled to measuring this type of benefits and they have taken inspiration from Pareto, in saying that one social state is better than another, if there is at least one person preferring the former than the latter. If the ones in favour of a certain condition compensate the ones against it, the policy is justified. However, this view entails some problems, as explained by Sagoff. Indeed, Pareto’s principle, even if mitigated by the compensation rule, tries to identify society’s benefit as a whole, without considering the personal view of each person or without

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<sup>353</sup> M. SAGOFF, *Risk-Benefit Analysis in Decision Concerning Public Safety and Health*, Dubuque, I.A., 1985, p. 2.

<sup>354</sup> See J.S. MILL, *Utilitarianism* (1863), London, 2008.



making interpersonal comparisons of welfare and utilities. In doing so, risk-benefit analysis misunderstands a big point: it assumes that if someone prefers one policy to another, then the whole society will prefer the former. It also equates the preference of something to its better value as if preferring something meant it is better than the rest. As Hirschman proves, it is not so true that people who have more things are necessarily happier<sup>355</sup>.

Furthermore, the deep focus on efficiency tends to neglect other purposes of policies such as equity (i.e. a right distribution of resources) and justice.

### 5.3.3. Risk Trade-Off Analysis and its Limits.

This procedure aims at identifying hidden risks, weighing risks against each other and ranking them, in order to ensure maximum safety for the lowest cost. This approach turns away from individual risks and goes towards a holistic view of them<sup>356</sup>. So, risks do not appear in isolation, like it does in risk-benefit analysis. The removal, or targeting, of one risk may be accompanied by a “countervailing risk”, which means that *«the risk of an adverse outcome from a measure that was intended to address a target risk»*<sup>357</sup>. Here a “target risk” should be understood as the risk that is considered as the primary focus of risk-reducing efforts, while the “countervailing risk” is the adverse risk that results from an activity whose purpose is to reduce the target risk. The term “risk” here means any chance of an adverse outcome to human health, the quality of life, or the quality of environment. So, this approach refers to physical and probable risks. So, *«the guiding idea behind risk trade-off analysis is simple and intuitively appealing: regulations undertaken to minimize or eliminate certain health risks often have the perverse effect of promoting other risks. A serious analysis of a regulation should therefore pay attention not only to the regulation’s primary effects in reducing the so-called target risk, but also to the secondary effects*

<sup>355</sup> A.O. HIRSCHMAN, *Shifting Involvements: Private Interest and Public Action*, Princeton, N.J., 1982.

<sup>356</sup> The concept of “risk-risk” was first explained in L.B. LAVE, *The Strategy of Social Regulation: Decision Frameworks for Policy*, Washington, D.C., 1981. About risk trade off see J.D. GRAHAM, J.B. WEINER (EDS.), *Risk versus Risk: Tradeoffs in Protecting Health and the Environment*, Harvard, 1995; R.L. KEENEY, *Mortality Risks Induced by Economic Expenditures*, in *Risk Analysis*, 10, 147, 1990; A. WILDAVSKY, *Searching for Safety*, Piscataway, N.J., 1988.

<sup>357</sup> J. ZANDER, *op.cit.*, p. 26.

*of the regulation in calling forth “countervailing” or “ancillary” risks. In this way, risk trade-off analysis promises a more rational technique for the evaluation of regulation»<sup>358</sup>.*

Such a method allows the regulator to put some of the hidden consequences of regulation, as well as non-regulation, on the ground. Once all the effects of regulation are visible, the regulator can choose what approach to follow, aiming at the way that best focuses on the overall risk level, and not on the isolated risk. This may include the ranking of risk-reducing policies. The ranking may be based upon cost-effectiveness, but also on how best to ensure overall safety, regardless of the costs.

According to Rascoff and Revesz, at the core of the risk trade-off analysis lies an important methodological flaw: the inattention to ancillary benefits<sup>359</sup>. Indeed, *«risk trade-offs and ancillary benefits are simply mirror images of each other. There is no justification for privileging the former and ignoring the latter»<sup>360</sup>.*

#### *5.3.4. Cost-Benefit Analysis in International Law.*

An example of C.B.A. in the international law context is given by the World Charter for Nature, where there is the reference to the weighting of costs and benefits, and to reverse the burden of proof, away from the regulator and onto the regulated party, in order to prove that the benefits of the proposed activity outweigh the potential risks.

The Bruntland Report also looks at the environment from an economic viewpoint.

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<sup>358</sup> S.J. RASCOFF, R.L. REVESZ, *The Biases of Risk Trade-off Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*, in *The University of Chicago Law Review*, 69, 4, Autumn 2002, p. 1765.

<sup>359</sup> S.J. RASCOFF, R.L. REVESZ, *op.cit.*, p. 1767-1768.

<sup>360</sup> *Ibid.*, p. 1793.

### 5.3.5. Cost-Benefit Analysis in European Union Law.

As it has been extensively discussed in the earlier section, in Europe there is a non-binding reference to C.B.A. which is included in the Communication on the precautionary principle by the Commission<sup>361</sup>. The principle of proportionality (mentioned in art. 5 of the T.E.C.) contains the application of some form of cost-benefit analysis, although it is not defined or formalised<sup>362</sup>.

The reference to art. 130 R (now art. 191 T.F.E.U.) has also lent support to C.B.A..

More generally, as for the whole regulation and governance of the policies of E.U., the Protocol on application of the principles of subsidiarity and proportionality<sup>363</sup> mentions the importance of necessity and of the evaluation cost-benefits before adopting any act.

C.B.A. is also quoted in reference to the risk evaluation phase indicated in the “Mapping Guidelines” by Commission (2010)<sup>364</sup>. Indeed, the risk criteria on the basis of which the significance of a risk is evaluated include associated costs and benefits, legal requirements, socioeconomic and environmental factors, and concerns of the stakeholders, etc.

In case-laws, the principle of proportionality is the closest to C.B.A.. It implies that the means to reach a purpose must be adequate and necessary, the objective legitimate, and the choice goes upon the least restrictive measure. So, when enacting a measure, the E.U. Institutions should evaluate the “cost-benefits” of that measure. If they are opting for a precautionary measure in presence of risks, the only role for the E.U. Court is to examine the validity and proportionality of the measure itself<sup>365</sup>.

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<sup>361</sup> COM (2000) 1, cit., p. 18.

<sup>362</sup> See J. JANS, *Proportionality Revisited*, in *Legal Issues of Economic Integration*, 27, 3, 2000, p. 239–265.

<sup>363</sup> See *O.J. C 306/2007*.

<sup>364</sup> See footnote 178.

<sup>365</sup> See C-453/03, *Joint Cases ABNA Ltd and Others v. Secretary of State for Health and Food Standards Agency*; C-11/04, *Fratelli Martini & C. SpA and Cargill Srl v. Ministero delle Politiche Agricole e Forestali and Others*; C-194/04, *Nederlandse Vereniging Diervoederindustrie (Nevedi) v. Productschap Diervoeder*.

### 5.3.6. Cost-Benefit Analysis in the United States of America.

In the U.S.A. the regulatory measures are usually preceded by Regulatory Impact Assessments<sup>366</sup>, which include risk assessment, cost-benefit analysis, the motivated need for the proposed action by the agency, and an examination of alternative approaches. Risk trade-offs are also considered, and there is a ranking of risks in order of priority.

From 1946, the Administrative Procedure Act imposes on any administration the duty to evaluate their measures from the CBA point of view, so that any agency uses this method to increase its accountability and to found its reasonableness. The Office of Management and Budget has the role to review the regulatory proposals<sup>367</sup>. The last act, which asks the administrations to evaluate even in a retrospective mood their choices, on the basis of benefits and costs, is the Executive Order 13, 563 (January 2011).

A meaningful demonstration of the application of C.B.A. is found in the U.S. Supreme Court jurisprudence. It has indicated its role simply in the checking of the «*non arbitrary and capricious*»<sup>368</sup> choices enacted by the agencies, without having the power of substituting the agency's evaluation with its own. One of the most recent decisions is the case of *Entergy Corp. v. Riverkeeper Inc.*, where the U.S. Supreme Court rejected a challenge to the Environmental Protection Agency (E.P.A.)'s use of cost-benefit analysis in regulating water pollution by power plants. The Court said that, even if C.B.A. was not imposed or provided by the law, nevertheless it could not be considered as implicitly forbidden. Therefore, the E.P.A. acted reasonably in weighing the costs and benefits of various technologies when it promulgated regulations under the Clean Water Act.

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<sup>366</sup> OFFICE OF MANAGEMENT AND BUDGET, *Regulatory Analysis, Circular A-4 To the Heads of Executive Agencies and Establishments*, 17<sup>th</sup> September 2003, p. 2.

<sup>367</sup> See OFFICE OF MANAGEMENT AND BUDGET, *Guidelines and Discount Rates for Benefit-Cost Analysis of Federal Programs*, Circular n. A-94 Revised, 29<sup>th</sup> October 1992, Memorandum For Heads Of Executive Departments And Establishments, at [http://www.whitehouse.gov/omb/circulars\\_a094](http://www.whitehouse.gov/omb/circulars_a094) (last visited 28<sup>th</sup> January 2013).

<sup>368</sup> Case *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Life Insurance Company*, 463 United States Reports 29, 42-43 (1983).

### 5.3.7. *Cost-Benefit Analysis in the United Kingdom.*

The first application of C.B.A. in U.K. happened in the field of transports<sup>369</sup> and the environment, because of the influence of Bruntland Report<sup>370</sup>.

U.K. Governments acts emphasise the utility of cost-benefit and risk-trade off analysis, and the importance of involving the general public in the decision-making process. The 1990 White Paper, “*This Common Inheritance*”<sup>371</sup>, where P.P. is associated with cost-benefit analysis, is very meaningful. This approach is confirmed by 1995 Environment Act, where the Environment Agency is charged with the role of considering the costs and benefits of its actions<sup>372</sup>.

### 5.3.8. *Cost-Benefit Analysis in Italy.*

In Italy, the first reference to the cost-benefit analysis has been offered by the Law n. 50/1999, and it is aimed at the simplification of norms and procedures. In particular, art. 3 establishes the “Nucleus for the Simplification of norms and procedures”, which must be composed of experts of C.B.A. Moreover, the Analysis of the Impact of Regulation (A.I.R.) has been imposed to all the administration, as well as to the independent authorities<sup>373</sup>. There are some specific legislation which refers to C.B.A., such as in the sector of usage of hydro resources (with regards to the use of water, the costs of management, the prices for the cession of the resource), that gives application to Directive 2000/60/EC.

The Constitutional Court has expressly mentioned the C.B.A. in some rulings: n. 482/1995 and n. 401/2007.

The first one is concerned with the presumed violation by the Italian State of the sphere of competence recognised to Regions in the subject of “public works”

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<sup>369</sup> See HIGHWAY AGENCY, *Economic Assessment of Road Schemes: COBA Manual*, vol. 13 of Design Manual for Roads and Bridges, London, 1997.

<sup>370</sup> For deepening this issues, see D. PEARCE, *Cost-Benefit Analysis and Environmental Policy*, in *Oxford Review of Economic Policy*, 14, 4, 1998, p. 84-100.

<sup>371</sup> WHITE PAPER, *This Common Inheritance: A Britain’s Environmental Strategy*, presented to Parliament, September 1990, HMSO, Cm 1200.

<sup>372</sup> See also H.M. TREASURY, *Managing Risks to the Public: Appraisal Guidance*, 2005, at [http://www.hm-treasury.gov.uk/consult\\_greenbook\\_index.htm](http://www.hm-treasury.gov.uk/consult_greenbook_index.htm) (last visited 28<sup>th</sup> January 2013).

<sup>373</sup> See l. 22/2003 and 262/2005.

(with regards to law 109/1994)<sup>374</sup>. It makes reference to C.B.A. in the part in which it states that the need of the subject of “public works” is to determine what public works can really be realized on the basis of financial resources and “according to an order of priority that is based upon the evaluation of costs and benefits”. The Court, beyond the specific *thema decidendum*, observes the importance of C.B.A. in the phase of project and realization of public policies.

The second ruling is again a case about the competences among State and Regions, and it retakes into account the same principles, by stating that the subject of “protection of competition (among enterprises)” includes any intervention of regulation for ensuring competition and for solving situation of unbalance of it. Both the aims of the regulation must include a proper C.B.A., and must be based upon proportionality and reasonableness.

#### *5.4. The Proactionary Principle and its Limits.*

The proactionary perspective supports the idea that the *«emerging science and technology should be considered safe, economically desirable and intrinsically good unless and until it is shown to be otherwise, which means that the burden of proof is on those who want to slow down a given line of research»*<sup>375</sup>.

The proactionary principle<sup>376</sup> is an ethical principle, elaborated as part of extropic philosophy by Extropy Institute, which is a transhumanist organization that deals with meeting the technology-driven challenges and opportunities of the future<sup>377</sup>. Its vision is founded upon the following points:

(1) freedom to innovate, i.e. the need to protect the freedom to experimentation, progress and innovation, meant as critical to future survival and well-being, so that to allow technology to flourish, rather than limiting its potential

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<sup>374</sup> More precisely, the Regions stated that the Government regulations invaded the sphere of competence provided to Regions at the light of Italian Constitution (art. 117).

<sup>375</sup> E. PARENS, J. JOHNSTON, J. MOSES, *Ethical issues in Synthetic Biology. An overview of the debates*, in *SYNTHETIC BIOLOGY*, n. 3, June 2009, p. 18.

<sup>376</sup> See, M. MORE, *The Proactionary Principle*, 29<sup>th</sup> July 2005, at <http://www.maxmore.com/proactionary.htm> (last visited 28<sup>th</sup> January 2013).

<sup>377</sup> See <http://www.extropy.org/> (last visited 28<sup>th</sup> January 2013).

with an overcautious, precautionary approach. It derives that the burden of proof therefore belongs to those who propose restrictive measures;

(2) objectivity: the necessity to use a decision process that is objective, structured, and explicit, through evaluating risks according to available science, and not through emotionally shaped perceptions, adopting explicit forecasting processes, reducing biases by selecting disinterested experts, by using the devil's advocate procedure with judgmental methods, and by using auditing procedures such as review panels;

(3) comprehensiveness: the focus must be given upon all reasonable alternative actions, including no action, and take into account the costs and risks of all the options;

(4) openness/transparency: the mood of taking into account the interests of all potentially affected parties, and keeping the process open to input from those parties;

(5) simplicity referring to the methods to adopt for the evaluation;

(6) Triage: the priority must be for ameliorating known and proven threats to human health and environmental quality over acting against hypothetical risks;

(7) Symmetrical treatment to technological and to natural risks;

(8) Proportionality: it means to adopt restrictive measures only if the potential impact of an activity has both significant probability and severity. If the activity also generates benefits, it is necessary to discount the impacts according to the feasibility of adapting to the adverse effects;

(9) prioritize (prioritization): the priority must be assigned to risks to human and other intelligent life over risks to other species; to non-lethal threats to human health priority over threats limited to the environment; to immediate threats over distant threats; to more certain over less certain threats, and to irreversible or persistent impacts over transient impacts;

(10) renew and refresh: revision of the decisions, if in the future the conditions may have changed significantly.

The proactionary principle is founded on the idea that, historically, all the most important technological innovations and their consequences were not so well understood at the moment of their invention, but if research was impeded, they would have never been realized and promoted human progress. So, this approach

encourages the aggressive pursuit of technological change, leaving “doors” open to it and insisting that the best way to learn is through experimentation (empiric way) and not through thinking *a priori* about something, i.e. making a decision without actually taking any action.

What the enthusiasts of this approach fear is the public scepticism that can slow down the progress: that’s why they consider risks as irrational fears and support the education of the public opinion.

The proactionary principle is quoted in cases of physical risks and non-physical concerns. Indeed, in the first case, the proactionary approach could be used with reference to uncertain and probable risks, stating that until a proof or a very deep suspicion that a technology could give rise to a serious harm is not produced, the technology should go on; with regards to non physical concerns, it suggests that the natural world should be seen as a chattel that belongs to human beings and that it could be freely modified with the intellectual and human mind. Thus, no limits to research should be fixed, and the moral, economic, social issues are secondary.

Even if a lot of the aspects considered by the proactionary principle cannot be neglected and may be relevant in a management of risks, the peril is that the proactionary principle could slide into extreme positions, that are the opposite - but in the end, identical – to the ones mentioned for the precautionary principle. In fact, if assumed in its extreme version, the proactionary principle is against regulation in any sense and would permit a complete openness, without any limit, to technological development.

Furthermore, the reference to the aforementioned cost-benefit analysis is not so feasible in a lot of situations, as quantifying (economically) the value of some goods seems to be very hard. With reference to new technologies, the risks and benefits are not completely known and are too uncertain to be possible to evaluate them under a cost-benefit analysis. As mentioned previously, it is especially difficult to quantify long-term risks, as that would need a discount which is not morally acceptable (for example, discounting the value of future lives)<sup>378</sup>. So, although the importance of weighing benefits and risks should not be underestimated, the centrality given to the economical analysis appears sometimes problematical and not

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<sup>378</sup> D.A. KYSAR, *Climate Change, Cultural Transformation, and Comprehensive Rationality*, in *B.C. Environmental Affairs Law Review*, 31, 555, 2004, p. 578.



working. It should also be considered that some goods, such as the environment or life or health are valued in different ways, according to the different perceptions<sup>379</sup>. In addition, it could be specified that, for example in synthetic biology, the possible applications are heterogeneous and numerous, so that such economic analysis should be conducted in a differentiated way, according to any single application, «*thus overwhelming available risk management resources*»<sup>380</sup>.

#### 5.4.1. *The Application of the Proactionary Principle.*

Since the proactionary principle has been elaborated only in recent years at the philosophical level, at present its application in statutory regulations and its reference in case-law is not visible.

However, the approach followed by W.T.O. Appellate Body at the international level and by U.S. Supreme Court and U.S. legislation appear, in some cases, very close to the proactionary approach, despite proaction is not mentioned explicitly as a principle. In the U.S.A., in particular, the fears for introduction of new technologies are less than in Europe, where the P.P. shows a meaningful role. So, in general, the approach that is followed in the U.S.A. is more a proactionary than a precautionary one. Moreover, when the different Courts (for example, the Italian Constitutional Courts) make references to the principle of proportionality and to the one of reasonableness to evaluate the legislator's choice in cases of scientific uncertainty, they show to adopt a sort of proactionary approach, whereby new developments should be considered safe unless and until proven otherwise.

With respect to the application of the proactionary approach, therefore, I refer to most of the considerations that I formulated in the subsection about C.B.A..

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<sup>379</sup> C.R. SUNSTEIN, *Laws Of Fear*, cit., p. 131.

<sup>380</sup> G.E. MARCHANT, D.J. SYLVESTER, K.W. ABBOTT, *Risk Management Principles for Nanotechnology*, at <http://www.law.upenn.edu/academics/institutes/regulation/papers/MarchantRiskManagementPrinciples.pdf>, p. 5 (last visited 28<sup>th</sup> January 2013).

6. *The “Risk and Concern Communication” within Synthetic Biology.*

After the long excursus concerning the possible solutions that have been adopted so far in the phase of “risk management”, the last phase of the traditional model to be examined is the phase of “risk communication”.

In my view, this phase should also be grounded on “*prudent vigilance*”. In particular, the stakeholders should opt for a joined process between themselves and establish a regular control of the state of technology through the continuous communication between actors and recipients of synthetic biology, so that to generate legitimacy and accountability of new technologies, and, among the society, a trust towards them.

Therefore, it is useful to implement in any phase of risk governance «*a series of interactions among scientists, professionals and engineers developing the technology, policymakers and regulators involved, either in promoting science and innovation, or in regulating its products; and citizens and advocacy groups with concerns, either positive or negative, about the implications of the technology concerned*»<sup>381</sup>.

So, the communication is in reality not the last and final phase of the process, but an ongoing procedure that connotes the analysis since the beginning. Indeed, only through the progressive exchange of data, coordination, feedback from the all stakeholders involved a “good” analysis of risks and concerns of synthetic biology could be conducted. A “good” risk and concern communication determines a “good” diffusion of science and technology. The divulgation of scientific and technological progress is part of an ambitious project of social cooperation, oriented in promoting a general access to knowledge and culture. If pursued in a responsible way, it can avoid situations of hostility towards new technologies by public, due to a lack of information (cognitive deficit) and/or to a wrong perception of risks, because of the weakness of mechanisms of social control of technologies, supervision and reports of accidents.

Some mistakes arising from the means of communication may alter public perception. For example, a wrongly transmitted message that is too much simplified

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<sup>381</sup> See IRGC, *Risk Governance for Synthetic Biology*, Geneva, 2009, p. 16.

or too much focused on irrational fears or emotional aspects could determine the social refusal of a new technology. So, it is necessary that the networks of communication avoid distortions, irrationalities and ideological falls, through the mechanisms of social transparency, and the involvement of stakeholders in participating to debates about risks and conflicts of values with respect to a new technology, such as synthetic biology.

In a nutshell, such “risk and concern communication” phase, if based on the ongoing interaction with all the stakeholders, shows the importance of the “democratization” of access to scientific progress, and it is the most suitable way to escape from any kind of ignorance, fanaticism, dogmatism and superstition as pertaining to new technologies.

#### *7. Summarising: the Suitable Model of Governance of Synthetic Biology.*

As it has been established thus far, and summarising what has been said, in the face of physical risks and non-physical concerns, the most rational approach to adopt in the context of synthetic biology appears to be the one of “*prudent vigilance*”.

It gives attention to both the categories, i.e. it does not neglect the relevance of social, ethical, legal, environmental and political values that are usually avoided by cost-benefit and risk-benefit analysis. It provides to start from an assessment of both concerns and benefits of synthetic biology, thus assembling all the possible knowledge through a constant research that is an ongoing and periodically revised process, to be conducted by taking into account the interests of all potentially “victims” of risks and by involving public society and private companies, in accordance with a «*network of interests*»<sup>382</sup>. Indeed, it is relevant to take into consideration all the stakeholders in a democratic, open and transparent manner such as for the weak precautionary principle or the procedural version of it or the proactionary principle. Therefore, the comprehension of concerns should be

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<sup>382</sup> M.A. EISNER, *Institutional Evolution or Intelligent Design? Constructing a Regulation for Nanotechnology*, in C.J. BOSSO (ED.), *Governing Uncertainty: Environmental Regulation in the Age of Nanotechnology*, Washington, D.C., London, 2010.

discussed both within enterprises and into a public forum accessible to everyone, in the name of a culture of dialogue and exchange with public opinion, as controlling the consequences of scientific and technological progress cannot be the sole concern of economic players or associations. Moreover, the assessment cannot avoid the ancillary benefits or risks that are not taken into consideration by the risk trade-off analysis, trying to offer a whole and integral vision of the situation and possible outcomes when deciding about whether introducing or not a new technology. So, the approach is a proactionary one, in the sense of being proactionary with reference to research about the risks and in the search for an adequate management of them.

With respect to the management, “*prudent vigilance*” entails a dynamic, iterative, cooperative, reflexive and incremental approach<sup>383</sup> in the decision-making process. Such approach shows, then, the option for a proportional set of actions, i.e. actions that could be proportional to the potential harms, with the consideration of positive and negative consequences and with an assessment of the implications of both action and inaction. Therefore, “appropriateness” is linked to the principle of proportionality that helps to balance different interests at stake (such as freedom of research and public security reasons), so as to find an equilibrium between means and aims, and choosing the necessary measures for dealing with risks in the respect of human dignity, right to environment, individual liberties. Such a proportionality corresponds to «*the famous toxicology admonition of Paracelsus: the dose makes the poison*»<sup>384</sup>, thus a measure implemented at a certain level is not negative, and not excessive. The proportionality principle reminds us of the weak version of the precautionary principle and, moreover, it is the underlying concept for cost-benefit analysis.

With regards to the phase of risk and concern communication, the model suggests a continuous involvement of all stakeholders along all the phases.

Analysing the aspects of the relationship among “*prudent vigilance*” and the other models of governance with risks, it emerges that C.B.A. is not denied, but it is elaborated in a comprehensive sense, thus without dismissing some elements in the

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<sup>383</sup> See, for example, L. PADDOCK, *Keeping pace with nanotechnology: a proposal for a new approach to environmental accountability*, in *Environmental Law Reporter*, 36, 2006, p. 10943-10952.

<sup>384</sup> C. STARR, *Being Cautious About Precautionary Principle*, in *Electric Perspectives*, November/December 2003, p. 56-62.

understanding of the whole situation (including all the primary and secondary benefits, risks, costs of risks, costs for mitigating or regulating the risks, costs for inaction). Instead, the appeal to cost-benefit analysis is excluded, if some non-economic and non marketable values are at stake, or at least C.B.A. should be integrated with the attention upon ethical, legal, environmental, political and social issues<sup>385</sup>. Furthermore, «*when particular products pose theoretical risks but not empirically-established ones; when any adverse effects would likely occur only in the relatively distant future; and when the link between the product and any distant adverse effects could well escape notice, or at least be difficult to establish as a matter of “but for” causation*»<sup>386</sup>, so when calculations are not possible, thus in such cases the precautionary measures (in a weak sense) may come at stake and can «*correct an imbalance between our perception of the costs of regulatory action and our understanding and consideration of the costs of regulatory inaction*»<sup>387</sup>. These measures must be intended as an intervention in advance towards some risks, by taking into account the social, ethical, political, legal, environmental values at stake, by balancing interests and rights, and by choosing, however, provisional measures that can vary in future at the light of new scientific discoveries.

The framing of “*prudent vigilance*” also deals with the vagueness problems of the precautionary principle. First of all, it does not put into contrast the traditional risk analysis with the precautionary one. Instead, Charnley, the then president of the Society for Risk Analysis, declared in 1999: «*the precautionary principle is threatening to take the place of risk analysis as the basis for regulatory decision making in a number of places, particularly in Europe*»<sup>388</sup>, by underling that risk analysis is «*threatened by a serious, growing, antirisk-analysis sentiment that is challenging the legitimacy of science in general and risk analysis in particular [...]. And what is it being replaced with? The so-called precautionary principle or the*

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<sup>385</sup> This approach is defined E3LS approach by Calgary Igem Group (see [http://2008.igem.org/Team:Calgary\\_Ethics](http://2008.igem.org/Team:Calgary_Ethics), last visited 28<sup>th</sup> January 2013).

<sup>386</sup> D.A. DANA, *The Contextual Rationality of the Precautionary Principle*, in *Northwestern University School of Law, Northwestern University School of Law Scholarly Commons, Faculty Working Papers*, Paper 195, 2009, at <http://scholarlycommons.law.northwestern.edu/facultyworkingpapers/195>, p. 19 (last visited 28<sup>th</sup> January 2013).

<sup>387</sup> *Ibid.*, p. 33.

<sup>388</sup> G. CHARLNEY, *President’s message*, in *RISK Newsletter*, 19, 2, 1999.

“*better-safe-than-sorry*” approach<sup>389</sup>. With this view, risk analysis - the practice of using science to draw conclusions about the likelihood that something harmful will happen - is put into opposition with the precautionary approach, since the latter cannot find an agreement with a scientific approach to risk assessment and risk management.

In response to this criticism, the approach suggested by the U.S. Presidential Commission makes the precaution work within the pattern of the traditional risk assessment, management and communication. The path does not consist of adopting the rigid and strict strong P.P. that leads nowhere, or the one at stake in cases of mere hypothetical risks. It also does not adopt the one asking for whatever scientific basis in the risk assessment phase for justifying the introduction of precautionary measures in the risk management context. This is because the “strong” version of P.P., as seen, would lead to the complete block of research. Moreover, the mere suspect of risk (even not scientifically grounded) for legitimising the adoption of precautionary measures would lead to a general stagnation of activities, and, thirdly, even the necessity of anchoring the P.P. to a scientific basis (enucleated in the risk assessment phase that demonstrates the existence of risk in a scientific way) could have problematic facets. As a matter of fact, giving prevalence to science and affirming that whatever scientific opinion that shows the existence of risk is sufficient for triggering the application of P.P. means to give science a preeminent role over the policy phase (so using P.P. as an instrument for de-politicization). On the contrary, it could push policy makers to look for scientific basis (a minority one as well) in order to found whatever political choice, and in this case P.P. would mould as a mere political instrument, and as an means for justifying whatever decision that needed to be made.

In order to avoid all these problematic issues, the “*prudent vigilance*” shapes P.P. as a “guideline”, as a criterion of method rather than as a strict and rigid principle. P.P. ought to be used in a flexible way, admitting calculations, flexibility, ongoing research, so as to adopt measures that are grounded on the scientific knowledge of risks but without forgetting the economic, social, political, ethical aspects (so that the scientific paradigm is not the dominant one). These measures are

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<sup>389</sup> G. CHARLNEY, 1999 *Annual meeting: Past President’s message: risk analysis under fire*, in *RISK Newsletter* 20, 3, 2000.

also periodically revised and modified, if required by the new development of science and by other non-scientific instances, and are in line with suitability and proportionality principles.

So, the “*prudent vigilance*” model seeks to “throw a bridge” between a science that is uncertain and incomplete and a law that is called upon to regulate situations of risk itself and is uncertain at the same time. Thus the model poses itself at the border of scientific evaluation and political-discretionary choices. It considers all the approaches as integrated and complementary to one another. The result consists of the adoption of a framework of governance that could really be able to pursue the innovation and progress of science and technology without prejudicing the protection, the safety, the security, the values of people, the environment, and the society.

Certainly, a certain level of vagueness about what measures to adopt still remains and the risk of dependence upon the decisions and conclusions reached by the majority (in a democratic sense) – so that to meet a «*dictatorship of the majority*», as Tocqueville stated<sup>390</sup> - is a tangible one. In order to anchor the decisions about how to tackle risks that arise from new technologies, the following means are required to be followed: (a) referring to scientific and numerical data when possible (even if those data are, by definition, never complete and full, and are subject to continuous revision), thus avoiding to make the fears and irrationalities prevail, (b) looking for a balance between concerns, benefits, interests, values and rights, (c) taking into account non-quantifiable aspects such as legal, social, ethical, political issues (so that scientific paradigm is not the prevalent one), and (d) involving all the stakeholders in the field. All these means can represent a rational “antibody” to the criticism of vagueness and majority domain, that, however, any decision tool shows. They can also be a valid “antibody” to the risk that the pre-eminence of the scientific paradigm could eliminate some actors from intervening, by making prevail the sole scientific community.

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<sup>390</sup> See A. DE TOCQUEVILLE, *Democracy in America* (1835-1840), New York, 2000.

*PART II: WHO SHOULD BE IN CHARGE OF ADOPTING THE CHOSEN MODEL OF GOVERNANCE, AND IN WHICH WAY?*

After showing that, in my opinion, the best way to approach the risks and concerns of synthetic biology is based on “*prudent vigilance*”, the question which then arises is about who should have to apply such a model and in which way.

The problem is about actors and sources of law.

With regards to the subject called upon for the production of rules and policies in line with the “*prudent vigilance*” model, the alternatives could be:

(1) the legislator (or government in a broad sense) that should enforce to “*prudent vigilance*” and adopt such a perspective while regulating synthetic biology, i.e. enacting regulations that demonstrate this approach (“top down” and “hard law” source);

(2) the scientific community and its professional bodies, giving themselves their own set of rules (“bottom up” and “soft law” source).

Moreover, the questions that originate here are (a) whether the regulatory instruments (hard law and soft law) are mutually exclusive, or (b) can these regulatory instruments integrate each other or (c) whether one prevails and the other is residual and subsidiary.

Thus, if the “hard law” model is the prevalent regulatory means, a closed system emerges and no other actor but the legislator appears as the competent one to intervene in the regulation matter with the statutory source.

However, in the hypothesis that “hard law” is not the proper mode to follow, the involvement of other actors than the legislator and the usage of other sources of law than statutes emerge.

Beyond considering the “pure” top down and bottom up approaches as mutually exclusive, there is a “hybrid or mixed model” characterised by the engagement of many actors (stakeholders and the public too) and the mixture or integration of different sources.

The table below summarizes the options with regards to the decision-making process.



<b>ACTORS</b>	<b>INSTRUMENTS FOR ACHIEVING POLICY</b>
Top down (government)	Hard law
Bottom up (scientific community)	Soft law
Hybrid or mixed model	Engagement approach and mixture of sources

Then, with reference to the role of enforcement, oversight, control (and eventual sanctioning) of the rules, this role could be conferred to<sup>391</sup>:

- (1) judges through case-law, in which they concretely realize a balance of rights;
- (2) governmental agencies;
- (3) an independent and professional body (such as a body of representatives of scientific community);
- (4) a multi-stakeholders' body including ethical, scientific, government, social components (such as ethical and bioethical committees).

Also in this ambit of enforcement, oversight, control and sanctioning of rules, the three aforementioned subjects could be considered (a) as mutually exclusive, or (b) integrating each other.

The table below summarizes the options for the enforcement, oversight and control phase.

<b>ACTORS</b>	<b>INSTRUMENTS FOR EXERCISING ENFORCEMENT, OVERSIGHT, AND CONTROL</b>
Judges	Case law
Governmental Agencies	Administrative law
Independent and Professional Body	Autonomous set of measures
Multi-stakeholders' Body	Autonomous set of measures
Hybrid or mixed model	Integration of all the mechanisms

As per the organization of discussion in part I, the organization of this II section will start by showing which model could be the best one, and then compare it with other solutions that have been suggested for dealing with risks and concerns of synthetic biology.

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<sup>391</sup> See, for some of the suggested alternatives, the model proposed by Penasa (S. PENASA, *The Need for a Procedural Approach to Human Embryonic Stem Cell Research: An Emerging Regulatory Model within EU*, in *Dilemata*, n. 7, 2011, p. 39-55).

## 8. The “Prudent Vigilance” and Decision-Making Process.

### 8.1. The Shift from “Government” to “Governance”.

As formulated in the previous section, the most suitable model for tackling with synthetic biology is the one governed by “*prudent vigilance*”. This approach shapes the “actors” and “sources of law” issues as well. Indeed, the “*prudent vigilance*” model leads to opt for a governance in which “hard law” and “soft law” are not one opposite to each other, but rather they integrate reciprocally. The actors are not only the institutions, but they include the scientific community, the stakeholders and the general public who are also involved in the “engagement” approach.

Traditionally, the role of regulation and of choosing or adopting of a policy is associated with the “government” in a large sense. This means that «*the official institutions for governing*»<sup>392</sup> use the traditional source of “hard law” (binding legislative source). The increase of uncertainty, risks and concerns in the new emerging technologies have brought to alter the traditional landscape. In this sense, the contribution of S.T.S. studies (Science, Technology and Society studies)<sup>393</sup> is a meaningful one. In fact, since the growth of science and technology pervades society, a new concept of “law” that takes into account the social requests and that does not limit itself to institutions is needed. The law cannot simply be a system of norms with technical contents, or the fruit of political determinations and deliberative processes, made out by political bodies that enact a regulation, approve it and make it binding. The law has to tackle with the uncertainties, emerging from the intersection

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<sup>392</sup> H. SHIROYAMA, *Governance of Science and Technology. Innovation and Society*, paper prepared for the IIPS Symposium on Globalization and Japan’s Science and Technology Strategy, 2007, at <http://www.iips.org/07tech/07techShiroyama.pdf> (last visited 28<sup>th</sup> January 2013).

<sup>393</sup> STS studies are, in brief, the study of how social, political, and cultural values affect science and technology, and how these, vice versa, affect society, politics and culture. The main representatives of this area are MacKenzie and Wajcman (D. MACKENZIE, J. WAJCMAN (EDS.), *The Social Shaping of Technology: How the Refrigerator Got Its Hum, Milton Keynes*, New York, 1999), Bijker, Hughes and Pinch (W. BIJKER, T. HUGHES, T. PINCH (EDS.), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology*, Cambridge, M.A., London, 1987), Fuller (S. FULLER, *Philosophy, rhetoric, and the end of knowledge: The coming of science and technology studies*. Madison, WI, 1993). See also S. JASANOFF, G. MARKLE, J. PETERSEN, T. PINCH (EDS.), *Handbook of Science and Technology Studies*, Thousand Oaks, C.A., 1994.

and interaction among different actors and stakeholders, such as the scientific community and the public.

The concept of “governance” should not be seen as being opposite to “government”, i.e. to be «*understood as encompassing a wide range of systems - including the customs of society and markets – that are outside the official institutions of government*», thus referred to «*the whole range of institutions and relationships involved in the process of governing, [and] self-organising, inter-organizational networks*»<sup>394</sup>. Under this perspective “government” and “governance” are opposing forces, since the former refers to a hierarchical and vertical structure, while the latter admits horizontal and multi-stakeholders’ involvement, and must be connected to the growing incapacity of the State to respond to dynamic processes of policy making<sup>395</sup>.

In my opinion, and in line with Caporaso, I believe that it is preferable not to see “government” and “governance” as opposing terms. Instead, we should conceive the latter as «*the process of governing; collective problem solving in the public realm*»<sup>396</sup>, i.e. intending it as a broad category<sup>397</sup>, a continuum that goes from hierarchy, to co-governance, to self-governance<sup>398</sup>, including even the government option, as one of the possible options for governing new technologies, together with other social structures such as markets, communities, networks that coordinate in a non-hierarchical way. However, trying to combine the two views of governance, it could be said that a narrow notion of governance refers to just the non-hierarchical coordination between public and private actors, on the one hand, and among private actors only, on the other, in the setting and implementation of norms and rules for the

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<sup>394</sup> R.A.W. RHODES, *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability*, Buckingham, 1997. See also R.A.W. RHODES, *The New Governance: Governing Without Government*, in *Political Studies*, 1996, XLIV, p. 652–667.

<sup>395</sup> In line with this view, see Schmitter: «*Governance can be defined as an arrangement for making binding decisions that engages a multiplicity of politically independent but otherwise interdependent actors – private and public - at different levels of territorial aggregation in more or less continuous negotiation/deliberation implementation [...] that does not assert a stable hierarchy of political authority to any of these levels*» (P. SCHMITTER, *Neo-functionalism*, in A. WIENER, T. DIEZ (EDS.), *European Integration Theory*, Oxford, 1994, p. 49).

<sup>396</sup> J. CAPORASO, *The EU and forms of state*, in *Journal of Common Market Studies*, 34, 1, 1996, p. 32.

<sup>397</sup> F.W. SCHARPF, *Games real actors could play: positive and negative coordination in embedded negotiations*, in *Journal of Theoretical Politics*, 6, 1994, p. 27-53.

<sup>398</sup> G. MARKS, F.W. SCHARPF, P. SCHMITTER, W. STREEK, *Governance in the European Union*, London, 1996.

provision of public goods and services, while a broad governance includes different ways of acting (institutional and non).

The concept of governance<sup>399</sup> reshapes and redesigns the relationship between the State and citizens. The social contract that marked the beginning of our society according to Thomas Hobbes and others is completely rebuilt, as the State is pushed to involve citizens in scientific decisions, to create (and try to maintain) a public trust about science and technology, to keep the citizens informed about the evolution of new technologies, and to cooperate with stakeholders<sup>400</sup>.

In conclusion, the model of “*prudent vigilance*” opts for the mentioned broad notion of governance, so as to produce a new model entailing a more collaborative, flexible, multi-stakeholder regulatory process and development, that makes the respective “top down” and “bottom up” procedures coexist. Hence, there is an active mobilization of the public in science risk assessment, risk management and communication, and political actors «*no longer refer to top down decision-making. Instead [...] they are talking about interdependence, networks and partnerships*»<sup>401</sup>.

## 8.2. The “Regulatory Parsimony” and “Democratic Deliberation”.

Two of the subprinciples of the “*prudent vigilance*” model explained by the US Presidential Commission must be quoted now with respect to the “actors” and “source of law” issues.

In particular, as a corollary to the principle of “*intellectual freedom and responsibility*”, the Commission endorsed a principle of “*regulatory parsimony*”, recommending only as much oversight as is truly necessary to ensure justice, fairness, security, and safety while pursuing the public good. This is meant to be a sort of “compromise” among the temptation to enact lot of rules to stifle innovation on the

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<sup>399</sup> It is used in an economic and managerial sense, or a political one (such as in this context) to mean a new way of intending “democracy”, in particular in reference to the relationship among science, law and society (see M.C. TALLACCHINI, *Democrazia come terapia: la governance tra medicina e società*, in *Notizie di POLITEIA*, XXII, 81, 2006, p. 15-26).

<sup>400</sup> See M.C. TALLACCHINI, *Politica della scienza e diritto: epistemologia dell'identità europea*, in M.C. TALLACCHINI, R. DOUBLEDAY (EDS.), Introduction to *Notizie di POLITEIA. Politica della scienza e diritto. Il rapporto tra istituzioni, esperti e pubblico nelle biotecnologie*, n. 62, 2001.

<sup>401</sup> F. MALI, *Bringing converging technologies closer to civil society: the role of the precautionary principle*, in *Innovation. The European Journal of Social Science Research*, 22, 1, March 2009, p. 57.

basis of uncertainty and fear of the unknown, and the “laissez faire” approach. Indeed, statutory means may inhibit the distribution of new benefits, and be counterproductive to security and safety by preventing researchers from developing effective safeguards. However, a total freedom of action, avoiding any kind of regulation can be negative and entail many more risks and problems than what it currently possesses.

In addition, the principle of “*democratic deliberation*” should be mentioned. It expresses «*an approach to collaborative decision-making that embraces respectful debate of opposing views and active participation by citizens. It calls for individuals and their representatives to work toward agreement whenever possible and to maintain mutual respect when it is not*»<sup>402</sup>. At the core of the democratic deliberation is an ongoing, public exchange of ideas, a process of active deliberation, the promotion of debate, thus encouraging participants to adopt a societal perspective over individual interests.

This principle must be implemented in the assessment phase of emerging technologies, since the gathering together of the different actors and stakeholders allows the understanding of all the possible benefits to science and society, coupled with the comprehension of concerns and risks and the discovery of what *kinds* of remedies are thereby triggered.

In view of the uncertainty, the ongoing review of science, the broad engagement and the open and well-informed dialogue among the scientific community, policy-makers, and the citizenry are useful for fostering progress, without forgetting the attention to the possible risks<sup>403</sup>. In absence of this, public support would lack and the knowledge about the whole benefit landscape, the interests at stake, and the concerns would be incomplete.

So, «*the emergent stage, in particular, with a high degree of uncertainty and a low degree of attachment to a status quo, can present a unique opportunity to bring*

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<sup>402</sup> A. GUTMANN, *The Ethics of Synthetic Biology: Guiding Principles for Emerging Technologies*, in *Hastings Center Report*, 41, 4, 2011, p. 19.

<sup>403</sup> With regards to the necessity of involving the public in the construction of rules for new technologies, see A. IRWIN, *Constructing the scientific citizen: science and democracy in the biosciences*, in *Public Understanding of Science*, 10, 2001, p. 1–18.

*together diverse stakeholders to produce a collaborative governance system rather than a resource draining adversarial battle»<sup>404</sup>.*

The same view of the U.S. Presidential Commission is shared by the European Union. Since 2000<sup>405</sup> there underlines the necessity for the public authorities to ensure the plurality of perspectives, the intervention of scientific experts, the involvement of stakeholders and public in the evaluation and management of risks and concerns of new technologies, in the light of a “responsible science”. So, U.S. and E.U. go forward in the same direction, opting for a model where scientific expertise and citizens work together for the governance of science. Thus a redistribution of powers, knowledge and roles occurs.

### *8.3. The “Prudent Vigilance” between Actors and Sources of Law (in the Decision-Making Process).*

The ongoing process of attention towards synthetic biology requires a lot of the actors to be involved and the integration among different sources of law.

This section offers a summary and the reframing of the previous observations:

(1) the “hard law” enacted by the legislator that must operate according to a regulatory parsimony. Such a legislator can work at the international, national, European level. It is useful to consider that, since the field of synthetic biology is an international enterprise that has global effects, an international (i.e. national and transnational) coordination is required. Some authors suggest the assignment of a regulatory role to an international body, composed of leading scientists in the field of synthetic biology in addition to an ethical, industrial and governmental component. Thus, a legislator would become an heterogeneous subject that could really represent the interests of all<sup>406</sup>.

Such legislator (i.e. institutional bodies) should be responsible in the giving of the general rules and principles, and in building them, the intervention of technical

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<sup>404</sup> G. MANDEL, *op. cit.*, p. 76.

<sup>405</sup> See the COMMISSION OF THE EUROPEAN COMMUNITIES, *Plan Science and Society*, 2001, and *European Governance. A White Paper* (COM(2001) 428 final).

<sup>406</sup> J. ANDERSON, N. STRELKOWA, G-B. STAN, T. DOUGLAS, J. SAVULESCU, M. BARAHONA, A. PAPACHRISTODOULOU, *op. cit.*, p. 589.

bodies, stakeholders and experts is desirable (those involved in the “engagement approach”). Indeed, the legislator should take into account all the needs of the involved parties and the scientific elements at stake. Thus, the law must recognise the expertise role in the decision-making process, as underlined by Italian Constitutional Court<sup>407</sup>. The experts’ opinions have a binding force within the legislative process, and they can also enjoy a “reserved competence” in determining scientific content of some activities.

(2) the “soft law”, meant as the standards of behaviour, the *«legal tools working on the basis of voluntary compliance and not supported by legally institutionalized sanctions»*<sup>408</sup>. This group includes *«(a) declarations and opinions worked out by governmental and non-governmental organizations or by national, supranational, and international institutions; (b) technical regulation based on standards or self-regulation, such as codes of conduct or audit systems (voluntary self-regulation) and (c) private regulations enforced by the government (enforced self-regulation)»*<sup>409</sup>.

In particular, the professional ethics codes or codes of conduct by technical bodies assume a meaningful role. Their codes represent a deontological source of law, protect fundamental rights, and can also *«allow the delicate and difficult passage from ethical to legal discourse»*<sup>410</sup>, with an elasticity and capability of adaptation to the evolution of science and society.

Casonato states that such a source of law is partially conventional, in the sense that it is the result of a codification by professional orders (such as biologists), or it could be understood as a customary law, being binding for the category and seen as a due behaviour to follow. So, this is not only a set of rules for the protection of the category, but a legal – not legislative - source that can integrate the legislative source<sup>411</sup>.

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<sup>407</sup> See decisions 185/1998; 188/2000; 282/2002; 159/2009.

<sup>408</sup> E. PARIOTTI, *Law, Uncertainty And Emerging Technologies. Towards a Constructive Implementation of the Precautionary Principle in the Case of Nanotechnologies*, in *Persona y Derecho*, 62, 2010, p. 24.

<sup>409</sup> See I. AYRES, J. BRAITHWAITE, *Responsive Regulation: Transcending the Deregulation Debate*, New York, 1992, p. 103 ff.

<sup>410</sup> E. QUADRI, *Il codice deontologico medico ed i rapporti tra etica e diritto*, in *Responsabilità civile e previdenza*, 2002, p. 925 ff.

<sup>411</sup> C. CASONATO, *Introduzione al biodiritto*, Torino, 2012, p. 145 ff.

In a few words, near the typical “hard law” or “command-and-control regulation” (that, however, is produced not by the mere institutional bodies, but with integration of stakeholders and experts), the “soft law” source is a relevant one for fostering «*the distribution of responsibility and to promote stakeholders’ participation*»<sup>412</sup>. Although contested by some authors that claim that “soft law” fragments legal sources and erode legal rationality<sup>413</sup>, in my view they show a close link between law and society and express the overcome of the formalistic view of law: indeed, “soft law” looks for compliance and more acceptability by the whole society, thus expressing a new view of “law”.

In a nutshell, the “*prudent vigilance*” approach should be applied through a mix of “hard” and “soft law” that can own the flexibility and dynamism to manage the potentialities and concerns of emerging technologies, such as synthetic biology.

#### 9. The “*Prudent Vigilance*” Policy and its Enforcement, Oversight, and Control.

With regards to the phase of the enforcement, oversight and control of the mentioned “*prudent vigilance*” policy, the most preferable solution seems to be the one that involves judges, government bodies, professional independent bodies, and a body which assembles different components of society. So, the preference goes for the integration of the four subjects, which operate with case-law, administrative rules, and the autonomous set of rules enacted on the basis of “soft-law”.

The role of judges should never be under evaluated, as they do not simply “state” and “apply” the law (as they are conceived in a Enlightenment view), but interpret the norms, even filling the gap left empty by legislators with their rulings in a “creative” way. The judges are the recipients of the needs of society and have a meaningful role in balancing rights, interests and values at stake. Indeed, «*the judge lives in the society which is by nature an entity that continuously evolves, [...] that transforms every day, [...] realising what has been defined as the perennial evolution*

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<sup>412</sup> E. PARIOTTI, *op. cit.*, p. 25.

<sup>413</sup> See J. KLABBERS, *The Undesiderability of Soft Law*, in *Nordic Journal of International Law*, 67, 1998, p. 381-391.



of costumes»<sup>414</sup>. So, the judicial decisions are the seat for “legalising” values and principles promoted by social conscience, answering scientific evolution and circumstances of the case<sup>415</sup>. The U.S. and the U.K. Courts have been the first ones to claim a role of “gate keeping”<sup>416</sup> towards science and to deal with scientific knowledge by stating that they could evaluate scientific data.

Governmental bodies (such as agencies, delegated by the central government) which apply administrative rules cannot be forgotten as well.

Similarly, independent bodies where specialized and professional members sit can have a meaningful role. Indeed, these bodies are composed of people that have a specific competence in the field that could be delegated for controlling the members which belong to the same category. For example, scientific community can delegate to itself through a body of its representative people the role of controlling the activities that are pursued by scientists. In this case, the tools that such professional independent body could use for the oversight and control upon the members are autonomous measures. They should be based on codes of conduct or ethic codes, and deontological codes (“soft law”) that have been enacted in the ambit of the self-governance of the scientific community.

Moreover, the importance of the involvement of the public in the phase of enforcement and oversight as well (not only in the decision-making process) is at stake in the proposal of instituting a body which assembles people from all the different areas of the society, i.e. scientists, members of industrial and companies, ethicists, sociologists, religious people, lawyers, government agents, and so on. Such a body should represent the interests of everyone. In this way, the democratization of the phase of control could generate a sort of “social” control of new technologies. The public, through its representatives and through a multidisciplinary dialogue, could participate not only to the decisions as for the policies to take, but also to the enforcement of them.

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<sup>414</sup> Translation from R. LIVATINO, *Il piccolo giudice*, Palermo, 1992, p. 22.

<sup>415</sup> See, for example, C. CASONATO, L. BUSATTA, S. PENASA, C. PICIOCCHI, M. TOMASI, G. VACCARI, *Circolazione dei modelli e dialogo fra sistemi: le peculiarità del biodiritto*, 2012, at <http://www.jus.unitn.it/biodiritto/pubblicazioni/docs/PRIN%202006%20def.pdf> (last visited 28th June 2013).

<sup>416</sup> See decisions in the cases of *Frye v. United States* (Court of Appeals of District of Columbia 54 App. D.C. 46; 293 F. 1013; 1923 U.S.) and *Daubert v. Merrell Dow Pharmaceuticals Inc.*, 509 U.S. 579 (1993) in the U.S.A.; and *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118 and *Bolitho v City and Hackney Health Authority* (House of Lords, 13<sup>th</sup> November 1997) in U.K..

The same relevance of engagement of stakeholders and society (engagement that must be developed especially at the international level) is particularly stressed by I.R.G.C.<sup>417</sup>, according to which international dialogue has a role of regulatory oversight and is the key for diminishing the conflict among stakeholder groups, for controlling foreseeable risks, and for responding effectively to the emergence of unexpected risks. The stress is posed, indeed, on the coordination and collaboration among heterogeneous actors, such as scientists, policymakers and regulators, citizens and advocacy group, that work together for making a rigorous monitoring of the effects of decisions, in a dynamic governance system.

In a summary, the model of “*prudent vigilance*” entails the cooperation and the integration of all the different ways for exercising the control over the application and respect of the policies. Judges, government bodies, professional and multi-stakeholders’ bodies could altogether be called upon for the enforcement and oversight phase<sup>418</sup>. Thus, the “virtuous cycle” that gathers together institutions, judicial and government bodies, stakeholders, industries, and the public is the best way in applying a “*prudent vigilance*” policy, and is the «*ideal condition for facing with diffuse concerns*»<sup>419</sup> about emerging technologies, such as synthetic biology.

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<sup>417</sup> I.R.C.G., *Concept note: Synthetic Biology*, cit.

<sup>418</sup> For example, the U.S. Presidential Commission recommends the activities of ongoing and coordinated review of developments in synthetic biology to be carried out by the Office of Science and Technology Policy in the E.O.P. (Executive Office of the President), or the Emerging Technologies Interagency Policy Coordination Committee, in consultation with relevant federal agencies. These bodies are called for developing «*a clear, defined, and coordinated approach to synthetic biology research and development across the government*» (recommendation n. 4). Moreover, the E.O.P., through the Department of State and other relevant agencies such as the Department of Health and Human Services and the Department of Homeland Security, «*should continue and expand efforts to collaborate with international governments, the World Health Organization, and other appropriate parties, including international bioethics organizations, to promote ongoing dialogue about emerging technologies such as synthetic biology as the field progresses*» (recommendation n. 8). In recommendation n. 11, the government is charged with supporting a continued culture of individual and corporate responsibility and self-regulation by the research community, including institutional monitoring, and enhanced watchfulness; in addition, academic and private institutions, the public, the National Institutes of Health, and other federal funders of synthetic biology research should be engaged in this process.

<sup>419</sup> L. MARINI, *OGM, precauzione e coesistenza: verso un approccio (bio)politicamente corretto?*, in *Rivista giuridica dell’Ambiente*, 1, 2007, p. 1.

### 10. Other Models of Governance.

After presenting the model of governance that, in my opinion, should be the best model to adopt in the field of synthetic biology, it is of course prudent to review the other models that have been proposed to address the issue. Indeed, a lot of organizations (governmental and private) in Europe and in the U.S.A. have dealt with the topic of risks and governance within the area of synthetic biology by means of reports, publications and so forth.

The reports analysed (and ordered here in a chronological list) are as follow:

- “*Constructing Life. Early Social Reflections on the Emerging Field of Synthetic Biology*” (Rathenau Institute 2006)<sup>420</sup>;
- “*Extreme Genetic Engineering: An Introduction to Synthetic Biology*” (E.T.C. 2007)<sup>421</sup>;
- “*Synthetic Genomics. Options for Governance*” (A. Sloan Foundation, 2007)<sup>422</sup>;
- “*Synthetic Biology: Social and Ethical Challenges*” (The U.K. Biotechnology and Biological Sciences Research Council, B.B.S.R.C. 2008)<sup>423</sup>;
- “*Opinion on Ethics of Synthetic Biology*” (European Group of Ethics in Science and New Technologies, E.G.E. 2009)<sup>424</sup>;
- “*Biological Machines? Anticipating developments in synthetic biology*” (The Netherlands Commission on Genetic Modification COGEM 2009)<sup>425</sup>;
- “*Synthetic Biology: scope, applications and implications*” (The U.K. Royal Academy of Engineering 2009)<sup>426</sup>;

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<sup>420</sup> H. DE VRIEND, *op.cit.*

<sup>421</sup> E.T.C., *Extreme Genetic Engineering*, cit.

<sup>422</sup> M.S. GARFINKEL, D. ENDY, G.L. EPSTEIN, R.M. FRIEDMAN, *op.cit.*

<sup>423</sup> A. BALMER, P. MARTIN, *Synthetic Biology. Social and Ethical Challenges*, Nottingham, 2008, at [http://www.bbsrc.ac.uk/web/FILES/Reviews/0806\\_synthetic\\_biology.pdf](http://www.bbsrc.ac.uk/web/FILES/Reviews/0806_synthetic_biology.pdf) (last visited 28th January 2013).

<sup>424</sup> EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (EGE), *Opinion on Ethics of Synthetic Biology*, Opinion n. 25, 2009, at [http://ec.europa.eu/european\\_group\\_ethics/docs/opinion25\\_en.pdf](http://ec.europa.eu/european_group_ethics/docs/opinion25_en.pdf) (last visited 28th January 2013).

<sup>425</sup> NETHERLANDS COMMISSION ON GENETIC MODIFICATION (COGEM), *Biological Machines? Anticipating developments in synthetic biology*, COGEM Report CGM/080925-1, 2009, at <http://www.cogem.net/index.cfm/en/publications/publicatie/biological-machines-anticipating-developments-in-synthetic-biology> (last visited 28th January 2013).

<sup>426</sup> U.K. ROYAL ACADEMY OF ENGINEERING, *op. cit.*

- “*Synthetische Biologie*” (The German Research Foundation, the German Academy of Sciences and the German Academy of Engineering 2009)<sup>427</sup>;
- “*New life, old bottles. Regulating first-generation products of synthetic biology*” (Woodrow Wilson Centre 2009)<sup>428</sup>;
- “*Synthetische Biologie – Eine ethische-philosophische Analyse*” (The Swiss Commission of Ethics in Biotechnology 2009)<sup>429</sup>;
- “*The New Biomasters. Synthetic Biology and the Next Assault on Biodiversity and Livelihoods*” (E.T.C. 2010)<sup>430</sup>;
- “*Realising European potential in synthetic biology: scientific opportunities and good governance*” (European Academies Science Advisory Council (E.A.S.A.C.) 2010)<sup>431</sup>;
- “*La Biología Sintética*” (Comité de Bioética de España y del Conselho Nacional de Ética para as Ciências da Vida de Portugal 2011)<sup>432</sup>;
- “*The Principles for the Oversight of Synthetic Biology*” (Friends of the Earth, E.T.C., International Center for Technology Assessment and other 111 organizations 2012)<sup>433</sup>.

Before considering the different models of governance that they propose and trying to categorise them, it should be highlighted that some of the reports come from professional associations or academies (German Commission, I.R.G.C., E.A.S.A.C.,

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<sup>427</sup> DFG (DEUTSCHE FORSCHUNGSGEMEINSCHAFT), AKATECH (DEUTSCHE AKADEMIE FÜR TECHNIKWISSENSCHAFTEN), LEOPOLDINA (DEUTSCHE AKADEMIE DER NATURFORSCHER, NATIONALE AKADEMIE DER WISSENSCHAFTEN), *Synthetische Biologie. Stellungnahme*, Bonn, 2009, at [http://www.dfg.de/download/pdf/dfg\\_im\\_profil/reden\\_stellungnahmen/2009/stellungnahme\\_synthetische\\_biologie.pdf](http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2009/stellungnahme_synthetische_biologie.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>428</sup> WOODROW WILSON CENTRE, *New life, old bottles. Regulating first-generation products of synthetic biology*, 2<sup>nd</sup> March 2009, at [http://www.syntheticbiologyproject.org/process/assets/files/6319/nano\\_synthetic\\_biology2\\_electronic\\_final.pdf](http://www.syntheticbiologyproject.org/process/assets/files/6319/nano_synthetic_biology2_electronic_final.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>429</sup> J. BOLDT, O. MÜLLER, G. MAIO, *Synthetische Biologie – Eine ethisch-philosophische Analyse*, Bern, 2009.

<sup>430</sup> E.T.C., *The New Biomasters. Synthetic Biology and the Next Assault on Biodiversity and Livelihoods*, 2010, at [http://www.etcgroup.org/upload/publication/pdf\\_file/biomasters.pdf](http://www.etcgroup.org/upload/publication/pdf_file/biomasters.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>431</sup> EUROPEAN ACADEMIES SCIENCE ADVISORY COUNCIL (E.A.S.A.C.), *Realising European potential in synthetic biology: scientific opportunities and good governance*, December 2010, at <http://www.easac.eu> (last visited 28<sup>th</sup> January 2013).

<sup>432</sup> COMITÉ DE BIOÉTICA DE ESPAÑA Y DEL CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA DE PORTUGAL, *La biología sintética*, 2011, at [http://www.comitedebioetica.es/documentacion/docs/es/CBE-CNECV\\_Informe\\_Biologia\\_Sintetica\\_24112011.pdf](http://www.comitedebioetica.es/documentacion/docs/es/CBE-CNECV_Informe_Biologia_Sintetica_24112011.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>433</sup> FRIENDS OF THE EARTH, E.T.C., INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, ET AL., *The Principles for the Oversight of Synthetic Biology*, 2012, at <http://www.foe.org/news/blog/2012-03-global-coalition-calls-oversight-synthetic-biology> (last visited 28<sup>th</sup> January 2013).

Switzerland Commission), while others are commissioned by academies or advisory bodies (B.B.R.S.C.), others are published by independent advisory councils (E.G.E.).

For reasons of simplification, the possible models of governance mentioned above have been reclassified in the following categories<sup>434</sup>:

(1) preventative: policies that tend to block or ban the new technology without any sort of compromises;

(2) precautionous: policies that slow down the spread of technologies (according to strong or weak P.P.);

(3) promotional: based on the proactionary principle, these policies allow products to be launched into the market before prior assessment of risks, and just screened in order to check that they could not produce harms similar to the ones provoked by previous generations of products. The latter approach determines a reaction after the hazard has been showed empirically, i.e. in response to scientifically proven impacts.

### *10.1. Preventative Options.*

The category of preventative policy does exclude any intersecting with other possible categories of governance, since it simply provides that a new technology must be banned, being too risky and entailing serious harm.

The appeal for a ban of synthetic biology, at least for the current times, can be found in two reports: “*Extreme Genetic Engineering*”, and “*The New Biomasssters*” by the E.T.C. Group (Action Group on Erosion, Technology and Concentration). This is a Group settled in Canada which is «*dedicated to the conservation and sustainable advancement of cultural and ecological diversity and human rights*»<sup>435</sup>. With regards to synthetic biology, their view consists of perceiving it as an extreme form of genetic engineering that aims at manipulating, modifying and creating life rather than proceeding according to a model of “cut and paste”. Their approach asks that «*at a minimum - there must be an immediate ban on environmental release of de*

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<sup>434</sup> From R.L. PAARLBERG, *Governing the GM Crop Revolution: Policy Choices for Developing Countries. Food, Agriculture and the Environment Discussion Paper 33*, Washington, D.C., 2000.

<sup>435</sup> At <http://www.etcgroup.org/en/about> (last visited 28<sup>th</sup> January 2013).

*novo synthetic organisms until wide societal debate and strong governance are in place»*<sup>436</sup>. So, synthetic biology is considered a dangerous technology, a threat for human rights, biodiversity, global justice, and its applications must be banned for the moment. The E.T.C. focuses on biosafety, biosecurity, ethical, social and economic risks and applies to all of them a preventative policy, in particular suggesting:

- a broad societal debate about socio-ethical, economic implications of synthetic biology;
- a prohibition of release on environment of new synthetic organisms;
- the creation of an international body to assess the societal risks of synthetic biology;
- the I.P. rights to be restricted on the “building blocks of life”.

A preventative reference is visible in E.T.C. since 2006, when the Group strongly criticised the “SB 2.0” conference which adopted a declaration about self-governance of scientific community reminiscent of the historical Asilomar Conference in 1975 about recombinant DNA techniques (in which scientists agreed to impose a short-lived moratorium on some of their work)<sup>437</sup>. According to E.T.C., the Asilomar Conference and SB 2.0 are not places of responsible restraint by scientific community, but ways of pre-empting government oversight. So, in response to the SB 2.0, E.T.C. and other 38 civil society groups (included social justice advocates such as Third World Network, environmental groups such as Greenpeace International and Friends of the Earth, farm groups such as the Canadian National Farmers Union, bioweapons watchdogs such as The Sunshine Project, trade unions, such as the International Union of Food Workers, and science organisations, including the International Network of Engineers and Scientists for Global Responsibility) drafted an open letter<sup>438</sup> to the Conference attendants, in order to put aside any self-governance policy. However, the Conference quoted this policy among the others without excluding it. Subsequently, E.T.C. has insisted with the opposition against self-governance in the mentioned reports, recommending the need

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<sup>436</sup> E.T.C., *Extreme Genetic Engineering*, cit., p. 1.

<sup>437</sup> See P. BERG ET AL., *Potential Biohazards of Recombinant DNA Molecules*, in *Science*, 185, 4148, 1974, p. 303 ff.; P. BERG ET AL., *Summary Statement of the Asilomar Conference on Recombinant DNA*, in *Proceedings of the National Academy of Sciences of the U.S.A.*, 72, 6, 1975, p. 1981-1984.

<sup>438</sup> The text of the Open Letter is available at <http://www.etcgroup.org/en/materials/publications.html?id=8> (last visited 28<sup>th</sup> January 2013).

of a broad societal debate about synthetic biology at regional, national and international levels, and the interaction of scientists with the society in deciding what to do about synthetic biology according to a democratic process. The suggested governance is a strong one that asks for zero tolerance and prohibition of any dangerous product until proven harmless, even if the suspected risks are speculative and costs are high.

The concept has been recently reasserted in “*The Principles for the Oversight of Synthetic Biology*” (a declaration signed by 111 organizations from around the world and drafted especially through the initiative of Friends of the Earth, E.T.C., International Center for Technology Assessment, i.e. «*the first global declaration from civil society to outline principles that must be adopted to protect public health and our environment from the risks posed by synthetic biology*»<sup>439</sup>), in the part in which it is stated that there should be a ban on using synthetic biology to manipulate the human genome in any form, including the human microbiome.

### *10.2. Strong Precautionary Policies.*

This type of policies is founded on the strong version of the precautionary principle, and it consists of the statement of the need of an immediate action to prevent potential exposures to risks, until safety of the technology at stake is demonstrated. Strong precautionary policies usually result in being directly connected with a “top down” model of governance, since the action of the government (or authoritative bodies, external to the scientific community), through “hard law”, is required. However, the involvement of the society and stakeholders (“bottom up” approach) is not denied, even if they cannot have a decision and deliberative role, but rather only a consultative one.

This approach is opposite to self-regulation and “soft law” measures, which are considered as anti-democratic, diminishing transparency and not providing a proper protection of human rights, health, safety, security and the environment. Indeed, in this perspective there is the consideration that public society does not

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<sup>439</sup> FRIENDS OF THE EARTH, E.T.C., INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT, ET AL., *op.cit.*

accept the self-governance models so much, as the codes enacted by the scientific community give rise to doubts about the legitimacy and the credibility, as well as public trust. In particular, there are doubts as to whether the codes must be implemented by the scientific community itself or whether the public authorities should enact and monitor them. Problems about information, transparency and participation of the public are also directly connected.

The strong precautionary approach usually asks for a robust and mandatory regulatory regime, strong enforcement and liability mechanisms, and an ongoing monitoring for unintended consequences. In other words, strong regulations that should complement and strengthen, not replace, any other applicable or current regulation. These regulations should also be considered, in this view, as a framework for new biotechnology laws. Otherwise, in the waiting for rules and in absence of a specific set of them, it requires a declaration of a moratorium on the release and commercial use of synthetic organisms and their products to prevent direct or indirect harm to people and the environment. Such a vision is well expressed by “*The Principles for the Oversight of Synthetic Biology*”, where it is stated that «*standard forms of risk assessment and cost-benefit analyses relied on by current biotechnology regulatory approaches are inadequate to guarantee protection of the public and the environment. The Precautionary Principle is fundamental in protecting the public and our planet from the risks of synthetic biology and its products*»<sup>440</sup>.

A similar view is shared by the Swiss Commission, according to which a “step by step” approach must be taken, in the sense that the data about risks must be assumed progressively, in order to pursue a real risk assessment. However, in case of absence of such data and insufficient knowledge of risks, it is preferable not to act at all and stop research, since data are lacking to evaluate risks.

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<sup>440</sup> Ibid., p. 1.



### 10.3. Weak Precautionary Policies.

The weak precautionary approach appears as the most adopted one: indeed, lots of reports make reference to the weak precautionary principle as the most suitable one for tackling with the problems of synthetic biology. Thus, they do not avoid a balance between bad and good outcomes and the acceptability of minor risks (differently from strong precautionary principle). These reports are against positions that call upon for banning synthetic biology and against positions that consider synthetic products as unlikely to be risky, because of their being only lab products that could not survive outside and not cause any damage. Weak precautionary policies, instead, think that an external government regulation of synthetic biology together with public engagement that is in alternative, or at least in addition to self-governance, is the best solution. So, the weak approach opts for top down sources and public involvement, affirming that the governance by the mere scientific community is not sufficient.

However, within this group some differences are evident.

Some versions of the precautionary policy model are, in reality, very close and analogous to the “*prudent vigilance*” approach, providing the opportunity of an hybrid governance (top down and bottom up approaches). For instance, the German Commission, considers it necessary to draw up specific regulations (“top down” and “hard law”) pertaining to the establishment of additional rules relating to risk assessment, monitoring and controlling research and applications of synthetic biology. These regulations should be coupled with some self-governance rules by the scientific community (“soft law”), provided that such soft rules are conducted through establishing suitable interdisciplinary discussion platforms which enforce dialogue among society, thus promoting general acceptance of the new technology. As said previously, these aspects would be in line with the “*prudent vigilance*” approach, apart from the fact that the appeal to the precautionary principle is due in reference to situations of complexity and uncertainty, *«in cases for which proven methods of assessing the consequences of technology and risk analysis are not*

*applicable or if the expected consequences are associated with large uncertainties»<sup>441</sup>.*

The similar view is shared by the Report realised by Palmer and Martin and commissioned by B.B.R.S.C., where the proposal consists of a multi-level governance framework that suggests *«the establishment of new professional norms in the scientific community (e.g. codes of conduct concerning dual use technology), local and national research oversight, statutory regulation (e.g. new laws and formal regulatory agencies) and international co-operation and treaties»*. Thus it tries to find a balance between formal statutory regulation and self-regulation of the scientific community (“hard and soft law”), acting in an anticipated way. Indeed, the authors stress the importance of scientific community in taking *«a lead in debating the implications of their research and engaging with broader society around the issues raised by synthetic biology»<sup>442</sup>*, but without waiting for particular issues to arise, as this will be too late. Anticipatory interventions are essential, and they must be developed through a robust governance framework to be put in place before many of the applications of synthetic biology are realised. The Report asks for a thorough review of existing controls and regulations, and the development of new measures where needed.

The precautionary policy is sometimes considered as more suitable to be conducted through an engagement approach among stakeholders and society, but the engagement here is intended in a different way than in the proactionary approach. The engagement is invoked so as to inform the people of the development of research and try to slow the pace of progress. In fact, *«when advocates of the precautionary attitude call for «public engagement», they tend to mean allowing citizens to offer an upstream critique of science and technology»<sup>443</sup>*. The goal is to avoid repeating the mistakes of the past, with regards to technologies that were brought to market before their impact, risks and concerns had been carefully and

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<sup>441</sup> DFG (DEUTSCHE FORSCHUNGSGEMEINSCHAFT), AKATECH (DEUTSCHE AKADEMIE FÜR TECHNIKWISSENSCHAFTEN), LEOPOLDINA (DEUTSCHE AKADEMIE DER NATURFORSCHER, NATIONALE AKADEMIE DER WISSENSCHAFTEN), *op. cit.*, p. 61.

<sup>442</sup> A. BALMER, P. MARTIN, *op. cit.*, p. 30.

<sup>443</sup> D. GUSTON, D. SAREWITZ, *Real-Time Technology Assessment*, in *Technology in Society*, 24, 2002, p. 93-109.

democratically addressed<sup>444</sup>. Such an engagement could slow the progress, as said, but, on the other hand, it could influence the decisions about applications and research priorities, and test the taken policies. So, the “public engagement” becomes a type of governance, as highlighted in the Dutch COGEM Report, that talks of an interactive governance based on public debate. The preference goes for the precautionary principle in cases when «*the characteristics of a synthetic organism cannot be adequately assessed*»<sup>445</sup>, but it recognizes that the application of the principle may entail considerable costs. However, it seems that it is the most suitable policy to adopt for dealing with risks and for leading proper interventions, since it guarantees a high containment level of risks. According to COGEM, each party of society has a specific role and public engagement is particularly due, since it is «*an asset that can assist in the generation of well-developed, robustly debated and considered policy - rather than as a ‘box to tick’ or a public relations exercise to convince people to accept a new technology*»<sup>446</sup>. In particular, the government, beyond its regulatory role, should «*provide information, for example on the safety and economic aspects*»<sup>447</sup>, should intervene by adopting stimulus measures, such as research programmes and subsidies, and prepare a policy that takes into account the ethical and social issues raised by synthetic biology.

The U.K. Royal Academy of Engineering report also underlines the relevance of a the public engagement and stresses that, in tackling a new technology, scientists should focus on how their research is interconnected with the ethical and social issues, institutions are meant to be an intermediary among the scientists and the society, organizations and media must organize discussions about synthetic biology and spread information about it, citizens should be enrolled in an active role of discussion, the government should operate together with academies, scientists, engineers, civil society, organisations, by creating arenas of dialogue, exchange and exploration of ideas, so that to check that regulations are in line with public demands and needs, are consistent with the development of synthetic biology, and the public is constantly informed.

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<sup>444</sup> M.A. O’MALLEY, J. CALVERT, J. DUPRÉ, *The Study of Socioethical Issues in Systems Biology*, in *American Journal of Bioethics*, 7, 4, 2007, p. 67-78.

<sup>445</sup> COGEM, *op. cit.*, p. 18.

<sup>446</sup> *Ibid.*, p. 46.

<sup>447</sup> *Ibid.*, p. 6.

A similar engagement approach, together with top down intervention, is followed by the Report realised by Rathenau Institute and by Wilson Centre. Indeed, the first one makes reference to the involvement of all the stakeholders, the appeal not to neglect ethical and social issues, to integrate scientists with social scientists, politicians with the general public is provided, in order to reach a proper and balanced regulation of the matter. The second one believes that only a thoughtful engagement of all interested parties can frame a good system of governance of synthetic biology, without falling into the danger of the “Goldilocks dilemma”, dealing with finding the right and balanced regulation, i.e. neither the too precautionary one (which can lead to keep valuable new products off the market) nor the not precautionary enough (which could bring to the market that may cause unacceptable harm). So, the suggestion is not to over regulate nor under regulate, but to maximize benefits and minimize risks, and this can be achieved through involvement of stakeholders.

A precautionary policy that mixes hard and soft law, top down and bottom up decisions, and pushes for an engagement tool too is the one in the Opinion n. 25, enacted by the European Group on Ethics in Science and New Technologies, affiliated to the European Commission. It recognises that a governance model in synthetic biology is difficult to elaborate, since synthetic biology covers different fields and entails the interaction of numerous actors. According to the Group such a model *«should address several dimensions of synthetic biology policy and activities, such as: political level (monitoring research and safety issues); ethical level: (monitoring ethical criteria be properly implemented in each synthetic biology research sector); legal level (E.U. legislation and international legislation or regulation including clarification of grey areas); professional level (self-regulation and codes of conduct); scientific level (justification of expected scientific results, priority setting, resource allocation); institutional level (risks assessment; and implementing measures for risk management); societal level (public goods, citizens rights and liberties)»*<sup>448</sup>. Although the Group understands the difficulties of self-governance models and soft law rules, in the end it suggests to adopt a precautionary principle, through a *«review of the legislation applicable to synthetic biology*

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<sup>448</sup> EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES (E.G.E.), *op.cit.*, p. 36.

(*recommendation n. 13*), *involvement of stakeholders, guidelines for scientists, global collaboration*». So, the approach is a comprehensive one that chooses a precautionary principle, meant as a «*a dynamic tool to follow developments in a sector and continuously verify that the conditions for the acceptability of a given innovation are fulfilled*»<sup>449</sup>, and asks not to refrain from action, as this may also involve risks, but to carefully study and evaluate synthetic biology, through an impact assessment that includes both the risks and benefits of it. It means that a favourable assessment about a product before being authorized to be spread out should be made, and it is necessary to «*encourage scientific advances and uses of research which may [have] benefit[s] [...] and at the same time to safeguard it from misuse*»<sup>450</sup>.

The option chosen by E.G.E. shows that, «*while the positions of the EGE and the PCSBI [Presidential Commission for the Study of Bioethical Issues] might not be identical, they are not as different as it may appear at first glance. There is clearly room for transatlantic dialogue*»<sup>451</sup>.

Another weak precautionary approach that focuses especially on bottom up and engagement views is the one from the Spanish Bioethics Committee and the Portuguese National Ethics Council for the Life Sciences. The declaration denies that synthetic biology arises from completely new issues and proposes to follow the same pattern used for other emerging technologies, such as the reference to risk assessment and management that must be applied to dual use activities as well. This means that the activities should be subject to prior authorization, monitoring, and inspection in accordance with the precautionary principle. However, the committees suggest to harmonize it (recommendation n. 4) with a “step by step” principle<sup>452</sup> (so that a new activity is only carried out when the evaluation of the previous steps reveals that it is possible to proceed to the next step without risk) and “a case by case” analysis (considering each situation in a single view and evaluating the risks associated with each biological procedure or product individually, without making excessive

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<sup>449</sup> Ibid., p. 43.

<sup>450</sup> Ibid., p. 52.

<sup>451</sup> S. DICKEL, *Vigilance vs. Precaution: Diverging Directions in U.S. and European Technology Governance?*, in *American Institute for Contemporary German Studies Transatlantic Perspectives*, June 2011, p. 4.

<sup>452</sup> A step by step principle is quoted in COGEM report as well, where it is stated that, as soon as the knowledge grows, the assessment of risks must be shaped in accordance with the reached knowledge.

generalisations)<sup>453</sup>. Moreover, the precautionary principle could work only when there is a context of scientific uncertainty, and the possibility of a serious and irreversible harm to arise. It asks for appropriate and moderate measures (not for inaction or ban), and it refers to product and processes, according to E.U. law standards. The committee also invokes a principle of responsibility, upon public, scientific authorities, companies, entrepreneurs, media professionals (recommendation 5). Transparency, good and precise information to public, participation processes must be followed. This report differs from others in proposing the creation of commissions at a national, autonomous community and/or local level, having the role of *«monitoring, supervising and following up activities related to the emerging biotechnologies, including synthetic biology, or for delegating these responsibilities to other suitable bodies already in existence»* (recommendation n. 9), or for carrying out executive functions, issue related reports, so that in this case the center out decisions indicate specific commissions rather than the scientific community as a point of reference. The role of public authorities and civil servants is supposed to consist *«not in direct actions for eliminating or preventing risks, as that would be impossible, but instead in managing them with the aim of keeping them within acceptable limits»*<sup>454</sup>.

#### 10.4. Promotional Policies.

In the category of “promotional policies”, different approaches can be found. There are some that call for a minimal governance in the sense of “self regulation”, thus not requiring the government to intervene. On the other hand, there is the reference for a “public engagement”, which is meant to be different from the precautionary perspective, as the ethical framework that lies at the basis is divergent.

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<sup>453</sup> It should be observed that the “*Principles for the Oversight of Synthetic Biology*” also quote the “case by case” analysis, in the part in which there is a certain “mitigation” of the strong PP: *«in time, different methods and techniques of synthetic biology may need different forms and levels of oversight. Therefore any new risk assessments, cost-benefit analyses and regulations must flexibly encompass different applications, uses and products. Furthermore, assessments should include full comparative consideration of alternative approaches»* (p. 4).

<sup>454</sup> COMITÉ DE BIOÉTICA DE ESPAÑA Y DEL CONSELHO NACIONAL DE ÉTICA PARA AS CIÊNCIAS DA VIDA DE PORTUGAL, *op. cit.*, p. 18.

Indeed, it is intended as a «*promotion of educational activities aimed at getting the public on board, so that the benefits of the research are not diminished*»<sup>455</sup>.

In the first category, the role of scientific community is considered crucial, as «*initiatives developed by the synthetic biology community may be more effective than government regulation precisely because they are more likely to be respected and taken seriously*»<sup>456</sup>. So, the protection from risks and concerns is conferred upon the scientific community's will, capacity, and commitment to regulate itself.

Some self-regulatory approaches can be found in the Sloan Foundation – funded report, “*Synthetic Genomics: Options for Governance*”, drafted by Drew Endy of M.I.T., several members of the J. Craig Venter Institute team and from the Center for Strategic and International Studies. Focusing on a particular set of risks (biosecurity and biosafety), the project behind the report brought together individuals with a variety of policy, legal, scientific, ethical, business and social science expertise to identify areas for possible policy interventions and specific options for such interventions.

Although it does not make any specific recommendations as to which option should be pursued, the preference goes to self governance or, however, no intensive (minimal) regulation and public engagement.

The authors aim to formulate governance options «*that will minimize safety and security risks from the use of synthetic genomics, without unduly impeding its development as a technology with great potential for social benefit*»<sup>457</sup>, i.e. «*a policy solution [that] would both minimize the risks from nefarious uses and minimize the impediments to beneficial uses of the technology. [...], a series of governance options, recognizing and evaluating the trade-offs between their ability to reduce the safety and security risks from the use of synthetic genomics and the burdens that they would impose on scientists, industry, and the government*»<sup>458</sup>. The approach is based on risk-benefit analysis and is an engagement one, since it suggests to involve in the

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<sup>455</sup> WOODROW WILSON CENTRE, *Ethical issues in synthetic biology. An Overview of the Debates*, Synthetic biology 3, June 2009, p. 18.

<sup>456</sup> S.M. MAURER, L. ZOLOTH, *Synthesizing Biosecurity*, in *Bulletin of the Atomic Sciences*, 63, 6, 2007, p. 16-18. See also S.M. MAURER, K.V. LUCAS, S. TERRELL, *From Understanding to Action: Community-Based Options for Improving Safety and Security in Synthetic Biology*, Berkeley, C.A., 2006.

<sup>457</sup> M.S. GARFINKEL, D. ENDY, G.L. EPSTEIN, R.M. FRIEDMAN, *op.cit.*, p. 16.

<sup>458</sup> *Ibid.*, p. 17.

discussion the scientific community, potential regulators, customers of synthetic biology applications. It also suggests a hybrid model of governance, by proposing a mixture of mildly adapted, existing regulations for bio-safety, new informal institutions for self-regulation among researchers and open standards and information sharing will best combat bio-safety and risk concerns and foster an environment for further research and commercialization.

In line with a proactionary approach are also the reminders of the self-regulation adopted the aforementioned Asilomar Conference on Recombinant DNA (rDNA) in 1975. This is meant as a shining example of scientists regulating themselves. At that point, the 140 scientists gathered in Asilomar sought to find a path to continue rDNA work: they chose to end the voluntary moratorium on rDNA experiments called for by molecular biologists in 1974, and after a three-day discussion of the safety risks<sup>459</sup>, they elaborated a set of laboratory guidelines, according to the experiments to be pursued. These recommendations formed the basis of the 1976 “*National Institutes of Health (N.I.H.) Guidelines for Research Involving Recombinant DNA Molecules*”<sup>460</sup>, which were used by N.I.H.’s Recombinant DNA Advisory Committee (R.A.C.) to oversee gene-transfer research.

So, the Asilomar experience is seen as a successful story for self-regulation, and is quoted by proactionary supporters<sup>461</sup>, such as Stephen Maurer (attorney and director of the Information Technology and Homeland Security Project at Berkeley’s Goldman School of Public Policy) and his colleagues<sup>462</sup>. Indeed, in 2006 they were asked by two foundations to investigate what level of oversight those working on synthetic biology deemed appropriate. Their work led to a white paper<sup>463</sup> proposing a short list of soft, self-governance guidelines, that were formally adopted in the form

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<sup>459</sup> The concerns about ethical, social and economic issues were deliberately left off the agenda. See A. MORGAN CAPRON, R. SCHAPIRO, *Remember Asilomar? Reexamining Science’s Ethical and Social Responsibility*, in *Perspectives in Biology and Medicine*, 44, 2, 2001, p. 162-169.

<sup>460</sup> See at [http://oba.od.nih.gov/rdna\\_rac/rac\\_about.html](http://oba.od.nih.gov/rdna_rac/rac_about.html) (last visited 28th January 2013).

<sup>461</sup> In reality the same quotation of Asilomar is also invoked by those that sustain the necessity of a moratorium for synthetic biology (see D. FERBER, *Synthetic biology. Time for a synthetic biology Asilomar?*, in *Science*, 303, 159, 2004).

<sup>462</sup> The reference goes to Berkeley Synthetic biology Policy Group, a joint project of Keasling’s lab and the University of California, Berkeley’s Goldman School of Public Policy and funded by the Carnegie and MacArthur Foundations.

<sup>463</sup> S.M. MAURER, K.V. LUCAS, S. TERRELL, *From Understanding to Action. Community-Based Options for Improving Safety and Security in Synthetic Biology*, Berkeley, C.A., 10<sup>th</sup> April 2006.



of a declaration<sup>464</sup> at the Synthetic Biology conference in Berkeley in May 2006 (SB 2.0), in order to avoid more stringent government regulations, thereby proposing to institute a system of self-regulation. Even if the resolution was not adopted at the meeting, because E.T.C. and other groups opposed and because of the internal disagreements among the scientists about whether the resolution was the next logical step (some proposed, for example, that a professional organization should be established before self-regulation was undertaken), it is a meaningful example of the mentioned pattern.

A reference to self regulation is found in the previously mentioned Rathenau Institute Report, which pays attention on rules that «(a) allow for scientific development and technological innovation, (b) cover real risks sufficiently, and (c) create sufficient trust among public and politicians»<sup>465</sup>. So, self-regulation is considered a flexible mechanism of regulation, that «seems most appropriate for new technologies in an early and uncertain stage of development, when there are still many unknowns»<sup>466</sup>.

The proactionary approach also has the feature to put into brackets the social and inherently ethical aspects about the notion of life that could be altered by synthetic biology or the questions whether it is a good idea to tackle with nature, since it encourages the productivity and considers the necessity of facing with these issues only if a real (and not theoretical) problem arises. Moreover, this approach suggests an engagement model, conceived as a means for educating people and making them aware of the benefits of a research, so that they do not slow down the progress but encourage and sustain it.

For example, E.A.S.A.C.'s Report shows a soft law approach, in the sense of encouraging voluntary codes of conduct (and programs of education) from scientific community and considering that «regulation should neither stifle research nor impede transparency in communication». It also stresses the accent upon societal engagement that should be done proactively, «not simply as a reaction to emotive media reports», so that information by academia must be clear and accurate (and

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<sup>464</sup> Declaration of the Second International Meeting on Synthetic Biology, 29<sup>th</sup> May 2006, at [http://openwetware.org/wiki/Synthetic\\_Biology/SB2Declaration](http://openwetware.org/wiki/Synthetic_Biology/SB2Declaration) (last visited 28<sup>th</sup> January 2013). The resolution has not been resurrected at subsequent synthetic biology meetings.

<sup>465</sup> H. DE VRIEND, *op.cit.*, p. 68.

<sup>466</sup> *Ibid.*

developed throughout all European Academies and Committees on Science and Ethics, which are responsible for good communication). In dealing with synthetic biology its cost-effectiveness should be taken into account and the preparation for longer-term advances cannot be forgotten.

*Conclusion.*

The road undertaken in this chapter has led us to enucleate a model of governance to be adopted in facing with risks and concerns arising in the context of synthetic biology. Such model aims to be a balanced one that protects rights, values, and interests at stake without hindering the development of the nascent technology. This enables to be adapted at the technological and scientific advance, to involve all the stakeholders in the decision-making process and the phases of oversight and control in a transparent and dialogic way, and to maintain confidence in the emerging technology, while being at the same time constantly vigilant of its development and growth. Such a model of “*prudent vigilance*” that entails a full consideration of risks and concerns, an attitude of attention and care and, from the sources of law viewpoint, a mixture of “top down” and “bottom up” approaches, coupled with an integration of systems of enforcement, seems the best and most rational way to assume in order to tackle the complexity of synthetic biology. It opens the path to a new consideration of technologies, that is the passage from «*technology of hubris to technology of humility*», as stated by Sheila Jasanoff<sup>467</sup>. Indeed, the protection of safety, security, environment, health, justice, equality and so on must be pursued, but at the same time the technology cannot stop. There is the necessity to handle and govern a technology having the future in mind and considering both the potential benefits, and the risks of it. In this sense, there is space for a new model of governance, for a different engagement of experts, decision-makers and public, that substitutes the claims of objectivity of predictive methods (“*technology of hubris*”). These are designed to reassure the public, and to facilitate management and control, even in areas of high uncertainty, by making prevail a scientific paradigm. In reality,

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<sup>467</sup> S. JASANOFF, *Technologies of Humility: Citizen Participation in Governing Science*, in *Minerva*, 41, 2003, p. 238.

the methods of “*hubris*” are not able to face with uncertainty and are imposed by States and experts alone, keeping science separated from politics, interests and values<sup>468</sup>. For this reason, it is needed to substitute such “*hubris*” with an approach that considers all the possible unforeseen consequences of a technology, that supervises upon it without the claim of completeness of knowledge about risks and potentialities. It should collect plural viewpoints, thus making the scientific and technological progress walk together with ethical, social, political discussion in a transparent and democratic way.

Such approach, therefore, is a procedural one that aims at facing with uncertainty of a new technology such as synthetic biology by taking into account all the possible scientific and non scientific instances, by involving all the possible actors and by operating in a “case by case” perspective and in a responsible and prudent manner, so that the individuation of the means for dealing with concerns and risks of synthetic biology shapes in an open, plural, shared, and multilevel set of rules<sup>469</sup>.

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<sup>468</sup> See T.M. PORTER, *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life*, Princeton, N.J., 1995.

<sup>469</sup> See C. CASONATO, *Introduzione al biodiritto*, cit., p. 172 ff., who proposes «*an open biolaw having a variable geometry*», meant as a pluralist solution, that is the result of dialogue among different stakeholders coming from the world of science, medicine, law, ethics, sociology, and religion. In this way, in the end, «*non veritas nec auctoritas sed pluralitas facit legem*».



### CHAPTER III

## THE LANDSCAPE OF FUNDAMENTAL HUMAN RIGHTS IN THEIR RELATIONSHIP WITH SYNTHETIC BIOLOGY

*“Smiling, hugging, we are going  
to seek harmony beneath our stars,  
although we are different (we concur)  
just as two drops of clear water are”  
(W. Szyborska)*

*Introduction: Synthetic Biology and Human Rights.*

After considering the general approach that, in my opinion, should be the one adopted in the governance of risks of synthetic biology, this chapter aims to discuss in greater detail the legal issues that are emerging in this field. The focus of this chapter is the main fundamental human rights in a constitutional perspective are at stake in this field.

As Ruggiu affirms, many «*applications in the field of SB might be problematic in view of certain human rights, such as the right to life, the right to health, the right to safety, the right to an healthy environment, human dignity, the right to privacy, the right of property (when the intellectual property is at stake) and the right to a non modified genetic heritage, the principles of autonomy, self determination and non-discrimination and so on*»<sup>470</sup>.

When talking about the possibility of altering nature and the notion of life, the concept of dignity and how to shape and limit the freedom of scientific research as

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<sup>470</sup> D. RUGGIU, *Synthetic Biology And Human Rights In The European Context*, in FP7 “SYNTH-ETHICS” Report WP2 (deliverable 2) “Ethical and regulatory challenges raised by synthetic biology”, 2011, at <http://www.synthethics.eu/documents/ReportSDWP2-final.pdf> (last visited 28<sup>th</sup> January 2013), p. 54.

well as the reference to the dignity of non human animals emerges arise. During the consideration of biosafety issues, the risks to health and environment, the people's and workers' right to live in a healthy environment and to work in a healthy place also come into question. In the case of biomedical applications, the right of access to (synthetic) medicines and to therapies that involve the rights of the patients and the consumers, in particular the right to self determination, the principle of informed consent, and the principle of autonomy and equality in access to medicines need to be addressed. In the field of biosecurity, the right to life in a collective sense and the researchers' freedom of inquiry and the reasons of public security must be balanced. As for the issues of intellectual property rights, the researchers' freedom again together with the human dignity (for the morality and public order clause about the cases of ban of patentability) are involved. With regards to the international justice concerns, the reference goes to the prohibition of discrimination and the principle of equality and justice for the diffusion and free access to the outcomes of synthetic biology. The role of dignity, even that of non humans, must be analysed as well.

Before looking at the role of human rights within synthetic biology in greater detail, there is a need to considering in brief the relevance of the link between life sciences and human rights in general terms, keeping in mind that the same framework that we are going to describe hereafter applies to synthetic biology too.

Here, it is not the seat to deepen the issues related to the nature, and the fundament and content of human rights<sup>471</sup>. Suffice it to say, according to some opinions, they are moral positions where prerogatives or advantageous positions are granted to individuals in order to protect their existence as a moral subject<sup>472</sup>. For others, they are political entities or subjective legal positions of acting in front of a judicial authority and of being exercised in front of public powers. At the same time human rights also incorporate an objective element that is formalized within a Constitution<sup>473</sup>, and such objective element derives from nature (inherent in human

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<sup>471</sup> About these issues, see, for example, M.R. ISHAY, *What are human rights? Six historical Controversies*, in *Journal Of Human Rights*, 3, 3, September 2004, p. 359–371.

<sup>472</sup> See R. DWORKIN, *Taking Rights Seriously*, London, 1997, p. 89 ff.

<sup>473</sup> With regards to the birth and evolution of human rights, see for example B. DE CASTRO CID, *Derechos Humanos*, in C.M. ROMEO CASABONA (ED.), *Enciclopedia de Bioderecho y Bioética*, cit., vol. I, p. 613 ff.

nature or from a nature that has transcendent origin: naturalism<sup>474</sup>), or from a legal system that establishes the human rights (positivism<sup>475</sup>). In others' view, human rights were born as incorporated in the social habits of social life (sociological positivism<sup>476</sup>), or they pre-exist in society and are then included in it through social consent (contractualism<sup>477</sup>). It is also possible that human rights descend from human dignity that is a supreme legal and political value (humanism<sup>478</sup>).

Human rights are usually categorized into four groups: (1) political rights and civil freedoms (first generation of rights, typical of liberal societies); (2) economic, social and cultural rights (second generation, connected with the welfare state); (3) personal rights linked with the body and the inner dimension of individual (third generation: the right to privacy, to have a name and an image); and (4) the “new frontier of human rights”, such as group and collective rights, the right to self-determination, the right to a healthy environment, the right to natural resources, the right to participation in cultural heritage, the rights to intergenerational equity and sustainability, the rights connected to new technologies and the rights of next generations<sup>479</sup>.

Others<sup>480</sup> prefer a systematic categorization which is based around the following four criteria: (1) the discovery of freedom, (2) the formulation within bills, (3) the proclamation within Constitutions (constitutionalization), and (4) the coming out at the international level (internationalization).

The evolution and growth of the importance of human rights at the global level is plain, but the questions that remain of interest are: (1) Could human rights be

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<sup>474</sup> Usually, it is common to distinguish among the naturalism deriving from classical/ancient times, according to which the natural and immutable order of the Universe is the basis of the law and of human rights (see Aristotle and St. Thomas Aquinas as the most meaningful Authors) and the one of modern era, called jusnaturalism, according to which the rational nature and structure of human being should found human rights (see Hugo Grotius, Samuel von Pufendorf and John Locke).

<sup>475</sup> See H. KELSEN, *Teoria generale del diritto e dello stato* (1945), Milano, 1952.

<sup>476</sup> See C. SCHMITT, *Verfassungslehre* (1928), Berlin, 1989, p. 22.

<sup>477</sup> See T. HOBBS, *Leviathan* (1651), Oxford, 1996; J. LOCKE, *Second Treatise on the Government* (1690), Kingston, N.Y., 1980; J.J. ROUSSEAU, *Social Contract* (1762), Weardale, 2011.

<sup>478</sup> Humanism, mainly associated with the definition that was shaped during Renaissance times, is nowadays divided into secular, religious and inclusive sectors (see, for example, T. DAVIES, *Humanism The New Critical Idiom*, Oxon, 1997; B. ALLEBY, *Humanism*, in *Encyclopedia of Science & Religion*, vol. I, New York, 2003; N. WALTER, *Humanism – What's in the Word*, London, 1997).

<sup>479</sup> The theory of the four generations of rights was initially proposed in 1977 by Karel Vasak (K. VASAK, *Human Rights: A Thirty-Year Struggle: the Sustained Efforts to give Force of law to the Universal Declaration of Human Rights*, U.N.E.S.C.O. Courier 30, 11, Paris, November 1977).

<sup>480</sup> A.E. PÉREZ LUÑO, *Derechos Humanos, Estado de Derecho y Constitución*, Madrid, 2003.

a criterion of orientation for new technologies as well as regulation of new technologies, or (2) are they too instable, as they are subjected to historical and cultural relativism, and are not applicable to bioethics issues that arise in the context of new technologies?

First of all, it is necessary to observe that a relationship between new technologies and human rights already exists. Indeed, looking at *de facto* situation, it appears that the sciences and technologies are not exempt from affecting human rights, and human rights are often used as a tool that could boost the development of progress of science and technology.

New technologies could either affect the realization of human rights in a negative sense, or it could improve and ameliorate the enactment of human rights.

The impacts of the scientific and technological developments on human rights started to be apparent from the International Conference on Human Rights in Teheran (1968)<sup>481</sup>, where it was stated that the scientific and technological progress should not endanger the rights and the freedoms of individuals, in particular with regards to privacy, human personality, physical and intellectual integrity. Within the United Nations, the 1975 Declaration on the Use of the Scientific and Technological Progress in the Interest of the Peace and for the Benefit of the Mankind<sup>482</sup> fixed duties for the States in promoting development in science at the same pace of international peace, security, societal and economic development of the people, instead of focusing on individuals. In 1983<sup>483</sup>, then, U.N. encouraged the connection among human rights and life sciences and medicine suggesting the adoption of rules, ethical codes, and forms of cooperation at national and international level.

From that moment on, a lot of initiatives pertaining to specific fields of science and technology, such as in the genetic engineering field<sup>484</sup>, started developing, in order to protect specific rights coming at stake in the precise ambit.

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<sup>481</sup> Proclamation of Tehran, Final Act of the International Conference on Human Rights, 22<sup>nd</sup> April – 13<sup>th</sup> May 1968.

<sup>482</sup> U.N. Resolution 3384 (XXX), 1975.

<sup>483</sup> GENERAL ASSEMBLY ON HUMAN RIGHTS AND SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS, Resolution 38/112 and 113 of, 16<sup>th</sup> December 1983. See also COMMISSION ON HUMAN RIGHTS, Resolution 1986/9, Use of the scientific and technological developments for the promotion and the realisation of human rights and fundamental freedoms, 27<sup>th</sup> March 1983; and GENERAL ASSEMBLY ON HUMAN RIGHTS AND BIOETHICS, Resolution 1999/63, 28<sup>th</sup> April 1999.

<sup>484</sup> For example, see U.N. Convention on Biological Diversity of Rio de Janeiro, adopted in 1992, focused in particular on the right to healthy environment with regards to biotechnological



At the European Union level, the Charter of Fundamental Rights (which has become legally binding since 2009 with the entry into force of the Lisbon Treaty<sup>485</sup>) has enucleated specific human rights that must be respected in the fields of medicine and biology. Indeed, art. 3 of Nice Charter states the protection of the free and informed consent of the person concerned, the prohibition of eugenic practices, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings. Such principles, as explained by the Praesidium<sup>486</sup>, were previously stated in the Convention on Human Rights and Biomedicine, which was adopted by the Council of Europe<sup>487</sup>, posing the human rights at the centre of the scientific progress.

In the light of these preliminary considerations, it is clear that the link between sciences and technologies and human rights is generally highlighted. Thus brings me back to the question posed at the beginning of this chapter where it was asked whether human rights can really exercise a positive role in the evolution of science or are not necessary.

In my opinion, and in line with some authors like Ashcroft, the human rights own the merit to speak a universal language in the context of a global spread of technologies. As the new technologies alter the national borders and assume a global dimension, similarly the law should assume the same feature, and this seems to be visible in the context of human rights that are *«the last expression of a universal ethics in which indispensable values that make communication and dialogue possible in a regime of moral pluralism are reflected»*<sup>488</sup> and they are even “better” than bioethics language. Indeed, as Ashcroft affirms, human rights look like a *«global*

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development. See also UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION (U.N.E.S.C.O.), Universal Declaration on the Human Genome and Human Rights, 1997, and subsequently endorsed by the United Nations General Assembly in 1998; U.N. Declaration on Human Cloning, 2005; U.N.E.S.C.O., Declaration on Human Genetic Data, 2003.

<sup>485</sup> Charter of Fundamental Rights of the European Union, adopted in Nice (7<sup>th</sup> December 2000), adapted at Strasbourg (12<sup>th</sup> December 2007), became legally binding with the recognition of the art. I-6 of the Lisbon Treaty and its entry into force (1<sup>st</sup> December 2009). See in *O.J. C 364/2000*.

<sup>486</sup> Praesidium, CHARTE 4487/00 CONVENT 50.

<sup>487</sup> COUNCIL OF EUROPE, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4<sup>th</sup> April 1997, at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> (last visited 28<sup>th</sup> January 2013).

<sup>488</sup> G.D. PINTOS, *Human Rights: The Ethics Of Globalization*, in D.N. WEISSTUB, G.D. PINTOS (EDS.), *Autonomy and Human Rights in Health Care*, Milano, 2008, p. 37.

language for the discussion of social, legal, and moral issues, in contrast to the arguably ethnocentric language of bioethics»<sup>489</sup>. However, the issue of the universality of human rights leads some thinkers to believe that human rights are the product of imperialistic Western culture and of historical evolution, thus differing from culture to culture, not being really universal as they claim to be, but entirely relativistic<sup>490</sup>. As Veca states, the relationship between the claimed universality of human rights and the pluralism of cultures and tradition is a fact that generates challenges and problems<sup>491</sup>.

In my opinion, far from emphasising too much cultural differences that would lead to relativism and neglecting the differences between cultures in favour of universal standards or rights that would appear as absolutes, «*the mean between these extremes requires appreciation and tolerance of the undeniable differences of cultures and the undeniable basis of individual human rights*»<sup>492</sup>. In other words, human rights language grows in the comparison of, dialogue with, and consent about values among the different cultures<sup>493</sup>. Their universality is a point of arrival rather than the starting point. It is a “plural universality”, which is the fruit of different instances and pluralistic views, and particular contexts that are transcended in order to arrive at common agreements<sup>494</sup>. Even if the human rights are considered as Western values, it has been demonstrated that “functional equivalents” exist in other cultures (such as the Asian values)<sup>495</sup>, so that their “exportability” is not an issue. The universality, therefore, is essential to human rights in the sense that they express vital needs and basic demands that belong to each human being. Even in the context of dealing with new technologies, despite their implementation is then left to each

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<sup>489</sup> R. ASHCROFT, *The Troubled Relationship Between Bioethics and Human Rights*, in M. FREEMAN (ED.), *Law and Bioethics: Current Legal Issues*, 11, Oxford, 2008, p. 48.

<sup>490</sup> See, for example, A. FINKIELKRAUT *The Defeat of the Mind*, New York, 1995; C. MACKINNON, *Human rights watch looks within*, in *The New Yorker*, 64, 1993, p. 53-54; N. BOBBIO, *op.cit.*

<sup>491</sup> S. VECA, *I diritti umani e la priorità del male*, in M. IGNATIEFF (ED.), *Una ragionevole apologia dei diritti umani*, Milano, 2003, p. 111.

<sup>492</sup> R. RORTY, *Contingency, Irony and Solidarity*, Cambridge, 1989. See also D.C. THOMASMA, *Evolving Bioethics And International Human Rights*, in D.N. WEISSTUB, G.D. PINTOS (EDS.), *op.cit.*, p. 21.

<sup>493</sup> This position reminds of John Rawls’s consent through intersection through intercultural confrontation (see also R. PANIKKAR, *Is the Notion of Human Rights a Western Concept?*, in *Diogéne*, 120, 1982).

<sup>494</sup> For deepening this interpretation of the universalism of human rights, see B. PASTORE, *Per un’ermeneutica dei diritti umani*, Torino, 2003.

<sup>495</sup> See A. SEN, *Human Rights and Asian Values*, in *The New Republic*, 14<sup>th</sup> – 21<sup>st</sup> July 1997, p. 33-40; J. DONNELLY, *Universal Human Rights in Theory and Practice*, Ithaca, N.Y., 2003.

single State. In this way, universality and particularity coexist and are complementary one to each other.

So, in proving that human rights possess features of universality that are needed for facing a universally spread and global scientific and technological progress, the aim of the present chapter is precisely to focus on fundamental human rights in order to understand how they shape in the context of synthetic biology and, therefore, demonstrate how the Constitutions (meant in general terms as referred to all the catalogues and bill of rights at the international, European and national level) can respond to the challenges posed by this new emerging technology. In fact, Constitutions in a broad sense could shape the basis upon which building a (constitutionally oriented) regulation, that could be able to respond to the challenges posed by this new emerging technology.

### *1. The Right to Life.*

Synthetic biology has a lot of potentialities, especially in the field of biomedicine. Applications derived from synthetic biology, if developed in a correct and rational way, could be very meaningful to better protect human life and health. These application can be very helpful in the development of new diagnosis, treatments and medicines for numerous diseases. So, they could really lead to products that can save lives.

On the other hand, however, the damages that synthetic products could generate in their release, accidental or intentional, in the environment could affect inevitably and mortally a lot of human lives (besides the damages to environment).

In the light of these possible positive and negative consequences of synthetic biology, the right to life plays a relevant role here, and this section considers the way it can shape the field of synthetic biology.

*1.1. The Evolution of the Right to Life, its Proclamation in Legal Texts and its Enforcement.*

In order to check how the right to life affects the context of synthetic biology, some preliminary observations about its general meaning will be discussed hereafter.

Starting from a historical and legal perspective, the right to life is embedded within Constitutions only after the Second World War. This is a response to the terrible atrocities derived from the conflict. Until that moment the need to enucleate a right to life was not perceived, since it was obvious and implicit that life represented the due logical and ontological assumption for the coming to existence of all the other fundamental rights<sup>496</sup>.

With the Universal Declaration of Human Rights (U.D.H.R., art. 3<sup>497</sup>) and then the International Covenant on Civil and Political Rights (I.C.C.P.R. art. 6<sup>498</sup>), the Organization of United Nations opted for a solemn proclamation of the right to life, so as to make the need of respecting and protecting human life visible to all the nations at global level. The U.N. posed the right to life as a basis and source of the other rights<sup>499</sup>. The novelty was represented by the linking of the right to life with the notion of dignity, thus creating a strong binomial between the two. Although the Universal Declaration of Human Rights is, as its name suggest, a mere declaration, and is not a binding legal covenant, however, its influence on the development of international human rights is meaningful, as it continues to send a strong message of the rights it lists<sup>500</sup>. In the U.N. context, the right to life has been enucleated as a right which pre-dates positive protection in the laws of the Contracting States, but it is not as an absolute right.

At the International Law level, with reference to the regional human rights systems, the reference to right to life is given by the European Convention on Human

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<sup>496</sup> However, it should be specified that the proclamation of the right to life was already contained in the Declaration of Independence of the United States of America (1776) and in the French Declaration of the Rights of Men and Citizen (1789), even if in those cases they were merely declarations of principles.

<sup>497</sup> The Universal Declaration of Human Rights (U.D.H.R.) was adopted by the General Assembly of the United Nations on 10<sup>th</sup> December 1948.

<sup>498</sup> The International Covenant on Civil and Political Rights (I.C.C.P.R.) was adopted by the General Assembly of the UN in Resolution 2200 (XI) on 16<sup>th</sup> December 1966.

<sup>499</sup> U.N., *A United Nations Priority: Universal Declaration of Human Rights*, 1998, at <http://www.un.org/rights/HRToday/declar.htm> (last visited 28<sup>th</sup> January 2013).

<sup>500</sup> See P.G. LAUREN, *The Evolution of International Human Rights: Visions Seen*, Philadelphia, 2003.

Rights and Freedoms (E.C.H.R., art. 2)<sup>501</sup>, in the American Convention of Human Rights (1969, art. 4.1)<sup>502</sup>, in the African Charter on Human and Peoples' Rights (1981, art. 4)<sup>503</sup>. In the Asian context (1988, art. 3.2 of the Asian Human Rights Charter<sup>504</sup>) and in the Arab Charter on Human Rights<sup>505</sup> (1994, art. 5) the right to life is linked to the notion of human dignity.

In the context of the E.U. the Nice Charter of Human Rights has a similar structuring: meaningfully, it has decided to start the catalogue of rights from the title entirely dedicated to dignity, and it has put the right to life (art. 2) immediately after the article about dignity, thus linking them intrinsically.

Some National Constitutions<sup>506</sup>, then, clearly state the right to life, such as the Spanish one (art. 15) or the Canadian Charter of Rights and Freedoms (art. 7) or the Human Rights Act in the U.K. (art. 2), where the right to life is theoretically defined as absolute, despite the indication where it is not applicable in certain situations<sup>507</sup>. Similarly, in the U.S. Constitution, the Fifth Amendment, offers constitutional protection against self-incrimination, and it also includes the following prohibition: *«No person shall be [...] deprived of life, liberty, or property, without due process of law»*. This applies only against the federal government, but the Fourteenth Amendment extended the protection against States. However, such constitutional protection for life remains limited, since both the Fifth and Fourteenth Amendments do not address primarily life, because they are due process clauses.

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<sup>501</sup> The European Convention on Human Rights was adopted by the Council of Europe on 4<sup>th</sup> November 1950.

<sup>502</sup> Before it, the American Declaration of Rights and Duties of Man was adopted in Bogotá in April 1948 by the Organisation of American States, and it stated the right to life at art. 1. Then, the American Declaration was superseded by the American Convention of Human Rights, signed in San José in 1969, and enforced by the Inter-American Commission of Human Rights (established in 1959) and the American Court of Human Rights (established by the Convention). The American Declaration remains relevant to a few States that have not ratified the Convention (U.S., Canada, Cuba).

<sup>503</sup> The African Charter on Human and Peoples' Rights was approved by the Organisation of African Unity on 27<sup>th</sup> June 1981.

<sup>504</sup> The Asian Human Rights Charter was adopted on 17<sup>th</sup> May 1988 by the Asian Human Rights Commission.

<sup>505</sup> The Arab Charter on Human Rights was adopted on 15<sup>th</sup> September 1994 by the Council of the League of Arab States.

<sup>506</sup> With regards to the text of the National Constitutions to which I am referring here and further, see at <http://confinder.richmond.edu/> (last visited 28<sup>th</sup> January 2013).

<sup>507</sup> Indeed, a person's right to life is not breached if he/she dies when a public authority (i.e. the police) uses necessary force (however in a proportionate way) to stop people carrying out unlawful violence; make a lawful arrest; stop people escaping lawful detainment; stop a riot or uprising.

From the discussion above, the adoption of a natural rights philosophy first encouraged the constitutional and international recognition of fundamental human rights, and the legal protection of the right to life subsequently emerged based upon the idea that all human life is of equal value.

The implementation of this right occurs through the intervention of the courts. The contribution of the European Court of Human Rights in delineating the right to life cannot be forgotten in several areas<sup>508</sup>. The Strasbourg Court, on more than one occasion, has stressed that art. 2 «*ranks as one of the most fundamental provisions in the Convention*»<sup>509</sup>.

The U.N. Committee on Human Rights established by the I.C.C.P.R. as a non-judicial body, has heard numerous pleadings from individuals. In this seat, the Committee, which is the main interpreter of the I.C.C.P.R., despite it being able to release binding opinions, has dealt with death penalty<sup>510</sup>, police shootings<sup>511</sup> and deaths in custody<sup>512</sup>, describing the right to life as «*the supreme right*»<sup>513</sup>.

Under the American Convention, the Inter-American Human Rights Court is required to submit an annual report to the General Assembly of the Organisation of American States indicating which States have not complied with its judgments<sup>514</sup>.

Under the African Charter, individual complaints are heard by the African Commission on Human and Peoples' Rights. The Commission has intervened in

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<sup>508</sup> The case law of the Strasbourg Court about the right to life is very broad. Just to mention a few meaningful judgments, see: (a) about the killing by state agents, case *McCann v. United Kingdom* n. 18984/91, 27<sup>th</sup> September 1995; (b) about the positive obligation for the State to protect life, case *L.C.B. v United Kingdom* n. 23413/94, 9<sup>th</sup> June 1998; (c) about death penalty, case *Soering v. United Kingdom*, n. 14038/88, 7<sup>th</sup> July 1989; (d) about the issues as regard the beginning of life, case *Vo. v. France*, n. 5324/00, 8<sup>th</sup> July 2004; case *S.H. and others v. Austria*, n. 57813/00, 1<sup>st</sup> April 2010; case *Costa e Pavan v. Italy*, n. 54270/10, 28<sup>th</sup> August 2012; (e) about the end of life see case *Sanles v. Spain*, n. 48335/99, 20<sup>th</sup> October 2000; *Pretty v. United Kingdom*, n. 2346/02, 29<sup>th</sup> April 2002; *Haas v. Switzerland*, n. 31322/07, 20<sup>th</sup> January 2011.

<sup>509</sup> Case *McCann and others v. United Kingdom*, cit., § 147.

<sup>510</sup> See case *Lubuto v. Zambia* (Communication 390/1990).

<sup>511</sup> See case *Suarez de Guerrero v. Colombia* (Communication 45/1979).

<sup>512</sup> See case *Dermitt Barbato v. Uruguay* (Communication 84/1981).

<sup>513</sup> C.C.P.R. (Committee for Civil and Political Rights), General Comment n. 6, 1982, at [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/84ab9690ccd81fc7c12563ed0046fae3?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/84ab9690ccd81fc7c12563ed0046fae3?Opendocument) (last visited 28<sup>th</sup> January 2013).

<sup>514</sup> About the right to life, see, for example, the case of *Velásquez Rodríguez*, which concerned the practice of disappearances in Honduras and resulted in the finding of a violation of the right to life (Inter-Am Ct. H.R., 29<sup>th</sup> July 1988).

cases relating to serious right to life violations including massacres, extrajudicial executions, disappearances and police killings<sup>515</sup>.

In the Italian system the Constitutional Court has mentioned the right to life several times (for instance, in the rulings nn. 62/1969, 54/1979 e 223/1996). It has recognised the right to life as the first of inviolable rights referred to in art. 2 of the Italian Constitution. The right to life is also considered as the presupposition of the other rights. In its absence, all other fundamental rights will have no reason to exist.

The discussion in this section demonstrates the importance and the spread of quotation of the central right to life in many declarations and case laws.

### *1.2. The Contents of the Right to Life.*

From the International Law, the E.U. Law and the National Bills of rights as well as from the case law, it is evident that the right to life is recognised upon the human being, and the life that the right makes reference to is the human one. The diverse sources of law and the rulings seem to converge in this regard. So, the human being is the bearer of such right, and it is deserving of a special treatment in respect to all the other forms of life that are abounding all over the world. However, this begs the question of the meaning of human life and the identity of one what constitutes a human being.

This difficulty of selecting humanity for special treatment is well expressed by Diamond: «*If our ethical code makes a purely arbitrary distinction between humans and all other species, then we have a code based on naked selfishness devoid of any higher principle. If our code instead makes distinctions based on our superior intelligence, social relationships, and capacity for feeling pain, then it becomes difficult to defend an all-or-nothing code that draws a line between all humans and all animals*»<sup>516</sup>. The elements that make the difference between human and non-human animals are currently difficult to define. Should these elements be the

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<sup>515</sup> See, for example, the case of *Kazeem Aminu v. Nigeria* (205/97), where it was affirmed that arrests and detentions could violate the right to life in the absence of a loss of life.

<sup>516</sup> J. DIAMOND, *The Third Chimpanzee: The Evolution and Future of the Human Animal*, New York, 1992, p. 30.

language, or the consciousness or the evolutionary development of brain and the self, the meaning of human life still remains unclear. Moreover, the borders of human life are not easy to define. The issues of when life ends<sup>517</sup> and when it begins<sup>518</sup> are still questionable from the scientific and the legal viewpoint. At the same time, defining a “human being” remains unsolved. However, what appears plain here is that the right to life till now has been referred only to human beings. In the Council of Europe’s Handbook about art. 2 E.C.H.R., «‘Life’ here means human life: neither the right to life of animals, nor the right to existence of ‘legal persons’ is covered by the concept [...] The Convention does not otherwise clarify what ‘life’ is, or when it - and therewith the protection of Article 2 of the Convention - begins or ends. Indeed, in the absence of a European (or world-wide) legal or scientific consensus on the matter, the Commission when it still existed was, and the Court still is, unwilling to set precise standards in these regards”<sup>519</sup>. Therefore, following the self-restraint operated by the Council of Europe, and keeping aside the issue of the notion of human being and the borders of its life, it is evident that the right to life has an «irreversible character because it entails the disappearance of the subject upon which the right is recognised»<sup>520</sup>. The right to life entails both a negative and a positive obligation for the State. In the first sense, it means that the State must avoid any behaviour that could alter or damage the life of its members. Thus it cannot arbitrarily or intentionally kill individuals. In the second one, the State has, at the same time, the duty to intervene for removing any situation that potentially affects life and puts life into risk. Therefore, the right shows a subjective feature – it is recognised upon each person and exercisable in front of public powers. It also owns an objective facet, thus being an object of care and attention by the State towards the bearers of the right itself.

However, it should be noted that the right to life is not an absolute one, but it can enter into conflict with other rights.

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<sup>517</sup> With regards to the evolution of criteria for determining death see, among the others, E. WICKS, *The Right to Life and Conflicting Interests*, Oxford, 2010.

<sup>518</sup> With regards to the complex issues pertaining to the connection among the right to life, human dignity and the beginning of life, see A. PLOMER, *The Law And Ethics Of Medical Research International Bioethics And Human Rights*, London, 2005, p. 67 ff.

<sup>519</sup> D. KORFF, *The Right to Life: A Guide to Implementation of Article 2 of the European Convention on Human Rights*, Human Rights Handbook n.8, Strasbourg, 2006.

<sup>520</sup> Translation from P.R. LÓPEZ, *Los Derechos Constitucionales De Los Pacientes: Derecho a la Vida y a la Integridad Física*, in *Derecho y Salud*, 14, 1, 2006, p. 102.



For example, during times of war the protection of the collective lives and national security comes into conflict with the right to life of the enemies. Thus it is questionable as to which deaths can be justified and admitted, and under which conditions<sup>521</sup>. In the ambit of the prevention of crime, the right to life of innocent people and victims opposes to the right to life of the aggressors and criminals<sup>522</sup>. In the field of abortion, the conflict between the right to life for the mother and the right to life of the embryo is at stake. In the end-of-life issues, the right to life is in contrast with the right to autonomy and self-determination (as expressed in the form of refusal of life treatments), and the role of an intervention by the State, i.e. in pursuing its negative duty not to infringe an individual's autonomy or in making prevail a positive obligation to take reasonable steps to preserve life, is questionable.

In conclusion, the right to life is generally associated to human life, meaning its biological and physiological dimension. "Life" here is defined as in the sense of "being alive" from the beginning until the end, whatever this beginning and end could be. The right to life is also associated to the "social" dimension. In other words, such right includes the right to the biological existence (comprehensive of the right of physical integrity that connects to the principle of autonomy in its individual dimension, and to the protection of the bodies and public security in a collective sense) and a right to personality (included the right of a moral integrity, autonomy and self-determination).

So, to call upon the ancient distinction made by Aristotle, "life" is both "ζοή" (biological life) and "βίος" (personal/biographical life)<sup>523</sup>.

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<sup>521</sup> Humanitarian law and international criminal law state that a death can be lawful, provided that some conditions are respected. In particular, the proportionality in the action, and the military necessity, which must be justified by collective self-defence and for national interest.

<sup>522</sup> The main opinion states that, in this case, the aggressor's imminent violation of an innocent person's right not to be killed provides the ethical justification for the overriding of the aggressor's own right to life. So, the lethal force should be justified, as it would be the only means for saving innocent life, being in a context of perceived threat to life.

<sup>523</sup> S. RODOTÀ, *La vita e le regole: tra diritto e non diritto*, Milano, 2006, p. 205 ff.

### *1.3. How Does the Right to Life Shape the Context of Synthetic Biology?*

Synthetic biology divides the right to life into three perspectives: in the hypothesis that the human being is the bearer of the right to life, he or she has the entitlement to see this subjective right recognised and protected by public powers. More specifically, this entitlement entails (1) the right to have access to all the potential applications that synthetic biology could have in ameliorating human life and health (and in this case the right to life is strictly connected with the right to health and to the freedom of scientific research), and (2) the right to be protected from any case of damages that synthetic biology could provoke onto their lives (in the hypothesis of biosafety and biosecurity risks). (3) Moreover, since synthetic biology challenges the notion of life, it puts into doubt the reference of the right to life to the sole human being. Here, the right to life is challenged in its mere reference to “natural” humans.

#### *1.3.1. The Right to Life in its Connection with the Right to Physical Integrity and the Right to Health.*

From the State perspective, such right entails that human life should be an object of attention and protection. Indeed, the right to life implies the negative obligation upon the State to avoid any behaviour that could damage human life. This could be achieved by avoiding any research in synthetic biology that could kill human lives, for example in the non promotion of programs of biowarfare through the use of synthetic biology. At the same time, the State has positive obligation in defending human life from attacks by bioterrorists or in controlling the accidental release of synthetic products in the environment. This is achieved through licenses, enactment of protocols and guidelines for safety of the labs, oversight on the laboratories, and so on, as well as through a positive obligation in allowing and favouring the access of people to synthetic biomedical products.

In both cases, the right to life must be read in connection with the right to physical integrity (intended as the right to warranting the survival of humanity as

such) and the right to health. However, the right to health is to be shaped in the following manners: (a) in the case of the right to life intended as a subjective claim to have access to medicines, therapeutic devices and vaccines obtained synthetically, the right to health shows an individual dimension, and (b) in the case of protection of life from bioterrorism and accidental release of dangerous synthetic substances, the right to health linked together with the right to physical integrity acquires a collective facet, since it calls for the protection of the whole society (however, the society is here meant as the sum of individuals having each one the right to physical integrity).

So, the right to life in synthetic biology shapes as a fundamental individual right and, at the same time, as a collective interest to be safeguarded, in connection with the right to physical integrity and health and public health issues, which will be discussed in the subsequent sections.

It is meaningful to observe that such right to life must be recognized in a single human being as belonging to the State or, in broader terms, to humankind. Indeed, the principle of equality comes at stake in determining who the bearer of this right to life can be in the synthetic biology field.

In my opinion, indeed, and in line with Dworkin, the distinction between a human organism and a person is not consistent here. I refer to Harris's<sup>524</sup> and Singer's perspective, for instance, who claim that the right to life is «*not a right of members of the species *Homo sapiens*; it is [...] a right that properly belongs to persons*»<sup>525</sup>. This means that human beings who have some features that make them own a moral value can be labelled as "persons". Those features could be a capacity for reason (Singer) or a capacity to value one's own existence (Harris). Quoting Wicks, it should be noted that «*the problem with these theories is that they either include many other species within the concept of personhood (not necessarily objectionable in itself but requiring significant changes to our treatment of other species) or they exclude many human beings*»<sup>526</sup>. indeed, the differentiation between human organisms and persons would lead to the exclusion of infants and permanent vegetative state patients from moral status and thus from their right to life. Instead,

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<sup>524</sup> J. HARRIS, *The Value of Life: An Introduction to Medical Ethics*, London, 1985, p. 8.

<sup>525</sup> P. SINGER, *Rethinking Life and Death: The Collapse of Our Traditional Ethics*, Oxford, 1995, p. 206.

<sup>526</sup> E. WICKS, *op. cit.*, p. 16.

«the life of an individual human being matters morally not because that organism is sentient or rational (or free of pain, or values its own existence) but because it is a human life»<sup>527</sup>. The principle of equality elaborated in the ambit of human rights helps in this instance. It states that the life of each human being matters equally, regardless of the differences in rationality or other features that claim to characterize and differentiate the person from organisms. So, the right to life in the context of synthetic biology should be referred to anyone, as human life has value because – as Dworkin states again – it is not only a life created by God or nature, but there is a «human investment»<sup>528</sup> in each life. This is in the sense that each life is the culmination of millennia of evolution, with each one contributing to generations of human cultural development. Each life is made by the past and the present, by the investment that each single person has put in its life. In fact, «we are the highest achievements of either God's creation or evolution and there is a feeling that for this reason humanity should strive to survive, but we are also aware that the destruction of humanity would mean the loss of all knowledge, art and culture that previous generations have created»<sup>529</sup>.

So, each life has an intrinsic value and the same extends to humanity in general. Thus this life must be protected against the misuses of synthetic biology and be promoted through the applications of synthetic biology. In this sense, the right to life is at stake in the area of synthetic biology.

### 1.3.2. *The Right to Life as a Species-Right?*

Synthetic biology works with life and tries to alter and create it from scratch and from non natural elements. So, if the notion of life is reshaped by synthetic biology, it is relevant to see what happens to the right to life as a species-norm. Should it be extended to humans produced synthetically, or should it be not? The answer to this question is a difficult one, especially considering that we are now in a

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<sup>527</sup> Ibid.

<sup>528</sup> R. DWORKIN, *Life's Dominion: An Argument about Abortion and Euthanasia*, London, 1993, p. 82 ff.

<sup>529</sup> Ibid., p. 82.

preliminary stage and concrete examples of synthetic humans have not been elaborated yet.

Therefore, some preliminary observations about the notion of life are needed.

“Life” is a difficult notion to define for both the scientists and the philosophers and lawyers. The scientists think that the matter is too “philosophical” and the philosophers consider it as too “scientific”<sup>530</sup>. For this reason, the main scientific literature has opted for a «*list of property definition*» (essentialist approach), instead of a «*theory-based approach*»<sup>531</sup>, i.e. it prefers individuating a series of criteria and features that can qualify a being as “alive”, rather than saying what life is. Deplazes-Zemp, together with Deamer<sup>532</sup> and Koshland<sup>533</sup>, affirms that living being should show: (a) constant transformation through the exchange of energy with the environment, (b) material borders, (c) capacity of developing, growing, reproducing and self maintaining (autopoiesis), (d) metabolism, (e) capacity of keeping a balance between internal and external dimension of the body (homoeostasis), (f) a genetic program, and (g) belonging to a process of evolution and adaptation<sup>534</sup>.

According to the definition given to synthetic biology (see Chapter I), the notion of life changes its facets. In fact, if synthetic biology is simply considered as an evolution of genetic engineering, the focus for considering a being alive undergoes the possess of a genetic endowment and program. If the preference is for the DNA device construction and for the creation of new and non existing entities, life means having a metabolism and a genetic program. In the case of a minimal cell creation, the interaction with environment and autopoiesis are considered as the main ones for recognizing “life”.

However, whatever the notion of life is chosen, it is plain that within synthetic biology life is an object of transformation, manipulation, creation in

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<sup>530</sup> See M. BEDAU, *The nature of life*, in M.A. BODEN (ED.), *The philosophy of artificial life*, Oxford, 1996, p. 332 ff.

<sup>531</sup> C. NIÑO EL-HANI, *Theory-based approaches to the concept of life*, in *Journal of Biological Education*, 42, 4, 2008, p. 147.

<sup>532</sup> D. DEAMER, *Special collection of essays: What is life? Introduction*, in *Astrobiology*, 10, 10, 2010, p. 1001 ff.

<sup>533</sup> JR. D.E. KOSHLAND, *The seven pillars of life*, in *Science*, 295, 2002, p. 2215.

<sup>534</sup> A. DEPLAZES-ZEMP, *The Conception of Life in Synthetic Biology*, in *Science and Engineering Ethics*, 2011, p. 2 ff.

laboratory or through a computer or a rational design. Here the scission between living beings and machines blurs, the borders between “natural” and “artificial” become imperceptible and the link between theoretical research and experimental one becomes closer.

Life is not perceived as something “given”, or as the expression of an untouchable natural order, or having a “τέλος”, i.e. a finality that imposes on one not to touch the “nature”. Instead, life should be perceived as something that can be programmed and optimised, as if a «*second Nature*»<sup>535</sup> was being originated. The mentioned features that are associated to “life” are not inalterable, but are «*tools [...] on the one hand designed according to the wishes of their human designers; on the other hand, [to] serve specific purposes*»<sup>536</sup>. To paraphrase, life is a «*toolbox*», in which the *tools* are produced through a rational design and at the same time they are used as a means of production. Thus synthetic biology blurs «*the boundary between our understanding living and non-living matter*»<sup>537</sup>. Indeed, synthetic products result to be “living machines” and “synthetic organism”, i.e. combining elements of artificiality (proper of machines that have no real independence and act in a mechanical way) and elements of “nature” (typical of organisms, having the capacity of interact, reproduce, die and so on). For example, synthetic cells (in the subfield of “synthetic protocell biology”) have an artificial origin (made by men) but then evolve in a “natural” way that resembles the components existing in nature (they could take the name of “synthetic organisms”). Instead in bioengineering approach, the bioengineering product is similar to the traditional organisms in its origin but it is programmed to fulfil certain purposes (so they could be named “living machines”). Thus, «*synthetic organisms are not imagined as copies of human beings but as new, minimal forms of life. Living machines in synthetic biology are not imagined as mechanical beings but as organisms that are fully controlled by human beings. [...]*

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<sup>535</sup> M. SCHMIDT, *Xenobiology: A new form of life as the ultimate biosafety tool*, in *Bioessays*, 32, 4, 2010, p. 329 ff.

<sup>536</sup> A. DEPLAZES-ZEMP, *The Conception of Life*, cit., p. 13.

<sup>537</sup> A. DEPLAZES-ZEMP, M. HUPPENBAUER, *Synthetic organisms and living machines. Positioning the products of synthetic biology at the borderline between living and non-living matter*, in *Systems Synthetic Biology*, 3, 2009, p. 55.

*These new forms of life will affect the concept and evaluation of life and the idea of what constitutes a machine in society and in our culture»<sup>538</sup>.*

So, if synthetic biology allows life to be reproduced in a fundamentally different sense, nothing excludes the engineering perspectives or other synthetic processes to be applied to gametes too. Indeed *«rather than relying upon gametes to produce a life whose form is constrained by boundaries associated with existing life forms, synthetic biologists assemble synthesized building blocks of genetic materials into life forms which have not existed before in order that they might fulfil a pre-existing function [...]. Synthetic biologists may also use such building blocks to redesign existing life forms. Moreover, in that they are able to do so on an assembly line basis, mass production of new forms of ‘life itself’ may take place in the very near future»<sup>539</sup>.*

Numerous legal rules and regulations have been enacted in order to give safeguards to public and environment with regards to new reproductive techniques, for example the ban for reproductive cloning of human embryos, and the permission of pre-genetic diagnosis of embryos for specific disorders<sup>540</sup>.

The techniques adopted within the field of synthetic biology go into the same direction of constructing other inter-species “creatures”, whose right to life (meant as the right to come into existence and being worthy of legal protection) and whose moral significance are at stake, such as in the case of inter-species cytoplasmic hybrids, or cybrids<sup>541</sup>.

The question of whether synthetic humans could be generated and could be gifted with the recognition of a right to life remains unanswered for the moment. If the science and technology do one day generate synthetic humans, in my opinion, the options for their legal regulation could be as follows: (a) enacting a ban to create them, analogously with the ban for cloning, or (b) there could be a preference for

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<sup>538</sup> Ibid., p. 63.

<sup>539</sup> R. MACKENZIE, *Synthetic Biology and (Re)productive Liberties: Biosecurity, Biosecrecy, and Regulating New Technologies with Futures in Mind*, in M. FREEMAN (ED.), *Law and Bioethics: Current Legal Issues*, 11, 2008, Oxford, p. 251.

<sup>540</sup> See, for instance, in the U.K., the 1990 “*Human Fertilisation and Embryology Act*”, which regulates the provision of fertility treatment to humans.

<sup>541</sup> See U.K. ACADEMY OF MEDICAL SCIENCES, *Inter-species Embryos*, London, 2007; U.K. HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, *Hybrids and Chimera*, London, 2007, at <http://www.hfea.gov.uk/en/1517.html> (last visited 28<sup>th</sup> January 2013).

overcoming the “classical” association of the right to life to the human species as we know it, by leaving out of consideration what the generative action of the human creature is, but focusing only on the functions he/she could pursue, so that if a synthetic human pursues the same functions of a “natural” human he/she could be recognised with a right to life; or (c) there could be the possibility of elaborating a hybrid legal protection for the synthetic humans, different from the “classical” humans’ version.

(a) If a ban is chosen, the right to life would merely refer to human beings, thus implying the prohibition in extending it to others. In this context, such right would be connected with the right to genetic integrity<sup>542</sup>. This means that the right of not altering the individual human genome and therefore any intervention on human genome through synthetic biology would be banned<sup>543</sup>. Such interventions would affect human genetic integrity and alter the human genome defined as an endowment of humanity that has to be kept and preserved towards future generations. The matter of eugenics would retake power here too. Under this perspective, synthetic humans would be “degraded” humans much like the cloned humans. So, the ban for creating synthetic beings, based on the right to human life to be preserved together with genetic integrity, would be a means to protect the inviolability of the human species. Moreover, it would be a means for avoiding discrimination against human beings on the basis of their origin (“natural” or synthetic).

It is in the protection of genetic endowment that the following prohibitions find their origin: the formation of hybrids, the crossing of species through the transferring embryos from humans to animals and vice versa, and the eugenic

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<sup>542</sup> See, for example, with regards to genetic integrity and intangibility: U.N.E.S.C.O., Declaration on Human Genome, 1995, principle 1; Recommendation 934/1982 from the Council of Europe about genetic engineering, recommendation 7. From the doctrine point of view, see, among others, R. MALANDA, *Intervenciones genéticas sobre el ser humano y derecho penal*, Bilbao, Granada, 2006, p. 176 ff.

<sup>543</sup> The right to genetic integrity is so strongly perceived that some legal systems have decided to give it a legal protection by individuating a criminal rule for the violation of it. See, for example, Spanish Criminal Code (art. 159), which condemns genetic manipulations for non therapeutic purposes, by enacting a crime of (abstract) peril and result: the legal good is an individual one, the genetic integrity, and a collective one (intangibility of human genome: super individual interest); the action is a manipulation of human genes thus altering the genotype, referring to the action on the body of a person, on implanted embryos or viable fetuses and on embryos in vitro (introduction of modified genes, permanent alteration).



creations, such as chimeras. So, the ban of synthetic humans could be added to the mentioned list of prohibitions.

(b) In the second hypothesis, the right to life as extended to synthetic humans would cease to be a species-norm, and it would thereby transform itself into a “function-norm”. So, how the humans originate would not have further relevance, but if these synthetic humans would be able to pursue all the human functions and have human consciousness, they would be ascribed to the realm of humans as such and would be entitled with the same rights.

(c) In the third hypothesis, synthetic creatures would be intermediary between humans and chattels not having a legal protection, thus being gifted with a hybrid tutelage that should be elaborated. In this context, a risk of stigmatization and differentiation between humans of “series A” (as “naturally” born) and “series B” (as synthetically born) cannot be avoided of consideration.

The question of how to shape the right to life with reference to possible new synthetic humans is not clear. It is not my will to indicate “*the*” proper solution. However, some possible orienteering lines are likely to be formulated, and the engagement of society, philosophers, ethicists, sociologists, scientists, and religious people together with policy makers in the following years will certainly contribute to its comprehension.

## 2. *Human (and Non Human) Dignity.*

A concept that is strictly connected with the right to life is the one of dignity, and it must also be considered in the light of synthetic biology.

At first blush, human dignity seems to have nothing to do with this subject. However, it is only the first and rapid view that brings forth such a conclusion. Actually, if “Maya’s veil” is lifted, suddenly another perspective appears. Therefore, it is meaningful to check if and how dignity can play a role within synthetic biology. In order to understand it, it is better to offer some general observations about what human dignity means and where it is derived from.

### 2.1. *The Notion and Evolution of Dignity: Dignity as Virtue and Value, as Empowerment and Constraint.*

Keeping aside the deep discussion of the notion of dignity during ancient Roman times and in Christian tradition<sup>544</sup>, throughout history, the idea of dignity evolved from the reference to institutions, that were aimed at defending the “decorum” of States, and then it started to refer to persons, and thus assuming mainly two meanings during the course of time. On the one hand, it was meant as a value associated to a social position (referred to honour), and on the other as an absolute and inherent value that belongs to human beings as such<sup>545</sup>.

In this second perspective, dignity becomes a source of moral principles and responsibility, as it means to treat every being in accordance with the dignity that it possesses. In this sense, dignity extends to all human beings and not only to particular categories or groups as in the first meaning.

As de Miguel Beriain explains, in the first sense of “honour”, *«we are referring to a value that, as such, encompasses the characteristics of polarity (there exists an opposite, indignity, which counters this value), gradualness (there is the possibility of being more or less dignified), [...] When, on the other hand, we employ the idea of dignity as «an inherent value which is superior to any other», [...] dignity is not a value, but rather it is the value that is inherently possessed by something (in order to unravel this tongue twister it is perhaps better to say that dignity, when it is synonymous with honour, decorum, etc. is a virtue, and that dignity as a value that a being possesses is not a virtue at all)»*<sup>546</sup>. In this sense, human dignity would have a double meaning of “virtue” and “value”. The meaning of “virtue” links dignity to the social dimension and to the conception that a culture or society have of “dignified

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<sup>544</sup> For these aspects, see for example V. PÖSCHEL, *El concepto de dignidad en la Antigua Roma y después*, in *Ars Médica*, 2, at [http://escuela.med.puc.cl/publ/ArsMedica/ArsMedica2/04\\_Chuaqui.html](http://escuela.med.puc.cl/publ/ArsMedica/ArsMedica2/04_Chuaqui.html) (last visited 28<sup>th</sup> January 2013).

<sup>545</sup> See I. KANT (1785), *Fundamental Principles of the Metaphysic of Morals*, Rockville, M.D., 2008.

<sup>546</sup> I. DE MIGUEL BERIAIN, *Synthetic Biology: a Threat to Human Dignity?*. Paper written with support from the SYBHEL project: Synthetic Biology for Human Health: Ethical and Legal Issues (SiS-2008-1.1.2.1-230401; a project funded under the European Commission's Science in Society Programme of Framework Programme 7). Thanks to the Author for the kind concession of his article.

people”, and it implies a list of behaviours that should be pursued in order to keep the “status”. This view is culturally dependent, as MacIntyre states<sup>547</sup>.

It is the second perspective the one that has acquired a relevant role with the building of human rights.

Just to mention some examples of its quotation, human dignity is explicitly declared to be one of the foundational ideas in the Charter of the United Nations (1945), in the Preamble of the Universal Declaration of Human Rights (1948), and its partner Covenant on Economic, Social and Cultural Rights (1966), and Covenant on Civil and Political Rights (1966). Thus, the Preamble to each of these instruments recognizes the inherent dignity and the equal and inalienable rights of all human beings, and art. 1 of the Universal Declaration famously proclaims that «*all human beings are born free and equal in dignity and rights*», that is to say that each and every human being has an inherent dignity, which grounds the possession of *inalienable* human rights.

In the American ambit, the American Convention on Human Rights opts for considering dignity as a right and not the basis of other rights (art.11), defining it as the right to respect and reputation.

In the E.U., the European Charter of Fundamental Rights mentions dignity in the Preamble, as a universal and indivisible value upon which the E.U. is founded, and then it chooses to start the catalogue of rights by putting human dignity at the first place (Article 1), thus underlining the strong value of dignity as a source of the remaining human rights. The European Convention on Human Rights, instead, does not cite dignity, but it elaborates on it through the case-law<sup>548</sup>.

Furthermore, numerous Constitutions clearly express the importance of human dignity<sup>549</sup> by reserving to it a specific article (or more articles) or formulating it at the beginning of the whole bill of rights<sup>550</sup>.

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<sup>547</sup> A. MACINTYRE, *After Virtue*, London, 1981.

<sup>548</sup> See, for example, case *Tyrer v. United Kingdom*, n. 5856/72, 25<sup>th</sup> April 1978. For further details, see C. MCCRUDDEN, *Human Dignity and Judicial Interpretation of Human Rights*, in *European Journal of International Law*, 19, 4, 2008, p. 655-724.

<sup>549</sup> The dignity is explicitly mentioned in Constitutions of States that come from socialist experiences (see W. SADURSKI, *Rights Before Courts: A Study of Constitutional Courts in Postcommunist States of Central and Eastern Europe*, Dordrecht, 2008), from States that lived authoritarian experience (such as Germany, Italy, Portugal, Spain) and in almost the totality of Constitutions of Latin America (see G. ROLLA, *Il valore normativo del principio della dignità umana. Brevi considerazioni alla luce del*

Dignity is very much cited in legal texts, but it is still unclear what it is exactly is. Sometimes it has represented the source of rights and the ground upon which all the human rights are built<sup>551</sup> (in particular the right to freedom from inhuman treatment, the right to private life and family, the right to marry, the right to freedom of conscience and belief, the right to freedom of association, and so on). On other times it has been considered as an expression of freedom or equality, or as a subjective individual right itself (as in South African and Israelis Constitution<sup>552</sup>), closely related to concepts like virtue, respect, autonomy, or a right having collective dimension. There are also times when it has been seen as a limit (for example to the constitutional review, as in German Constitution), and in some others as a parameter in balancing operations and as a principle<sup>553</sup>. As Alpa says, «*“dignity” is not only a word, but it is at the same time a value, a principle, a general clause, a connotative element of a legal system, a limit and many other things, as it happens for all the words that are rich of history, for all the terms having a plenty of meanings, for all the works open to the interpreters’ texture*»<sup>554</sup>.

So, the importance of dignity is extensive. Nevertheless, this importance gives rise to so much controversy, because human dignity is a vague, elusive and

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*costituzionalismo iberoamericano*, in *Diritto pubblico comparato ed europeo*, IV, 2003). In particular: German Constitution puts human dignity at the basis of the whole Grundgesetz (art.1); South Africa Constitution affirms it in art. 1 (a), art. 7 (1), art. 10, art. 35 (2), art. 36 and, as non derogable right, in art. 37 (5); Israel Basic law provides the general protection of human dignity in section 1 and then it states a negative obligation not to violate it in section 2 and a positive obligation to promote in section 8; Belgian Constitution (art. 23) elaborates dignity for admitting, at certain conditions, the homicide of consentient person; Irish Constitution links dignity with the protection of the right to life (art. 40); Hungarian Constitution, as modified in 2011, states human dignity as inviolable and belonging to embryonic and foetal life from the moment of conception (Preamble and art. II). See also Finnish Constitution (artt. 1, 7, 9, 19); Greek (art. 7 about the prohibition of torture); Lituianian (artt. 21, 22 e 25); Polish (preamble and art. 30); Slovenian (artt. 21 and 34); Spanish (art. 10).

<sup>550</sup> A particular case is represented by the U.S., where dignity does not appear, but according to some scholars a reference of it was implicitly stated in the Declaration of Independence (see J.C. KNECHTLE, *Holocaust Denial and The Concept of Dignity in The European Union*, in *Florida State University Law Review*, 36, 41, 2008). In the U.S., however, the relevance of dignity grows as the human rights acquire their importance (see M.J. MEYER, W.A. PARENT, *The Constitution of Rights. Human Dignity and American Values*, Ithaca, N.Y., 1992).

<sup>551</sup> In Belgian Constitution human dignity is the base of social rights (see art. 23).

<sup>552</sup> Here dignity is quoted when a new right is necessary to be formed and it does not exist yet.

<sup>553</sup> About these facets of dignity, see, for example, R. ANDORNO, *Human dignity and human rights as a common ground for a global bioethics*, in *Journal of Medicine and Philosophy*, 34, 3, 2009, p. 223-240, at [http://www.unesco.org/uy/shs/red-bioetica/uploads/media/dignidad\\_Andorno.pdf](http://www.unesco.org/uy/shs/red-bioetica/uploads/media/dignidad_Andorno.pdf) (last visited 28<sup>th</sup> January 2013). With regards to dignity as the root of human rights, see J. RAWLS, *A Theory of Justice*, Cambridge, M.A., 1999, p. 157.

<sup>554</sup> G. ALPA, *Dignità personale e diritti fondamentali*, Intervento alla Conferenza internazionale “*I diritti umani e fondamentali nella formazione dell’avvocato europeo*”, Rome, 9-10<sup>th</sup> April 2010, at <http://www.europeanrights.eu/index.php?funzione=S&op=5&id=437> (last visited 28<sup>th</sup> January 2013).

flexible concept. At this point Alpa again speaks about it as a «*bustrophanic*» word, that can be used in opposite ways, especially in the field of biolaw, depending on the point of view of the interpreter. This vision has been shared by Aldergrove who compares dignity to an «*empty box*»<sup>555</sup>, which can be used either for manipulative interpretations, or as an argumentative role to support the rights and freedoms that have already been stated, thus assuming a mere «*ornamental function*»<sup>556</sup>.

Relevant examples of the ambiguity and vagueness of human dignity are visible with regards to end-of-life decisions' debate, where "dying with dignity" is appealed by the supporters of euthanasia, who consider a life in serious disease conditions as a not-worth-to-be-lived life, and death in accordance with an individual's wishes is a more dignified than one that ignores the autonomous choices of the individual. On the other hand, dignity is at the same time used as a "weapon" by the opponents of euthanasia who invoke it to sustain that euthanasia is a crime that affects human life and the inherent dignity that it owns. There are several views regarding the attitude towards the status of body parts (that are, for instance, assembled in research biobanks). The first view recognizes property rights upon the human body by using dignity to affirm that the lack of recognition of property rights to individuals upon their bodies would be a violation of human dignity and that the best model for safeguarding human dignity is through the affirmation of property rights upon the body. There is another view which assigns the nature of "commons", stating that assigning property rights to body parts confer a value of chattel to human body, thus infringing the human dignity of the whole person, as the attribution of property would make the body as a mere "object" to handle.

These examples show the vagueness of dignity. So, dignity assumes – once again – a double nature. Indeed, in the first position within end-of-life issue and in the first position about body parts, human dignity is strictly connected with individual autonomy, and such a concept of autonomy and self determination also leads to the notion of property. Here, dignity is conceived as «*empowerment*»<sup>557</sup>, to

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<sup>555</sup> J. ALDERGROVE, *On Dignity*, in J. ALDERGROVE (ED.), *Why We Are Not Obsolete Yet. Genetics, Algeny, and the Future*, Burnaby, B.C., 2000.

<sup>556</sup> W. SADURSKI, *Constitutional Courts in the Process of Articulating Constitutional Rights in the Post-Communist States of Central and Eastern Europe*, *EUI Working Paper*, n. 2003/1, p. 4.

<sup>557</sup> See R. BROWNSWORD, *Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies*, in T. MURPHY (ED.), *New Technologies and Human Rights*, Oxford, 2009, p. 26 ff.

be intended as the capacity to make one's own choices, or to value one's own preferences, even with regards to the body. It entails that those choices that one freely makes should be respected. This is reminiscent of Dworkin's position<sup>558</sup> which connects dignity to self-determination, thereby underlining its individualistic facet.

In the second position (connected to the sanctity of life and about the "commons" status to body parts) human dignity assumes the facet of «*dignity as constraint*»<sup>559</sup>, since it is a tool for limiting others' activities and imposing moral duties and obligations towards all human beings.

Such considerations could bring to consequence two problematic results: (1) *because of its ambiguity, dignity cannot really solve legal problems that arise in the context of synthetic biology and so it is not useful to be considered within a legal reflection*<sup>560</sup>, and (2) *thanks to its ambiguity, it can be «invoked as a polemical substitute for clear ideas»*<sup>561</sup>, to cover ambiguous and untidy thoughts or as a rhetorical device, so it is used in any situation and broadened without any limit in such a way that it results trivialized. Indeed, «*if the interpretation of morally saturated legal terms like 'human right' and 'human dignity' tend to be counter intuitively construed in too broad a sense, they will not only lose their power to provide clear conceptual distinctions, but also their critical potential*»<sup>562</sup>.

Out of these two extreme consequences, the challenge here consists of finding a "right" place to the multi-faceted concept of dignity even in the legal framework of synthetic biology.

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<sup>558</sup> R. DWORIN, *Is democracy possible here? Principles for a New Political Debate*, Princeton, N.J. 2006, p. 10 ff.

<sup>559</sup> Ibid.

<sup>560</sup> Some scholars think that dignity is simply a philosophical concept but does not have a legal role, thus the same effects that can be obtained quoting dignity are obtained through the principle of equality or reasonableness. For instance, Macklin states that «*dignity is a useless concept in medical ethics and can be eliminated without any loss of content*». In this view, dignity means no more than the respect for the notion of autonomy. So, it is a repetitive concept (R. MACKLIN, *Dignity is a useless concept*, in *British Medical Journal*, 327, 7429, 20<sup>th</sup> December 2003, p. 1419–1420).

<sup>561</sup> N. BOSTROM, *In Defense of Posthuman Dignity*, in *Bioethics*, 1, 3, 2005, p. 209.

<sup>562</sup> E.O. ERIKSEN, *The question of Deliberative Supranationalism in the EU*, Arena, Working Paper n. 99, 1999, at [http://www.arena.uio.no/publications/wp99\\_4.htm](http://www.arena.uio.no/publications/wp99_4.htm) (last visited 28<sup>th</sup> January 2013).

## 2.2. *Dignity for Humans and Non Humans?*

Before analysing whether dignity relates to synthetic biology and how, it is necessary to examine a further preliminary issue - whether there is a difference between human dignity and dignity. Indeed, all the human rights texts at the international, European and national level refer to human dignity<sup>563</sup>, thus qualifying it in a specific way. Such notion of dignity, associated to humans, subdivides into three more subcategories: (a) the dignity attaching to the whole human species, (b) the dignity of groups within human species, and (c) the dignity of human individuals<sup>564</sup>.

The first category, i.e. the objective facet of dignity, works for the protection of the integrity of the entire human species (such as the protection of the uniqueness of human genome). It also, by extension, originates and is at the basis of some social and economic rights, such as in the case of the regulation of environment, and of some duties towards nature, animals and earth.

The second attribute, i.e. objective and subjective dignity, operates in the contexts of discrimination, thus founding the claims of groups to be recognized and not discriminated against the others.

The third one, i.e. subjective dignity, is mainly invoked in the ambit of individual choices or situations affecting the self, thus leading to sustain the individual freedom, integrity, autonomy, respect of the self and self determination.

The movements for animal rights<sup>565</sup> have added the notion of non-human dignity. This notion leads to consider dignity as a broader notion that cannot be referred only to human beings, but must be extended to animals as well. This is on the basis of the fact that not only humans are rational animals and that human and non human animals share the same feeling of pain, and this can make both humans and animals be put on equal standing. It is relevant to observe that some of these

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<sup>563</sup> In reality, among the dichotomy human-non human dignity, there is also a third type of dignity, that we completely keep aside here: it is the dignity of the States.

<sup>564</sup> See D. FELDMAN, *Human dignity as a legal value: Part I*, 1999, p. 2, at <http://login.westlaw.co.uk/> (last visited 28<sup>th</sup> January 2013).

<sup>565</sup> See, for example, Helga Kuhse who considers human dignity as a slippery and inherently speciesist notion (H. KUHSE, *Is There a Tension Between Autonomy and Dignity?*, in P. KEMP, J. RENDTORFF, M. JOHANSEN (EDS.), *Bioethics and Biolaw*, vol. II, Copenhagen, 2000, p. 61-74).

authors found the idea of dignity upon some features that bring to exclude some humans from the recognition of dignity (in cases of humans that have no consciousness or rationality) and to include animals non-human for the possess of those features<sup>566</sup>. These positions would lead to elaborate a double notion of dignity: one for humans in general in the anthropological tradition, and the other (named “personal dignity”) referred to animals non-human and those humans having certain features.

### 2.3. *Dignity in the Context of Synthetic Biology.*

After a discussion of the multi-faceted notion of dignity in terms of value, virtue, empowerment, constraint, human, non-human in the previous section, it is the next logical step to consider the relationship between synthetic biology and dignity. At first sight, it seems as if synthetic biology and dignity appear as two distinct dimensions. However, on the contrary, there is some space for the dignity to act within the field of synthetic biology. As clearly underlined by the European Group on Ethics in Science and New Technologies in its “*Opinion on Ethics of Synthetic Biology*” (2009)<sup>567</sup>, dignity must be posed at the basis at the whole architecture of the regulation of synthetic biology. The Opinion, indeed, starts with the accent to human dignity, stating in the *incipit* that synthetic biology must respect the international framework about ethics and human rights. Most importantly, it must respect human dignity, intended not only as a fundamental right in itself, but as the real basis of fundamental rights. There is, then, a long list of fundamental rights to consider in the matter, so that the framework on which discussion about synthetic biology could be based is well-established. In particular, art. 6 of the T.E.U. (i.e. the common provisions concerning respect for fundamental rights), art. 168 of the T.F.E.U. on public health (previously, art. 152 T.E.C.), art. 1 and 3 of the Charter of Fundamental

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<sup>566</sup> In this respect the most eminent position is the one supported by Peter Singer who states that dignity is based upon some cognitive abilities, that do not belong to people that are mentally retarded (see P. SINGER, *Speciesism and Moral Status*, in *Metaphilosophy*, 40, 3-4, July 2009, p. 567-581).

<sup>567</sup> E.G.E., *op.cit.*



Rights of the European Union about human dignity and right to the integrity of the Person are expressly mentioned.

It should be noted that the concept of dignity assumed by the E.G.E. is the one as in Cheshire's definition, according to which human dignity is *«the exalted moral status which every being of human origin uniquely possesses. [...] The possession of human dignity carries certain immutable moral obligations. These include, concerning the treatment of all other human beings, the duty to preserve life, liberty, and the security of persons, and concerning animals and nature, responsibilities of stewardship»*<sup>568</sup>. So, the Opinion refers only to a human dignity and to the objective dimension of it, which is associated to the human species and entailing other rights and duties.

Other references to dignity in the field of biology (and, consequently, to synthetic biology) were made during the Oviedo Convention<sup>569</sup>, which invokes dignity with reference to biology and medicine, and considers dignity as a means to govern the scientific progress, as a value having individualistic and collective dimensions. Particularly symptomatic is the Preamble, where the statements such as the following: *«Conscious of the accelerating developments in biology and medicine; Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being; Conscious that the misuse of biology and medicine may lead to acts endangering human dignity; Affirming that progress in biology and medicine should be used for the benefit of present and future generations*, show the centrality of dignity in facing new technologies and progress<sup>570</sup>.

Moreover, the Universal Declaration on the Human Genome and Human Rights<sup>571</sup>, also declares that *«practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted»*. Once again, dignity is being referred to as an intrinsic value of all human beings.

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<sup>568</sup> W. CHESHIRE, *Ethics and Medicine*, 18, 2, 2002.

<sup>569</sup> See footnote 487.

<sup>570</sup> The emphasis on dignity is confirmed in the art. 1 of the Oviedo Convention as well. Dignity is shaped as the basis for all the human rights and freedoms.

<sup>571</sup> This Declaration was adopted by the General Conference of the U.N.E.S.C.O. on 11<sup>th</sup> November 1997.

So, these declarations and conventions demonstrate that human dignity cannot be dichotomously separated from biological activities, or genetics and medicine. Instead, it must follow step by step the development of science (included, therefore, the nascent field of synthetic biology). However, all these texts refer only to human dignity, and do not consider the possibility of a broader meaning.

Since it has been established that human dignity must play a role within synthetic biology, as affirmed by international and European documents, the following sections set out to consider (a) the ways in which human dignity relates to synthetic biology, and (b) the if and how in which non-human dignity can be relevant here, although it is not mentioned in any of the previously said texts.

### *2.3.1. Dignity in the Light of Biosafety and Biosecurity Risks.*

In the light of the meanings that human dignity can assume, it turns out that human dignity seen as the inherent value of human species as a whole is at stake with regards to biosafety and biosecurity risks.

In fact, with respect to the risks of unintentional and voluntary exposure to pathogens or their accidental or voluntary release, which could provoke environmental and health damages, the relevant category of dignity is that one which goes far beyond the mere individual sphere. It refers to the value of humanity as such, including future generations<sup>572</sup>. Such collective notion of dignity embodies the idea that the existence and integrity of humanity as such has intrinsic worth and therefore deserves to be protected, so it empowers the humankind integrity. This facet of human dignity entails that all the measures to prevent random and deliberate proliferation of harmful virus and bacteria must be taken. This is so that the right to a healthy environment is founded on it. In fact, thanks to the notion of dignity, the interaction between humankind and environment is emphasized: these two dimensions are not separated, but are complementary. Thus, the protection of nature cannot be considered to be separate from the protection of the person and of future generations. This is because a healthy environment could shape people's personality,

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<sup>572</sup> D. BIRNBACHER, *Ambiguities in the concept of Menschenwürde*, in K. BAYERTZ (ED.), *Sanctity of Life and Human Dignity*, Dordrecht, 1996, p. 114-115.

growth, existence, and could lead to live a dignified life. In this view, human dignity is the source of the right to have a healthy environment for both the individuals living in current times (that can realize their occupations and personality in that setting), and for future generations that have the right to find a good place where to live.

This “collective” notion of human dignity also founds the right to the security of people, of the right of not bearing unjust treatments (such as in the cases of bioterrorism) that would affect their integrity and their dignity as a species. In this case, the importance of dignity also leads to the maintenance of the right to life, as described in the previous section.

### *2.3.2. Dignity and Intellectual Property Rights.*

When moving to the ground of intellectual property rights in synthetic biology, the role of dignity should be taken into account again. As anticipated in the first chapter, synthetic biology challenges the intellectual property rights’ system. Whether a proprietary or an open model of innovation should be chosen is still in doubt.

The area in which dignity is at stake pertains to the patentability of synthetic products and/or processes.

As a premise, it should be noted that the issue of patentability of DNA and biotechnological inventions has been object of attention at international, European and national level.

At the international level, the framework is represented by the 1995 T.R.I.P.S. (Trade-Related Aspects of Intellectual Property Rights) Agreement<sup>573</sup> under the W.T.O.. The framework requires all the W.T.O. Member States to adopt a set of minimum standards of intellectual property rights protection. In particular, according to art. 27 T.R.I.P.S., the protection given to mechanical innovations must be the same as for material of human origin, since *«patents shall be available for any inventions, whether products or processes, in all fields of technology»*. Patents should be

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<sup>573</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization), [1995] ATS 8.

recognized if an invention shows «*novelty, creativeness, industrial application*». However, the patentability is excluded if an invention is contrary to public order or decent behaviour in order to protect human, plant, animal life and avoid damages to environment (art. 25).

In the U.S. the U.S. Patent Act<sup>574</sup> is the main statute concerning patents. It grants patents for any «*new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof*» (§ 101).

The patentability of DNA sequences finds its recognition in the decision of the case of *Diamond v. Chakrabarty* (1980). The case concerns the request by an engineer to patent a genetically engineered microorganism. Although the claim was not accepted by the patent examiner and subsequently by the Board of Patent Appeals and Interferences, the U.S. Court of Customs and Patent Appeals argued that the living status of the microorganism was not relevant for patent law. Successively, the Supreme Court ruled that a genetically altered bacterium was not a product of nature any more, but a completely human product, and thus was inventive enough to be patentable<sup>575</sup>. However, the Court did not define any boundaries for this new area of patentable material, and simply stated that «*anything under the sun that is made by man*»<sup>576</sup> constitutes patentable subject matter.

Prior to this case, the U.S. Congress had authorised limited protection for cultivated plant varieties and, after this case, the grant of patents for GMOs and other genetic materials in modified plants or eukaryotes became a praxis, provided that the material has been isolated, purified from the existing gene (in fact, the gene as it occurs in nature is not patentable, but if isolated by human hand it is), and if the application discloses a well established utility or assert a specific, substantial, and credible utility<sup>577</sup>.

During the 1980s the patentability of living organisms was further extended from bacteria to multi-cellular organisms and to higher plants and animals (as shown

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<sup>574</sup> 35 U.S.C. §1-376. The U.S. Patent Act was enacted in 1790 to fulfil the Constitutional duty to Congress to «*promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries*» (art. I, § 8 (8) ).

<sup>575</sup> Case *Diamond v. Chakrabarty*, 447 U.S. 303, 1980.

<sup>576</sup> Page 447 U. S. 309.

<sup>577</sup> See U.S.P.T.O., *Utility Examination Guidelines*, in *Federal Register*, 66, 4, Washington, D.C., 5<sup>th</sup> January 2001.

in granting the patent an engineered animal, the Harvard Onco-mouse<sup>578</sup>, described as a “*non-naturally occurring nonhuman multicellular living organism*”). The U.S. Patent and Trade Office (U.S.P.T.O.) did not provide any clarifications on the guidelines for patentable living organisms. Instead, it established a case-by-case review process for granting animal related patents. This arbitrary process with respect to patenting of living organisms is still in use in the U.S.. As for synthetic DNA preparations, the U.S.P.T.O. specifies that «*they are eligible for patents in the US because their purified state is different from the naturally occurring compound*»<sup>579</sup>.

In Europe, it took a long time to create harmonised patent legislation, because the European Patent Convention (E.P.C.)<sup>580</sup>, also known as Munich Convention, was signed in 1973 by 16 countries, but it only entered into force in 1977 and only for 7 out of the 16 countries. Over the years, the E.P.C. increased its importance and it actually is binding for 38 countries. It provides the legal framework for the granting of European patents via a centralised procedure and it also establishes the European Patent Organisation and the European Patent Office<sup>581</sup>, which has granted a large number of patents on genetic altered organism. Art. 52 considers patentable as «*any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application*»<sup>582</sup>.

The E.P.C. is integrated by the E.U. Directive 98/44<sup>583</sup>, whose art. 3 recognizes the patentability of inventions containing biological material or processes by which biological material is produced, processed or used, provided they are new, inventive,

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<sup>578</sup> U.S. Patent, n. 4,736,866, 12<sup>th</sup> April 1988. It should be noted that, differently from the U.S.A., Canada's Supreme Court rejected the patent on the Harvard Oncomouse in 2002, setting another distinction, namely between (patentable) lower and (unpatentable) higher forms of life. It did not specify how to draw the line, but transmitted the decision to the legislature, stating that the issue should be settled in the arena of representative democracy.

<sup>579</sup> U.S.P.T.O., *op. cit.*, p. 1093.

<sup>580</sup> See <http://www.epo.org/law-practice/legal-texts/epc.html> (last visited 28<sup>th</sup> January 2013).

<sup>581</sup> See <http://www.epo.org> (last visited 28<sup>th</sup> January 2013).

<sup>582</sup> See art. 52 E.P.C. for patentable inventions in general terms and Rules 26-29 implementing E.P.C. (*Implementing Regulations to the Convention of the Grant of European Patents of 5<sup>th</sup> October 1973*, 2001). In particular, see Rule 27, which states that «*biological material which is isolated from its natural environment or technically produced even if present in nature (nucleic acid molecules, proteins, cells, etc.); plants or animals if not confined to a particular variety, e.g. transgenic plants or animals; Microbiological processes and products (e.g. microorganisms)*» are also patentable.

<sup>583</sup> Directive 98/44/EC of the European Parliament and of the Council of 6<sup>th</sup> July 1998 on the legal protection of biotechnological inventions, in *O.J. L* 213/1998.

susceptible of industrial application. Plants, animals and essential biological processes are excluded from patentability and inventions concerning plants are only patentable if their technical feasibility is not confined to a particular plant or animal variety (art. 4). Elements isolated from the human body, including gene sequences, are patentable, even if the structure of the element is identical to that of the natural element (art. 5 § 2).

Both the U.S. and the E.U. patent system use traditional criteria for patents such as “*novelty, non-obviousness, and enablement*”. However, the point to note here is that they also refer to “*utility*” and “*moral utility doctrine*”.

“*Utility*” requires that a claimed invention either has a well-established utility or asserts a specific, substantial, and credible utility. “*Moral utility doctrine*”<sup>584</sup> prohibits the patenting of life-forms which are considered to be “*immoral, frivolous or injurious to the well being, to good policy, or to the sound morals of society*”. These two clauses have been especially invoked in the field of genetic engineered organisms, where it is much more evident that the doubt of whether those inventions and discoveries should be considered as the common heritage of mankind. However, in the U.S. the concept of “*moral utility*” is not very often quoted and there are no specific clauses providing exceptions for patentability. One of the few exceptions to this was the rejection of Dr. Newman and Jeremy Rifkin’s human-chimera patent application in 1998. It was rejected on the basis that it embraced a human being, so it could not be patentable<sup>585</sup>. On the other hand, in the European context, the concept of “*moral utility*” is more emphasised. In E.P.C. the patentability is denied when the commercial exploitation of inventions would be contrary to “*public order of morality*”<sup>586</sup>. The E.U.’s Biotech Directive also prescribes this “*moral clause*” (art. 6 § 2)<sup>587</sup>, in the part where it denies patentability of: “*(a) processes for cloning human*

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<sup>584</sup> T. MAGNANI, *The Patentability of Human-Animal Chimeras*, in *Berkeley Technology Law Journal*, 14, 443, 1999.

<sup>585</sup> See B. ENERSON, *Protecting Society from Patently Offensive Inventions: The risk of reviving the moral utility doctrine*, in *Cornell Law Review*, 685, 89, March 2004.

<sup>586</sup> See art. 53 (a) of the E.P.C.

<sup>587</sup> See also Rule 23 implementing E.P.C., which states the following: «(1) *The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions; (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element; (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application*».

*beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes”.*

Thus, within the European area, the invention cannot be patented if it violates human dignity and/or basic constitutional norms and values, and thus if invention undermines the foundations of the moral, social and institutional order.

When applied to synthetic biology, patent requirements are not difficult to satisfy. Indeed, with synthetic biology the “isolating” condition for the gene is not even necessary. It is entirely likely that one researcher uploads a DNA sequence onto a computer, “print out” a copy of that DNA sequence, and patent it as an invention, or he/she creates novel DNA sequences with computer algorithms and insert them into organisms, and thus patenting them. Currently, patents on synthetic products and processes/methods for building synthetic DNA, synthetic genes and DNA sequences, synthetic pathways, synthetic proteins and amino acids, and novel nucleotides that replace the letters of DNA have been patented in the U.S.A..

However, the requirements of “*utility*” and “*morality*” entail that synthetic products should be engineered and targeted for well-defined functions and they need to demonstrate at least one beneficial application to society in order to pass this test. With reference to the second requirement, the concept of human dignity could have something to say and, at least in Europe, it could limit the patentability of synthetic products and processes. Indeed, the focus on morality “opens the doors” to human dignity, and dignity is considered here as an intrinsic value that characterizes each human member<sup>588</sup> and as a limit to intervention in patentability, i.e. «*human dignity as constraint*»<sup>589</sup>. In other words, dignity here is seen both as a connotation of humanity and as a limit to some freedoms in order to protect public goods, such as morality and order. In fact, the patentability of synthetic products gives rise to moral dilemmas, beyond the techno-economic ones. In this sense, dignity could become a relevant element in order to mark the border of admissibility of some deliberative

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<sup>588</sup> H. SPIEGELBERG, *Human Dignity: A Challenge to Contemporary Philosophy*, in R. GOTESKY, E. LASZLO (EDS.), *Human Dignity. This Century and the Next*, New York, 1970, p. 55.

<sup>589</sup> D. BEYLEVELD, R. BROWNSWORD, *Human Dignity in Bioethics and Biolaw*, Oxford, 2002, p. 1-47.

actions in the patentability system. Thus, it constitutes a reason for restraining certain forms of biocommerce<sup>590</sup>, but it cannot be thought as a barrier in contrast with liberties. On the contrary, it is complementary to liberties and it is a way to emphasize the attention to some “common goods” (such as human species and environment), without which freedoms and liberties could not find fulfilment.

If the rationale underlying the “moral clause” is clear and its link with dignity is visible, what is not so evident is the identification of the cases in which the clause concretely applies.

Considering the international<sup>591</sup> and European<sup>592</sup> framework, however, it appears that there is one case in which the application of the “moral clause” is surely shared among the countries: it is the case of the patents that could violate the idea of human genome as a common heritage of humankind<sup>593</sup>. Indeed, if the patentability is requested for procedures or products claiming to alter the genetic identity of human beings, the dignity of each human singularly taken and of the whole humanity would be affected. In this sense, the human genome is assimilated to human dignity, and it is by nature untouchable and non patentable. So, the application of the “moral clause” could be at stake when dignity is affected by completely altering the genetic essence of humans through synthetic biology or, at least in the E.U. context (as art. 6 Directive 98/44 states), for example, during the creation of totipotent cells through

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<sup>590</sup> See ECJ, case C-377/98, *Netherlands v. EP and the Council*, 2001 E.C.R. I-7079, paras. 199-215.

<sup>591</sup> See U.N.E.S.C.O., Universal Declaration on Human Genome and Human Rights, 1997; U.N.E.S.C.O., Declaration on the responsibilities of present generations towards the future ones, 12<sup>th</sup> November 1997; U.N.E.S.C.O., International Declaration on Human Genetic Data, 16<sup>th</sup> October 2003; U.N.E.S.C.O., Universal Declaration on Bioethics and Human Rights, 19<sup>th</sup> October 2005; W.H.O., Declaration on cloning, 18<sup>th</sup> March 1997; W.H.O., Resolution on cloning in human reproduction, 14<sup>th</sup> March 1997; U.N., General Assembly, Declaration on human cloning, 8<sup>th</sup> March 2005; COUNCIL OF EUROPE, Recommendation n. 934/1982 on genetic engineering; Recommendation n. 1046/1986 on usage of human embryos and foetus for diagnostic, therapeutic, scientific, commercial, industrial purposes; Recommendation n. 1100/1989 on the use of embryos and foetus in scientific research; Recommendation 1512: Protection of the human genome, 2001; Convention on the human rights and biomedicine, 19<sup>th</sup> November 1996.

<sup>592</sup> E.U. PARLIAMENT, Resolution on ethical and legal problems of genetic manipulation, 6<sup>th</sup> March 1989; Resolution on artificial fecundation in vivo and in vitro, 16<sup>th</sup> March 1989; Resolution on cloning of human being, 28<sup>th</sup> October 1993; Resolution on the protection of human rights and dignity of human being as regards biotechnological and medical activities, 20<sup>th</sup> September 1996; Resolution on human cloning, 7<sup>th</sup> September 2000.

<sup>593</sup> The reference to DNA as a common heritage of humanity, whose patentability would affect human dignity, is highly criticised by Resnik (D. RESNIK, *The human genome: common resource but not common heritage*, 2005, at <http://edepot.wur.nl/137701>, last visited 28<sup>th</sup> January 2013), who affirms that there is not such a thing as a common genome, as the variations among humans are elevated, and only 1,5% of genome is typical of human species, while the rest is shared with other species; so, it would be better to consider it as a common resource to be protected, but not as a heritage.



synthetic methods, producing chimeras from germ-cells, cloning a human being, modifying germ-line cells, and so on.

In another hypothesis, such as with reference to pluripotent cells, the doubts of the application of the “moral clause” remain and a consensus about it has not yet been reached.

A recent and meaningful case in which the applicability of “moral clause” contained in the Directive 98/44 can be seen is in the *Brüstle* decision by the E.C.J.<sup>594</sup>, in response to a preliminary ruling concerning the interpretation of art. 6(2) (c) of the Directive. The case started, at the national level, from Greenpeace’s request for the annulment of the patent held by Mr Brüstle on isolated and purified neural precursor cells, the processes for their production from embryonic stem cells and their use for therapeutic purposes (as for treatment of Parkinson’s disease). More specifically, the researcher had obtained the patent for transplanting immature precursor cells, still capable of developing (i.e. cerebral tissue from human embryos existing only during the brain’s development phase, thus at blastocyst stage) into brains. Those immature precursor cells had to be destroyed for being implanted. The German Federal Court of Justice, after the annulment of the patent by the Federal Patent Court, addressed the E.C.J., asking, among other things, which definition of “human embryo” should be accepted within the meaning of and for the purposes of the application of Article 6(2)(c) of the Directive (so that to understand whether the cells used by Brüstle could be considered as “human embryos” and, therefore, the process could not be patentable), and whether an invention is unpatentable even though its purpose is not the use of human embryos (such as the patent for a product whose production necessitates the prior destruction of human embryos).

What matters here is that the E.C.J., after pointing out the necessity of a uniform interpretation of E.U. law about issues that are ethically sensitive among the E.U. States and towards which different views exist in the European territory, because of the different traditions, values and cultures, gives a definition of “human embryo” linking it with human dignity. The E.C.J. tries to enucleate a European public order and morality. It recognizes E.U. as a community based on human rights and human dignity, and not only as an economic union. In the light of these values

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<sup>594</sup> Case C-34/10, *Oliver Brüstle v. Greenpeace*, 18<sup>th</sup> October 2011.

and rights that are pointed out in the Preamble and in many parts of the Directive, as well as in Nice Charter, a concept of “human embryo” is offered. This concept is autonomous from national definitions and it refers only for the purposes of application of the Directive. Such concept is «*any human ovum, as soon as fertilised, since that fertilisation is such as to commence the process of development of a human being*» and also «*non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis*»<sup>595</sup>.

With regards to stem cells obtained from a human embryo at the blastocyst stage (such as Brüstle’s cells), the Court leaves to the national Tribunal to determine, in the light of scientific developments, whether they are capable of commencing the process of development of a human being and whether they are, therefore, included within the concept of “human embryo” within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive.

Moreover, the Court also considers an invention as unpatentable, even though the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos.

The broad interpretation of “embryo” has very much been criticised all over Europe<sup>596</sup>, as it would have detrimental effects on research, of which will be discussed in greater detail in subsequent sections. It needs to be stressed here, *claris verbis*, that the E.C.J. connects the “moral clause” to human dignity and seeks to delineate its own role as guardian not only of economic interests, but of values as well. Although it clearly says that its purpose is to remove obstacles to trade and to the smooth functioning of the internal market (that could arise when there is a lack of a uniform definition of the concept of human embryo which lead the authors of

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<sup>595</sup> Para. 35 and 36.

<sup>596</sup> It should be noted that in December 2012, the German Federal High Court, while apparently applying the E.C.J. decision in full and restricting the scope of Brüstle’s patent, exploited the margin of discretion that had been granted to it, in order to determine whether the pluripotent embryonic stem cells that are ultimately derived from human embryos (in this case, blastocyst) should themselves be classed as “human embryos”. To put it briefly, the Court stated that the mere embryonic stem cell would require very significant intervention to commence the path of development towards a person. Similarly, *in vitro* embryonic stem cells would be incapable of developing into person without significant intervention. On this basis, the Federal Court held that embryonic stem cells are not “human embryos” for patent purposes. So, embryonic stem cell lines that do not require the destruction of a “human embryo” (e.g. a blastocyst) remain patentable in Germany (see B.G.H. Decision of 27<sup>th</sup> November 2012, case n. X ZR 58/07).

certain biotechnological inventions to seek their patentability in the Member States which have the narrowest concept of human embryo), in reality the attempt is to offer foundations for a European public order and morality, as well as quoting human rights and dignity as central. However, the moral pluralism and the difference of cultures and traditions among the States cannot be neglected, and so this ruling does not solve the issue of what those clauses really mean and how a European interpretation could be related to national discretion.

In conclusion, the patentability of synthetic products or processes in the U.S. and in Europe is already following, and will continue to follow, the same requirements for patentability of biotech products or processes. It is probable that in the U.S. the limits to patentability will only be referred to “public order” reasons (in the light of W.T.O. framework and on the basis of interpretation of E.P.O.), such as when patentability is requested for products having bioterrorist reasons that would destroy the constitutional order<sup>597</sup>, while the “moral clause” related to human dignity will not be applied. Instead, in the E.U. context, it is much simpler to hypothesise that the limits for patents fixed by normative framework and by judicial decisions too will play a role for synthetic biology. In fact, the Brüstle case could have effects on patentability of synthetic elements too, in the hypothesis synthetic research is conducted upon human embryos, i.e. working with them and their genetic sequences for deriving synthetic DNA sequences or other products.

### *2.3.3. Dignity for Synthetic Organisms and Living Machines?*

Synthetic biology challenges the scientific concept of life, leading to produce entities that are entirely new or, however, different from our “traditional” conception of “natural” and “artificial”. Such novelty challenges the concept of “life” and, moreover, the notion of dignity that is usually associated to human beings and human life. Indeed, the alteration of “life” and the birth of synthetic organisms and living machines leads to the consequence of the thought on their moral status, i.e. their

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<sup>597</sup> See I. SCHNEIDER, *To Be or not IP? Exploring limits within patent law for the constitutionalization of intellectual property rights and the governance of synthetic biology in human health*, in *Law and the Human Genome Review*, 37, July-December 2012.

dignity. Thus, it is necessary to check whether it can go out of its “human” borders in relationship with synthetic products, and to discuss about whether these products have a moral status or not, and if they could be gifted with a dignity that is not the human one, but is recognisable to non-human beings. Therefore, it is evident that in this ambit synthetic biology challenges dignity on two sides: (a) with regards to the “what should be done” from the moral point of view, and (b) with regards to the “who possesses dignity”.

As demonstrated clearly by the Swiss Commission on Bioethics<sup>598</sup>, there are different positions in this regard, and the main ones are: (1) the anthropocentric view (which assigns value only to humans, for their coming from God’s image or for having particular features such as consciousness or rationality or others that make them superior to any other being); (2) the pathocentric one (which equalizes microorganisms to humans only if they can perceive a damage or feel pain); and (3) the biocentric view (that affirms that synthetic products have an inherent value and deserve moral value because they possess “life”).

According to the anthropocentrism, synthetic products do not have dignity and this concept remains attached to human beings only. This is because its broadness would lead to a “slippery slope”<sup>599</sup> in the sense of reducing life to a mechanic assemblage of elements and to lower the importance and value of it, thus damaging the image that humans have of themselves and of their own dignity<sup>600</sup>.

According to the other views, instead, synthetic products could have dignity, independent from the way they originate, simply because they have features such as feeling pain, and being equipped of life meant in its new conception, as previously

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<sup>598</sup> Similar views are also indicated in E.G.E., *op.cit.*, p. 41.

<sup>599</sup> The concept of “slippery slope” is frequently invoked in bioethical issues, such as end-of-life decisions, abortion, stem cell research by whom think that, once admitted a certain situation (such as the possibility of abortion or euthanasia), this would lead to a “chain effect”, to a spread of the activity, to abuses or to the broadness of legitimacy.

<sup>600</sup> For example, Joachim Boldt and Oliver Müller state that if synthetic beings are about to be considered as worth of dignity, it “*may in the (very) long run lead to a weakening of society’s respect for higher forms of life*” (J. BOLDT, O. MÜLLER, *Newtons of the leaves of grass*, in *Nature Biotechnology*, 26, 4, 2008, p. 387-389). In the same line there is Fukuyama, according to whom human beings are the only ones that possess “*a mysterious essential human quality called «Factor X», [...] unique about the human race that entitles every member of the species to a higher moral status than the rest of the natural world*” (F. FUKUYAMA, *Our Posthuman Future: Consequences of the Biotechnology Revolution*, New York, 2002, p. 149).

defined. If those synthetic creatures have a moral status and own a dignity, it follows that there are also some duties towards them.

The attribution of dignity to synthetic beings is a “hot topic” and synthetic biology could lead to the overturning of traditional models, founded on species as an attribution of morality and dignity, and leading to the assignment of an intrinsic value to synthetic organisms in contrast with an instrumental use of nature for human purposes. A new facet of dignity should be moulded with reference to synthetic biology products that are neither persons nor machines (and in this regard a new notion of «*biofact*»<sup>601</sup>, mixing “*bios*” and “*artefact*”, has been proposed).

With this, it is very meaningful to take into account, in a comparative perspective, the Swiss Constitution which has elaborated the “dignity of creature”, thus showing a biocentric approach. Indeed, Swiss Constitution distinguishes between “*human dignity*” defined as the “*moral right not to be humiliated*”, and “*dignity of creatures*”, conceived as the “*inherent value of nonhuman living beings*”<sup>602</sup>. As Balzer and others state, in the first case we are in front of a *right*. In the second we are in front of a *value*<sup>603</sup>, which is meant as a “second level” quality, since non human living beings own life but, differently from humans, they are not able to perceive humiliation and to react in cases of violation of it. The attribution of dignity to creatures avoids the matter of who the creator is<sup>604</sup> and entails to behave towards the creature in such a way to respect its “*well being*”. What the expression of “well being” means remains unclear. It could refer to (a) the specific features of the species to which the creature belongs, (b) to individual genome (in the sense that the genome should not be modified, otherwise the well being” of the creature would be altered), or (c) the sum of abilities and functions that are normally pursued by the

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<sup>601</sup> N.C. KARAFYLLIS (ED.), *Biofakte. Versuch über den Menschen zwischen Artefakt und Lebewesen*, Paderborn, 2003.

<sup>602</sup> See Federal Constitution of the Swiss Confederation, 18<sup>th</sup> April 1999. In particular, see art. 7 about human dignity and art. 119-120 for the dignity of creatures.

<sup>603</sup> P. BALZER, P. RIPPE, K.P. SCHABER, *Two Concepts of Dignity for Humans and Non-Human Organisms in the Context of Genetic Engineering*, in *Journal of Agricultural and Environmental Ethics* 13, 2000, p. 15 ff.

<sup>604</sup> For this consideration, see B. BAERTSCHI, *La vie artificielle. Le statut moral des êtres vivants artificiels*, *Beiträge zur Ethik und Biotechnologie*, vol. 6, Berna, 2009.

organism. The interpretation under (c) is the preferred one about the significance of “well being”<sup>605</sup>.

In art. 119, II, lett. b) of the Swiss Constitution it is forbidden to transfer (and fuse) non human germinal and genetic inheritance into (and with) the human one. This results in impeding a further development of synthetic biology as a “mixture” of genomes coming from different species. However, the following art. 120 of the Swiss Constitution about genetic engineering in non human ambit allows the use of germinal and genetic heritage of animals, plants and other organisms, provided that the dignity of creature is respected along with the security of human beings, animals and the environment. Therefore, it seems that some streams of synthetic biology could not be allowed under the Swiss Constitution, but the use of microorganisms for synthetic purposes (that look like an evolution of the genetic engineering in non human ambit) is possible. However, a particular care of not altering the dignity of the creatures is required. In this sense, the notion of dignity as referred to non human creatures would correspond to the concept of integrity and respect of the inherent functions of a being<sup>606</sup>. So, in line with the Swiss choice, the idea of dignity could find itself in the necessity of being re-shaped in the light of evolution and development of synthetic biology.

In my opinion, such coincidence between dignity and integrity that Swiss Constitution provides risks to confirm that idea that dignity is merely ornamental and does not have an autonomous function, but is used as synonym of other concepts. For this reason, I think that, in order to preserve the centrality of dignity, the two concepts must remain separate and not overlap. This does not mean to embrace a rigid anthropocentric view that recognises dignity as “attachable” only to humans, but neither to make dignity synonymous to other concepts. So, the “lesson” that could be learnt from Swiss Constitution is to recognise a value to creatures and to admit the importance of protecting their “well being”, and thus corresponding a sort of legal protection to them. However, the status of creatures cannot be the one of “dignity” in the terms that has been elaborated so far.

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<sup>605</sup> P. BALZER, P. RIPPE, K. P. SCHABER, *op. cit.*, p. 23 ff.

<sup>606</sup> In fact, the French translation of the Swiss Constitution does not mention «dignité», but «l'intégrité des organismes vivants», while the German version talks of «der Würde der Kreatur», the Italian about «dignità della creatura», the Rhaeto-Romanic of «la dignitad da las creatiras».

2.3.4. *Dignity in the Case of Human Enhancement: Post Human Dignity, or the Integrity of Gene Pool and the Rights of Future Generations?*

If synthetic biology could create beings that are able to express signs of rationality but do not belong to the human species, and thus referring to the frontier between machines and humans and challenging the notion of dignity as referred to these beings too or not, there is another aspect that cannot be under evaluated. This is the matter of “enhancement”<sup>607</sup>. Indeed, human beings could be the object of attention of synthetic biology that may be used for enhancing some human beings and for improving its features, beyond the intended therapeutic purposes.

At the moment synthetic biology focuses only on microorganisms that are the starting point or the final product of the activities of synthetic biology, but nothing excludes the possibility that in the long term synthetic biology could involve all living organisms, including human beings. As per Bhutkar question: «*would human embryos based on synthetically generated germ cells with a reduced set of «essential» genes, be possible?»*<sup>608</sup>. If the answer were “yes”, the immediate question that arises is: «*Will they have a “moral status” based on dignity or not?»*<sup>609</sup>.

Among the different kinds of enhancers, having short or permanent effects (such as smart drugs, doping for the first group or aesthetic surgery for the second category), there are the genetic modifications that affect the gene pool of generations. In the face of this type of enhancement that alters the human genome through germ-line interventions in human beings which are susceptible to being transmitted to the descendants, there is no general agreement and the debate seems to be dichotomised into two positions: (a) transhumanists affirm that enhancement manipulations are good and morally due for the benefit of humankind, while (b) bioconservatives are against any kind of intervention. Moreover, it is not clear how dignity is implicated here. The relationship between the integrity of human DNA and human dignity is, in fact, often questioned.

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<sup>607</sup> The topic of enhancement is very much dealt with in the contemporary bioethical debate. For further details, see N. BOSTROM, J. SAVULESCU (EDS.), *Human Enhancement*, Oxford, 2009.

<sup>608</sup> A. BHUTKAR, *op. cit.*, p. 26.

<sup>609</sup> *Id.*

To put it briefly, transhumanists<sup>610</sup> do not see any problem in manipulating human genome and making better human beings. Indeed, in their perspective, the interventions on humans through therapies after the birth is not different from the interventions before birth. They believe that there exists no human “essence” or “nature”, but only an organic complex of biological and psychological functions. In this way, some changes and interventions are not unwelcome, as they would affect no human “essence”<sup>611</sup>. Nature has no normative value and it is not the criterion for determining moral behaviours. Furthermore, they do not understand why it would be morally good to preserve the current human species, when a better species could be generated in the future. For these reasons, they propose to introduce a notion of «*post human dignity*»<sup>612</sup>. As Harris points out: «*Whether the new creatures are created by synthetic biology or by mixing the elements of different species or, indeed, through multiple forms of technology, we may, indeed, in all probability we must and we will, create new types of creatures that might join and, we may hope, will eventually replace us*»<sup>613</sup>. From here, the consequence is the urgency to «*take the «human» out of human rights. And indeed the “dignity” out of human dignity. Analogous arguments show that the concept of human dignity is equally vacuous and redundant*»<sup>614</sup>. So, transhumanists suggest that dignity is meant to be (a) a moral status, i.e. the intrinsic right to be treated with a basic level of respect, and (b) it is also the quality of being worthy or honourable. Such dignity as a right and as a quality must be possessed by the posthuman being. Transhumanists also think that

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<sup>610</sup> The term “transhumanism” is believed to be coined by Julian Huxley in 1957, with the meaning of a human going beyond his/her borders and realizing new potentialities of his/her nature (see J. HUXLEY, *New Bottles for new Wines*, London 1957). According to others, instead, the term comes out as an abbreviation of “transitional human”, elaborated by Fereidoun Esfandiary (1966), that wrote the famous text “*Are You a Transhuman?*” (F.M. ESFANDIARY, *alias* FM-2030, *Are you a Transhuman?*, London 1989). The main supporters of transhumanism currently are Max More that founded the *Extropy Institute* in 1992 and the *World Transhumanist Association* founded in 1997 by Nick Bostrom and David Pearce. In Italy a Transhumanist Association was born in 2004 and in 2008 it enacted a Manifest of transhumanist ideas, such as the belief in the liberation of humanity from suffering, the opening to any kind of progress and to the amelioration of humans (see at <http://www.transumanisti.it>, last visited 28<sup>th</sup> January 2013).

<sup>611</sup> See A. BUCHANAN, *Human Nature and Enhancement*, in *Bioethics*, 23, 3, 2009, p. 141-150. See also A. CAPLAN, *Is it wrong to try to improve human nature?* in P. MILLER, J. WILDSON (ED.), *Better humans? The politics of human enhancement and life extension*, London, 2006, p. 31-39.

<sup>612</sup> N. BOSTROM, *op.cit.*, p. 209.

<sup>613</sup> J. HARRIS, *Taking the «Human» Out of Human Rights*, in *Cambridge Quarterly of Healthcare Ethics*, 2011, p. 1.

<sup>614</sup> *Ibid.* See also R MACKLIN, *Dignity is a useless concept*, in *British Medical Journal*, 327, 2003, p. 1419–1420.



human and posthuman dignity are compatible and complementary, as they consider dignity as consisting «*in what we are and what we have the potential to become, not in our pedigree or our causal origin*»<sup>615</sup>. Like babies that are born from *in vitro* fertilization and have the same legal status and rights as “natural” babies, the possible synthetic humans should have the same rights belonging to “classical” humans. The extension of human capabilities through progress and the amelioration of their life conditions through technology has not changed human dignity. In the same way, transhumanists do not perceive a moral difference between technological and other means of enhancing human lives (such as through synthetic biology).

Instead, bioconservatives are generally opposed to the use of synthetic biology to modify human nature. They believe that if conceived as a human enhancement technology, synthetic biology would undermine our human dignity. Thus they propose broad bans on human enhancements and oppose to posthuman dignity as they believe that it is a threat to human dignity. In their perspective, tackling with nature and “playing God” would alter human nature, human species and human dignity<sup>616</sup>. Moreover, if the enhancement was pursued, it would create disparities and inequalities between the «*first and second-class humans*»<sup>617</sup>. In addition, the dream of ameliorating human life could lead to the opposite side of killing in the name of it, i.e. for the same reasons of amelioration that could be pursued by «*a power that has set itself as a warrant of population health, as one defending and perfecting not only the mechanisms of socio-political organization but also, and above all, the biological processes within social body. This leads to the tragic paradox according to which the safeguard of the whole, the species, requires the elimination of one part*»<sup>618</sup>.

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<sup>615</sup> N. BOSTROM, *op.cit.*, p. 213.

<sup>616</sup> Günther Anders for example speaks of a passage from *homo faber* to *homo creator* through tackling with nature (see G. ANDERS, *L'uomo è antiquato* (1956), 1, *Considerazioni sull'anima nell'epoca della seconda rivoluzione industriale* e Id., *L'uomo è antiquato*, 2, *Sulla distruzione della vita nell'epoca della terza rivoluzione industriale*, Torino 2003, vol. II, p. 15).

<sup>617</sup> See J. RIFKIN, *Biosphere Politics: A New Consciousness for a New Century*, New York, 1991; H. ROLSTON III, *What Do We Mean by the Intrinsic Value and Integrity of Plants and Animals?*, in D. HEAF, J. WIRTZ (EDS.), *Genetic Engineering and the Intrinsic Value and Integrity of Animals and Plants*, 2002, U.K., p. 5-10.

<sup>618</sup> Translation from R. ESPOSITO, *Biopolitica, immunità, comunità*, in L. BAZZICALUPO, R. ESPOSITO, *Politica della vita*, Roma-Bari, 2003, p. 126-129.

At the moment, the ban of altering the human genome and the protection of genetic integrity, grounded on dignity, is clearly mentioned in some Constitutions, like the aforementioned Swiss Constitution in art. 119. This is to safeguard human beings from the abuses of genetic engineering, and to prohibit any kind of cloning and intervention on the gene pool of gametes and human embryos and any transfer or fusion of non human gene pool into the human one<sup>619</sup>. Some other Constitutions, instead, do not quote the right to safeguard the genetic integrity but interpret the new rights of genetic ambit in the light of dignity, psycho-physical integrity, right to health, freedom of self-determination<sup>620</sup>.

The idea of human genome as a common heritage of humankind that must be preserved as untouchable non altered, and being beneficial for future generations, has been declared at international and European level. As previously mentioned, it is this rationale that justifies the oppositions to any alteration of it.

The focus is posed on current and future generations (that become subject of rights as well)<sup>621</sup>, since the intervention on human genome affects humans not only in the current time but in future as well<sup>622</sup>, and so the duty of current generations is to preserve it. The human genome, indeed, «*underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity*»<sup>623</sup>. In other words, it

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<sup>619</sup> For instance, the Portuguese Constitution recognizes the right to genetic identity (art. 26, III) of the human being and his/her dignity in the creation, development and application of technologies and in genetic experimentation.

<sup>620</sup> See A. D'ALOIA, *I diritti come immagini in movimento. Tra norma e cultura costituzionale*, Introduzione, in A. D'ALOIA (ED.), *Diritti e Costituzione. Profili evolutivi e dimensioni inedite*, Milano, 2003, XVII.

<sup>621</sup> For further details about the legal right to attribute to future generations, see J. CHET TREMMEL (ED.), *Handbook of Intergenerational Justice*, Cheltenham, U.K., Northampton, M.A., 2006. With regards to the ethical issues related to future generations, see N. BOBBIO, *op. cit.*, p. 63 ff.; A. TARANTINO, *Diritti dell'umanità e giustizia intergenerazionale*, in A. TARANTINO, (ED.), *Filosofia e politica dei diritti umani nel terzo millennio*, Milano, 2003, p. 431-474; G. LIMONE, *La scienza contemporanea al confronto con le generazioni future*, in L. CHIEFFI (ED.), *Bioetica e diritti dell'Uomo*, Torino, 2000, p. 1 ff.; F. FUKUYAMA, *op. cit.*

<sup>622</sup> See R. BIFULCO, *Diritto e generazioni future. Problemi giuridici della responsabilità intergenerazionale*, Milano, 2008; E. BROWN WEISS, *In Fairness to Future Generations: International Law, Common Patrimony and Intergenerational Equity*, Tokio, 1989; C.M. ROMEO CASABONA, *La globalizzazione e il ruolo dinamico dei diritti umani in relazione a una prospettiva comune per la biotecnologia umana*, in R. BIFULCO, A. D'ALOIA (EDS.), *Un diritto per il futuro. Teorie e modelli dello sviluppo sostenibile e della responsabilità intergenerazionale*, Napoli, 2008, p. 323 ff..

<sup>623</sup> U.N.E.S.C.O., Universal Declaration on the Human Genome and Human Rights, cit., art. 1.

must be intended as «*an intergenerational common good*»<sup>624</sup>, upon which any act of self determination cannot be pursued, as it would limit the self determination of future humans. It would condition them and the not-yet-born, thus deleting the uniqueness of each being and opening to processes of new eugenics<sup>625</sup>.

So, it is evident that dignity in the case of enhancement is challenged again and it is difficult to understand how to shape it and how to reach a solid conclusion on its role. The reassessment of it is necessary, and it can entail two possible solutions: (a) the shift from the concept of human dignity to a posthuman one, after allowing any modification and intervention on nature, so as to produce new “creatures”, or (b) the ban of any intervention in order to protect the integrity and intangibility of human genome in the name of dignity. These opposite solutions testify that we are in a transition phase.

In my opinion, the reductionist vision of nature as a sum of functions that have no normative value, and thus allowing any modification or alteration of beings up to the disappearance of the whole humanity in the long term, annuls *de facto* the notion of dignity. The fact of bringing dignity out of the human would mean to consider dignity as merely a “label” that can be “moved” in dependence of the

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<sup>624</sup> A. FALCONE, *Biotechnologie e tutela della biodiversità e delle risorse genetiche. Principi e diritti emergenti a tutela delle generazioni presenti e future*, in R. BIFULCO, A. D’ALOIA (ED.), *op.cit.*, p. 203 ff.

<sup>625</sup> This is the position expressed by Jurgen Habermas and Hans Jonas (see J. HABERMAS, *The future of human nature*, Cambridge, 2003; and H. JONAS, *The Phenomenon of Life: Toward a Philosophical Biology*, New York, 1966). In the same line, see Francis Fukuyama, according to which the transhumanist ideas would lead to lose the intrinsic value of beings that are the essence of liberalism (see F. FUKUYAMA, *op. cit.*). The term “eugenics” (literally “good birth, good descendance”) was coined by Francis Galton (1822-1911), Darwin’s cousin, to refer to a field of science that dealt with the study of factors that could ameliorate or block the racial qualities of future generations from the psychic and physical point of view (see F. GALTON, *Hereditary Genius: Inquiries into human faculty and its developments* (1869), at <http://galton.org/books/hereditary-genius/text/pdf/galton-1869-genius-v3.pdf>, last visited 28<sup>th</sup> January 2013). From his view, the ideas of selection of humans as a prerequisite of progress was formed. At the beginning of the 20<sup>th</sup> century eugenics appears as a policy of the State, culminated in the sadly known Nazi programs in extermination camps, such as “Aktion T4” and “Neue Aktion 14F13”. However, before Nazi policy, in the U.S. sterilization programs were promoted (see the bills about castration of mentally ill people, epileptic and habitual criminals in Michigan, 1898, or the laws of marriage restrictions in Connecticut, 1896, or the compulsory sterilization in Indiana, 1907. See also the case of *Carrie Buck v. Bell*, 274 U.S. 200 (1927). For further details, see D.W. MEYERS, *The Human Body and the Law*, New Jersey, 2006.). According to Habermas, nowadays such “State eugenics” is substituted by the new, liberal one, based on individual and private preferences. The intervention on human genome would be part of this group, altering the image of human beings, and the future beings’ right to uniqueness, to pluralism, to difference. In Jonas’s opinion, the admissibility of modification of genome would make impossible a shared ethics. Indeed, the fact of belonging to a same species and the recognition of the Other would become impossible.

changes upon humans. In this perspective, dignity is simply a quality which follows humans (from “natural” to “post humans”), thus depending on them. This position would empty the content and significance of dignity, making it a mere ornamental “label” and a piece of rhetoric. For avoiding such risk and preserve the original significance that dignity has, as from the interpretation of the aforementioned legal documents at the international, European, and national level, dignity should be brought back to its original position. This means that dignity is strictly inherent to human beings and has the role of indicating the way how to treat them. This is not to say that enhancement through synthetic biology should be banned, or that dignity entails the impossibility of any intervention. Instead, this is to say that in the matter of enhancement through synthetic biology the role of dignity in indicating the relevance of human value not only in its biological dimension should be taken into account, also by considering the importance of future generations. In this way, dignity could indicate the way how to develop enhancement projects as well. So, according to me, the interventions of enhancement through synthetic biology are not to be banned, but in their progress they should proceed in a prudent way and never arrive at the point of annulling human dignity.

### *2.3.5. Dignity and International Justice Concerns: the Connection with the Principles of Justice and Solidarity.*

Dignity is the basis for more specific principles, rights and obligations, and is also closely connected to the principle of “justice and solidarity” which finds itself playing a significant role in the light of international justice concerns. On this ground, dignity must be read both (a) in a collective sense, as a heritage and feature of the whole humankind, and (b) in connection with other human rights and principles, such as the right of equality and the principles of justice and solidarity<sup>626</sup>, in order to strengthen them. So, human dignity underlines the importance of an equal distribution of resources and of equal access to them by everybody all over the world, especially in front of the global development of “bioeconomy”.

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<sup>626</sup> The notion of solidarity lies on the Kantian concept of human being to be treated as an aim, never as a means.

The aforementioned legal texts at the international and European level stating dignity with reference to human genome<sup>627</sup> also state the right of all human beings in participating in the benefits that derived from the applications of scientific research in genetic field. Solidarity, composed of the indivisibility and integrity of duties, of the shared responsibility and the plurality of subjects, gives equality to the members of the human community and helps the progress go on. It should be perceived as fundamental to repress inequalities, not as a mere gesture of altruism, but as a necessary aptitude, that identifies itself in the behaviours that respect human dignity. So, solidarity defends dignity, as it protects individuals and their inner value, their belonging to humankind and their being equal in relationship to each other.

In the field of synthetic biology, «*global justice discourse affects issues of technology divide and common heritage, the question of inter-generational justice with implications for preserving the environment and natural resources for future generations*»<sup>628</sup>. In this sense, a reference to dignity, to justice, and solidarity can become a new bioethical paradigm for a good distribution of resources and benefits coming out from synthetic biology applications.

### 3. *The Right to Health.*

Synthetic biology could ameliorate health conditions through its applications, but at the same time it could put human health into risk. So, such double effect of synthetic biology must be investigated.

In order to show how the right to health is implicated within synthetic biology, this section offers a discussion of a few preliminary references of its general content.

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<sup>627</sup> See footnotes 591 and 592.

<sup>628</sup> A. DOBSON (ED.), *Fairness and Futurity. Essays on Environmental Sustainability*, Oxford, 1999.

### 3.1. *The Right to Health at the International, European and National Level.*

Traditionally, health was perceived as “the absence of disease”. The first laws containing health-related provisions go back to the era of industrialization<sup>629</sup>, when the right to health was shaped as a healthcare and public right, in the sense that public health was the primary object of care for the State (i.e. the State had to intervene in the cases of epidemic or pandemic diseases by providing adequate sanitation and quarantines and better work conditions)<sup>630</sup>. In 1903 the Office International d’Hygiène Publique (O.I.H.P.)<sup>631</sup> was created in order to coordinate the measures for public health, and it was later associated with the League of Nations, and ultimately becoming the Health Organization of the League of Nations.

Work-related issues of health were also dealt with in the International Labour Organization (I.L.O.), founded in 1919<sup>632</sup>.

During the Second World War, the right to health started developing as a human right, especially in response to the terrible experiments pursued by Nazi doctors that undermined human dignity and health for research purposes<sup>633</sup>.

At the United Nations (U.N.)<sup>634</sup> Conference on International Organization in San Francisco in 1945, this issue was taken up, and was later reflected in art. 55 of the U.N. Charter, and elaborated in the World Health Organization (W.H.O.).

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<sup>629</sup> The 1802 Moral Apprentices Act and the 1848 Public Health Act were adopted in the United Kingdom as a means of containing social pressure arising from poor labour conditions.

<sup>630</sup> About this historical development of the right to health at the international level, see E. RIEDEL, *The Human Right to Health: Conceptual Foundations*, 2009, at [http://www.swisshumanrightsbook.com/SHRB/shrb\\_03\\_files/01\\_453\\_Riedel.pdf](http://www.swisshumanrightsbook.com/SHRB/shrb_03_files/01_453_Riedel.pdf), p. 21-39.

<sup>631</sup> It was dissolved in 1947, when it was incorporated into the Interim Commission of the World Health Organization.

<sup>632</sup> See at <http://www.ilo.org> (last visited 28<sup>th</sup> January 2013).

<sup>633</sup> See the case of *United States v. Karl Brandt*, Trials of War Criminals Before the Nuremberg Military Tribunals (1948), quoted by J. KATZ, *Experimentation With Human Beings: The Authority Of The Investigators, Subject, Professions And State In The Human Experimentation Process*, New York, 292, 1972. From the Nazi doctors’ trial the so-called “Nuremberg principles” were derived. See also International Code of Medical Ethics of the World Medical Association International (adopted by the 3<sup>rd</sup> W.M.A. General Assembly, London 1949 and amended by the 22<sup>nd</sup> W.M.A. General Assembly, Sydney, Australia, 1968 and the 35<sup>th</sup> W.M.A. General Assembly, Venice, Italy, 1983) and Declaration of Helsinki (adopted by the 18<sup>th</sup> W.M.A. General Assembly, Helsinki, June 1964 and amended by: the 29<sup>th</sup> W.M.A. General Assembly, Tokyo, October 1975; the 35<sup>th</sup> W.M.A. General Assembly, Venice, October 1983; the 41<sup>st</sup> W.M.A. General Assembly, Hong Kong, September 1989; the 48<sup>th</sup> W.M.A. General Assembly, Somerset West, Republic of South Africa, October 1996; and the 52<sup>nd</sup> W.M.A. General Assembly, Edinburgh, October 2000).

<sup>634</sup> In the U.N. context the right to health sounds like «*the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*», shortened to the «*right to the highest attainable standard of health*» or the «*right to health*» (see U.N. Commission on Human Rights,

The big turn in the definition of health and the integration of it with social issues can, in fact, be found in the W.H.O.. In 1946, it started conceiving health in its social and public facet, defining it as «*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*»<sup>635</sup>, and thus integrating physical with social elements of well being.

In 1978 the Declaration of Alma-Ata on Primary Health Care (not binding) stated that the States pledged to progressively develop comprehensive health care systems to ensure effective and equitable distribution of resources for maintaining health<sup>636</sup>. So, the development of health care systems was seen as a means to give application to the right to health. In the context of the Alma-Ata Conference, the W.H.O. launched the “*Health for All by the Year 2000*” plan, which initiated goals and programs to achieve minimum levels of health for all<sup>637</sup>. Such objectives were repeated in the following conferences in Ottawa (1986)<sup>638</sup> and in Jakarta (1997), where a Declaration enucleating the requirements for the achievement of health («*peace, housing, education, social security, social relations, food, income, women’s empowerment, a stable ecosystem, the sustainable use of resources, social justice, respect for human rights, and equity*») was proclaimed<sup>639</sup>.

From the W.H.O. experience, several international and regional human rights instruments have been enacted<sup>640</sup>, such as (1) the Universal Declaration of Human Rights (art. 25), which recognises the right of all persons to an adequate standard of living, including guarantees for health and well-being, and thus adopting a broad view of health and underlining the relationship between health and other rights, such

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E/CN.4/2003/58). For further details, see P. HUNT, *The human right to the highest attainable standard of health: new opportunities and challenges*, in *Royal Society of Tropical Medicine and Hygiene*, 100, 2006, p. 603-607.

<sup>635</sup> See the W.H.O., Constitution, Basic Documents, Official Document n. 240, Washington, D.C., 1991. It was adopted by 61 States at the International Health Conference held in 1946 in New York.

<sup>636</sup> See W.H.O., Declaration of Alma-Ata, International Conference on Primary Health Care, 6-12<sup>th</sup> September 1978.

<sup>637</sup> W.H.O., *Global Strategy for Health for All by the Year 2000*, Geneva, 1981.

<sup>638</sup> First International Conference on Promotion of Health, which issued the Declaration of Ottawa.

<sup>639</sup> Jakarta Declaration on Health Promotion (1997).

<sup>640</sup> A lot of international conventions state the right to health as well. See, International Convention on the Elimination of All Forms of Racial Discrimination; the Convention relating to the Status of Refugees; the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families; the Geneva Conventions; the Declaration on the Protection of Women and Children in Emergency and Armed Conflict; the Standard Minimum Rules for the Treatment of Prisoners; the Declaration on the Rights of Mentally Retarded Persons; the Declaration on the Rights of Disabled Persons; the Declaration on the Rights of AIDS Patients.

as the right to food and the right to housing, as well as medical and social services, (2) the American Declaration on the Rights and Duties of Man<sup>641</sup> (art. XI) opting for the right to the preservation of health through sanitary and social measures, (3) the Organization of American States' Charter that stresses the importance of health as a contribution to the integral development of the person, and the relevance of access to knowledge of modern medical science, (4) the American Convention on Human Rights that alludes indirectly to the right to health when in art. 26 it encourages the States to take measures to guarantee *«the full realization of the rights implicit in the economic, social, educational, scientific, and cultural standards set forth in the Charter»*, (5) the Additional Protocol of San Salvador<sup>642</sup> in art. 10 explicitly lists six measures that should be taken by states parties to guarantee this right, including the development of universal primary care networks, and it also broadens the look to the right to a healthy environment (art. 11), as derived from the right to health, (6) the European Social Charter (art. 11 about the right to health, art. 3 about the right to safe and healthy working conditions, art. 13 about the right to medical assistance, art. 7 and 17 about the health and wellbeing of children and young persons, art. 8 and 17 about the health of pregnant women, art. 23 about the health of elderly persons), that complements the European Convention of Human Rights with regards to the protection of social and economic rights that in E.C.H.R. are not contemplated<sup>643</sup>, (7) the International Covenant on Economic, Social and Cultural Rights (art. 12) that refers to physical and mental health, and (8) the African Charter on Human and Peoples' Rights (art. 16) that enshrines the right to the highest possible level of health.

Under the U.N. Charter-based system (art. 55 about the right to health), various declarations have been elaborated, such as the U.N. Millennium Declaration of 8<sup>th</sup>

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<sup>641</sup> It was adopted by the Ninth International Conference of American States, Bogotá, Colombia, 1948. At the same meeting the "*Organization of American States' Charter*" was adopted.

<sup>642</sup> Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, Protocol of San Salvador, adopted on 17<sup>th</sup> November 1988.

<sup>643</sup> *European Social Charter* (E.S.C.) (C.E.T.S. n. 35) adopted in Turin on 3<sup>rd</sup> October 1961 (entered into force on 26<sup>th</sup> February 1965) revised in Strasbourg on 3<sup>rd</sup> May 1996 (C.E.T.S. n. 163, entered into force on 1<sup>st</sup> July 1999). See also, in the context of the Council of Europe, art. 3 of the Convention on Human Rights and Biomedicine that enshrines equal access to health care, art. 4 that provides that any intervention in the health field, including research, must be carried out in accordance with the professional obligations and standards (including relevant ethical codes), art. 5 which decrees the basic principle of autonomy of the individual and prescribes the free and informed consent to interventions in the health field.



December 2000<sup>644</sup>, adopted by the U.N. General Assembly, stressing the importance of health care and prevention of disease.

It is also worth mentioning the 2005 U.N.E.S.C.O. Universal Declaration on Human Rights and Bioethics, which in its art. 14 dwells on the right to health and it enunciates a broad view of health including access to quality health care and essential medicines, access to adequate nutrition and water, improvement of living conditions and environment, elimination of the marginalisation and exclusion of persons on any grounds, and the reduction of poverty and illiteracy. Moreover, in art. 15 the methods of benefit sharing are mentioned, such as access to quality health care, provision of new diagnostic and therapeutic modalities or products stemming from research, support for health services, access to scientific and technological knowledge, and capacity-building facilities for research purposes.

In the 1997 U.N.E.S.C.O. Universal Declaration on the Human Genome and Human Rights, art. 12 states that the *«applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole»*, so the benefits coming out from science should be available to everybody. In art. 15 the protection of public health through cooperation among the States and solidarity is promoted, while in art. 18 the importance of international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research is underlined.

Thus, from the international landscape it results that the right to health is usually connected to the right to food, to adequate housing, to healthy environment, to education, to work and working conditions, to right to life, to access to healthcare systems and to benefits of research for health, to physical integrity, to wellness and development.

At the E.U. level, the notion of health develops under two directions. (1) On the one hand, the protection of public health<sup>645</sup> must be pursued, and (2) on the other one, the individual notion of health as a right to be claimed by the single person is

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<sup>644</sup> U.N. General Assembly, *Resolution 2* session 55, United Nations Millennium Declaration on 18<sup>th</sup> September 2000.

<sup>645</sup> For further details, see T. HERVEY, J. MCHALE, *Health Law and the European Union*, Cambridge, 2004.

stated. With regards to the first meaning of health (public one and health as a policy to be pursued by Member States and Institutions, being a shared competence), the Lisbon Treaty has converted the previous art. 152 T.E.C. into the new art. 168 T.F.E.U., where the general idea of E.U. action in the field of health remains the same: «*Community action shall be directed towards improving public health, preventing, human illness and diseases, and obviating sources of danger to human health*» and this by «*encouraging cooperation between the member States*» and «*lending support to their action*». Art. 168 T.F.E.U. also reconfirms that «*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*»<sup>646</sup>. Thus E.U. public health policy objectives consist of protecting public health and fighting against the major health scourges, like cross-border health threats (in which field, E.U. also tries to improve cooperation among the States). The principle of subsidiarity must be respected, and the Council and Parliament should improve measures to protect public health and to fight health threats<sup>647</sup>.

Moreover, art. 3 T.E.U. sets out the main objectives for the European Union, and makes reference to wellbeing, stating that «*the Union's aim is to promote peace, its values and the well-being of its peoples*». Such mention of “well being” is reminiscent of the W.H.O. definition of health. Art. 9 T.F.E.U. also contains a “social clause” which specifically states that European Union policies should take into account requirements linked to social protection, the fight against exclusion, promotion of education and training and the protection of human health, all of which may impact on health policy and serve as a tool to promote health in other policy areas. In addition, art. 11 T.F.E.U. enucleates the duty for institutions to «*maintain an open, transparent and regular dialogue with representative associations and civil*

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<sup>646</sup> For implementing art. 168 T.F.E.U., the E.U. has developed the “*EU Health Strategy and Health Programme*”. For the assessment of emerging and epidemic threats, the European Centre for Disease Prevention and Control in Stockholm has been created, while the European Medicines Agency (E.M.A.), settled in London, coordinates the scientific evaluation of the quality, safety and efficacy of medicinal products.

<sup>647</sup> There are also articles in non health related areas which make reference to the protection of health. See art. 36 and 45 T.F.E.U. that allow limitation of the movement of goods and of the free movement of workers for the protection of human health; art. 114 T.F.E.U. which calls for protection of human health when establishing internal market policies; art. 153 T.F.E.U. which supports Member States in protecting workers' health and safety; art. 169 T.F.E.U. that states that the Union should contribute to «*protecting the health, safety [...] of consumers as well as promoting their right to information*»; art. 191 T.F.E.U. about the E.U. policy on environment, of which the protection of health is key objective.

*society*» could have an impact on health policies at E.U. and Member States' level. Therefore, the E.U. should strive to attain a higher level of health protection through all European policies and activities.

With regards to the second facet of health (individual right), the Nice Charter, now binding, clearly refers to it in art. 25: «*Everyone has the right to access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*». Other norms can also be intended as able to have implications for such right, such as art. 1 on human dignity (meant as the basis of all elements of the right to health), art. 2 that safeguards the right to life, art. 3 on the integrity of the person, art. 8 on the protection of personal data, included medical data of patients, art. 10 on freedom of conscience, belief and religion, that is relevant with regards to the principle of autonomy and self-determination that is a key one in the medical context, art. 26 on integration of persons with disabilities.

Moving to the national (and constitutional) level, it appears that the right to health is expressly mentioned in the national Constitutions as a freedom or an entitlement to some benefits guaranteed by States<sup>648</sup>, and even in the Constitutions that do not quote it refer to it in their preambles, in some of the content regarding social policy and in judicial decisions. Reference to health is sometimes developed in negative terms, when the Constitutions or laws list the limitations that may apply to certain civil and political rights for public health reasons.

Basic health care issues can be deduced from a more generic human rights provision, such as the human dignity provision which is read in conjunction with a “social state” or a solidarity principle, as under the German Basic Law in art. 1 and 20. The United States does not include any reference to health in its Federal Constitution. However, judicial decisions at the single States level can be found regarding the State’s responsibility to regulate health or its duty to ensure equal access to the beneficiaries of the health and welfare systems, and thus linking the

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<sup>648</sup> See, for example, in the European landscape the Austrian (art. 10), Belgian (art. 23), Cypriot (art. 7); Estonian (art. 20 and 28), Finnish (art. 19), German (art. 2), Greek (art. 21), Irish (art. 45), Maltese (art. 36), Dutch (art. 22), Polish (art. 39 and 68), Portuguese (art. 26 and 64), Slovenian (art. 51 and 52), Spanish (art. 43); Swedish (art. 5) Constitutions.

right to health with right to life. The Italian Constitution with its art. 32 for a long time has been the only one<sup>649</sup> to refer to health not only as a public issue and collective interest (health as the guarantee of hygienic conditions and object of social assistance), but also as an individual right, and as a condition to be preserved and kept by preventing others from affecting it (health as protection of physical and psychological integrity, from which the right to healthy environment derives<sup>650</sup>), through public policies and the access to medicines and technological medical devices. The right to health includes the right to healthcare and the right not to be cured (refusal of cures), and the right to self determination is descendant from it.

### 3.2. *The Facets of the Right to Health.*

The right to health mainly has two dimensions: (a) an individual dimension, and (b) a collective or public one.

The former focuses on health as a status, i.e. a situation of wellness belonging to the single human being who, on the basis of this right, can find him/herself in a claiming position towards both (1) the State, and (2) the other citizens.

The latter concentrates on population and intends this right as a right belonging to groups, to general society, and to the whole community<sup>651</sup>.

As seen in the Fact Sheet n. 31 by the Office of the United Nations and High Commissioner for Human Rights, together with the W.H.O.<sup>652</sup>, the right of health is multi-faceted. It (a) entails determinants, (b) contains freedoms, and (c) demonstrates entitlements.

It entails determinants, i.e. it is an inclusive right that encompasses the following: the right to water and adequate sanitation; the right to food and adequate nutrition; the right to housing; the right to healthy working and environmental

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<sup>649</sup> It should be noted that Italian Constitution has become a model for other Constitutions, such as the Spanish one, and through the Spanish one it has represented a model for the Latin America Constitutions as well.

<sup>650</sup> In this case, art. 32 must be read in connection with art. 9 of the Italian Constitution.

<sup>651</sup> See S. FOÀ, *Il fondamento europeo del diritto alla salute. Competenze istituzionali e profili di tutela*, in C.E. GALLO, B. PEZZINI (EDS.), *Profili attuali del diritto alla salute*, Milano, 1998, p. 57-93.

<sup>652</sup> UNITED NATIONS, HIGH COMMISSIONER FOR HUMAN RIGHTS, W.H.O., *The Right to Health*, Fact Sheet n. 31, June 2008, at <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf> (last visited 28<sup>th</sup> January 2013).

conditions; the right to health-related education and information; and the right to gender equality.

The right to health contains freedoms, like: the right to be free from non-consensual medical treatment, such as medical experiments and research or forced sterilization, and the right to be free from torture and other cruel, inhuman or degrading treatment or punishment.

The right to health demonstrates entitlements, such as: the right to a system of health protection providing equality of opportunity for everyone to enjoy the highest attainable level of health; the right to prevention, treatment and control of diseases; the right to access to essential medicines; maternal, child and reproductive health; equal and timely access to basic health services; the provision of health-related education and information; participation of the population in health-related decision making at the national and community levels. This right cannot be misunderstood with the right to be healthy and it is linked to the principle of autonomy and self-determination with regards to medical treatments (including the right to consent to treatments or to refusal of them).

The State has to balance individual and communal interests, both protecting individual rights and freedoms, and safeguarding the community interests in safety and security. The obligations upon the State are both “negative” and “positive”. Among the “negative” ones, there are: the duty not to violate the right to health by its actions, and the refrain from denying or limiting equal access for all persons to health care measures. The “positive” obligations, instead, entail: the duty of the State to prevent violations of the right to health by others, to supply people with measures of public sanitation for hygienic and prophylactic reasons, to introduce and enforce appropriate controls for the marketing of medical equipment and medicines by third parties, to eliminate, or at least reduce, the imbalances in the provision of health facilities, goods and services, providing a rational allocation of resources, ensuring high standards of health, through legislative, administrative, judicial, budgetary measures, without discrimination and according to equality<sup>653</sup>. The concrete

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<sup>653</sup> B.M.A. AND THE COMMONWEALTH MEDICAL TRUST, *The right to health: a toolkit for health professionals*, June 2007, p. 21-22.

application of the “positive” obligations upon the State, in reality, differ from State to State, as the systems of healthcare respond to diverse models<sup>654</sup>.

The right to health like any other rights, has a core and a penumbra, a maximum and a minimum<sup>655</sup>. Under such “maxi-min” definition of the right to health, the States have a duty to, at the very minimum, to protect individuals against serious health threats<sup>656</sup>. At the maximum, they have the duty to fulfil the attainment of the highest possible standard of health for all individuals. In this perspective, the right to health belongs to the category of social rights that are considered by someone and by some Constitutions and Courts as simply aspirations and programs (not real rights)<sup>657</sup>. This is because it can only be achieved progressively, and it is linked to the availability of resources. It requires the intervention by the State and it can be labelled as “economically conditioned”<sup>658</sup>. According to Sen and others, the right to health and the social rights have an intrinsic value. Sen’s very interesting notion of “capability” can be put for as an approach for founding social rights as the right to

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<sup>654</sup> See, for example, C. CASONATO, *I sistemi sanitari: note di comparazione*, in AA.VV., *La salute negli Stati composti. Tutela del diritto e livelli di governo*, Atti del XVI Convegno dell'Associazione di diritto pubblico comparato ed europeo, Torino, 2012, p. 5-28. Briefly, there are four main models of healthcare: (a) the Beveridge one (health care is provided and financed by the government through tax payments); (b) the Bismarck model (which uses an insurance system, usually financed jointly by employers and employees through payroll deduction); (c) the National Health Insurance model (that mixes elements of the Beveridge’s and Bismarck’s model, i.e. it uses private-sector providers, but payment comes from a government-run insurance program that every citizen pays into); and (d) the out-of-pocket model (having as the basic rule that the rich get medical care; the poor stay sick or die).

<sup>655</sup> L.O. GOSTIN, Z. LAZZARINI, *Human Rights and Public Health in the AIDS Pandemic*, Oxford, 1997.

<sup>656</sup> See COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (C.E.S.C.R.), *General Comment n. 14 on the right to the highest attainable standard of health*, 11<sup>th</sup> August 2000, UN Doc. E/C.12/2000/4. It states that the minimum set of obligations that cannot be denied by States are: «(a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups, (b) to ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone, (c) to ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water, (d) to provide essential drugs, as from time to time defined under the W.H.O. Action Programme on Essential Drugs, (e) to ensure equitable distribution of all health facilities, goods and services, and (f) to adopt and implement a national public health strategy and plan of action, on the basis of epidemiological evidence, addressing the health concerns of the whole population».

<sup>657</sup> See M. JORI, *Ferrajoli sui diritti*, in *Teoria politica*, 1/1999, p. 27 ff.

<sup>658</sup> For example, the Italian Constitutional Court has recognized that the right to health as a right depending on the choices made by the legislator in the field of public finance. However, the right to health in its core and essential nucleus must be respected. With this regards, see decision n. 185/1998 (about the notion of «minimal and essential content of the right to health») and decision n. 200/2005 (where it is stated that, even if the right to health depends on economic resources, the needs related to health remain primary rather than the needs of public finances). In the ruling n. 509/2000, the core of the right to health is linked with human dignity. About these issues, see R. BALDUZZI (ED.), *Cittadinanza, corti e salute*, Padova, 2007.

health and for considering them as fundamental rights: «*the notion of capability is essentially one of freedom - the range of options a person has in deciding what kind of life to lead*»<sup>659</sup>. In Sen's view, the freedom of people is limited because of economic poverty, the lack of food, mortality, and so forth. So, if social rights are satisfied, the freedom of individuals can increase. In this sense, the right to health becomes a means for freedom and capability, and its failure is a capability failure.

The accountability mechanisms, i.e. the means for making the right to health effective, are classified by Riedel into five types: «*Judicial; quasi-judicial; administrative; political; and social*»<sup>660</sup>. Under the judicial mechanism, the constitutional interpretations or other types of case-laws are included. Patients' rights commissions or health care commissions that receive complaints and decide the resolution of them belong to the category of quasi-judicial mechanisms. The administrative means entails to adopt a sort of right to health assessment before acting. The political mechanisms, instead, gives to the public powers the role to decide whether and how to implement the right to health. The social mechanism involves the general public and media, the private actors and the community. Currently, «*there is a move away from the State having a key responsibility for health, to partnership approaches that include the public, private and not-for-profit sectors and individuals*»<sup>661</sup>. Such a move to a partnership approach leads to the development of a context of shared responsibilities for health, and thus bringing the right to health from its common individual framework to a collective one.

Moreover, the right to health is strictly connected to the principle of equality, non discrimination, and development. This clearly entails that the services for healthcare and medicines are not to be reserved to a particular group or individuals, but must be accessible to everyone. No discriminations should exist between North

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<sup>659</sup> J. DREZE, A.K. SEN, *India: Economic Development and Social Opportunity*, Delhi, 1998, p. 11. For the notion of "capability", see A.K. SEN, *The Right Not To Be Hungry*, in G. FLØISTAD (ED.), *Contemporary Philosophy: A New Survey*, vol. 2, Hague, 1982; A.K. SEN, *Capability and Well-Being*, in M. NUSSBAUM, A.K. SEN (EDS.), *The Quality of Life*, Oxford, 1994; A.K. SEN, *Development as Freedom*, Oxford, 1999. For the "capability" approach, see also M.C. NUSSBAUM, *Capabilities and Human Rights*, in *Fordham Law Review*, 66, 1997, p. 273-300.

<sup>660</sup> E. RIEDEL, *op. cit.*, p. 33 ff.

<sup>661</sup> M. STUTTAFORD, *Balancing Collective and Individual Rights to Health and Healthcare*, in *Law, Social Justice and Global Development Journal*, 1, 2004. In England, for example, responsibilities for health are shared among the government and the community (see a paper published by the Social Exclusion Unit (U.K. CABINET OFFICE, *Preventing Social Exclusion*, 2001, p. 3 at <http://www.cabinet-office.gov.uk/seu/publications/reports/html/summary.html>, last visited 28<sup>th</sup> January 2013).

and South of the world, and the right to health must be conceived as one of the underlying determinants for the full realisation of the right to development. This means that it is «*an inalienable human right by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized*»<sup>662</sup>.

There is also the link to the right to life here, in the sense that the preservation of life can sometimes be pursued only through the adequate allocation of health resources, to health treatments, essential drugs.

Other connections are also visible between the right to health and the right to privacy (as referred to the treatments of medical data of patients), and between the right to health and the right to healthy environment<sup>663</sup>.

In summary, the right to health does not coincide with the right to be healthy or the right to healthcare. Neither is it a mere programmatic right. It should be meant as a fundamental human right, showing many entitlements, obligations and connections to other rights and principles as well.

### 3.3. *Health and Synthetic Biology.*

The right to health is connected to a status, and to a condition of wellness. The factors for achieving such wellness are not so determinable and can change depending on the technological evolution and progress. The notion of health itself has changed through the course of the years and has evolved together with the development of research, science and technology. Along this line of thought, it is clear that synthetic biology calls upon the right to health, as it can improve

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<sup>662</sup> U.N. GENERAL ASSEMBLY, Resolution 41/128 *Declaration on the Right to Development*, A/RES/41/128, 4<sup>th</sup> December 1986, Paragraph 1.1. See also World Conference on Human Rights, Vienna Declaration and Programme of Action, A/CONF.157/23, 12<sup>th</sup> July 1993, Paragraph 10.

<sup>663</sup> See, for example, the case *Guerra & Others v. Italy*, in which the European Court of Human Rights held that a council's failure to provide local residents with information about the potential environmental impact of a nearby fertiliser factory, which had been classified as "high risk", violated the residents' right to private and family life. So, the Court linked environmental health with human health and private life and stated that the right to information means that the residents must be allowed access to information about the factory given it related to their health (see *Guerra & Others v. Italy*, n. 14967/89, 19<sup>th</sup> February 1998).



conditions of health with its devices, discoveries, instruments. Indeed, the potential for healthcare coming from synthetic biology is high, as synthetic biology could help in «*better understanding of complex diseases, [for] speeding up the development of new vaccines, [...] for tailoring treatments to individual patients or groups of patients, and for monitoring how they respond to specific therapies*»<sup>664</sup>. Synthetic devices such as instruments for preventing the spread of infections, biosensors to recognise a drug when it is administered to a patient are only some of the possible benefits to health provided by this new field of research.

On the flip side, synthetic biology applications could potentially alter and affect human health such as in cases of biosafety and biosecurity risks.

Moreover, the notion of health itself as a species-norm (like the right to life) is challenged by synthetic biology.

Therefore, the right to health in synthetic biology field is at stake. It demonstrates its individual and public facet as two complementary facets. Thus conceived, the right to health asks for being actively protected by the State and by private actors with reference to the context of synthetic biology. In this section I will discuss in greater detail the individual and public facets of the right to health in synthetic biology respectively. I will also consider how the right to health could be affected as a species-norm.

### *3.3.1. Synthetic Biology and Individual Health.*

The relationship between synthetic biology and the right to health in its individual sense concerns, most of all, the possibility of access to synthetic products, applications and medicines.

Clearly synthetic biology is progressively improving in the field of medicine and therapeutic applications, it is evident that the right to health in its reference to each single human being of the community must be recognized and implemented. The attitude of the State cannot be the one of “indifference” towards a fundamental

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<sup>664</sup> R. WELLS, *Synthetic biology A challenge for healthcare*, in *O.E.C.D. Observer*, 281, October 2010, p. 17. See also W.C. RUDER, T. LU, J.J. COLLINS, *Synthetic Biology Moving into the Clinic*, in *Science*, 333, September 2011, p. 1248-1252.

right of the person (that is a pre-condition of all the others, such as the right to life), but it should be a behaviour aimed at correcting and balancing the inequalities among people in access to medicines, therapies and health applications obtained through synthetic biology.

However, the right to health exposes itself to a paradox here. As long as science and technology evolve, they are able to solve many more health problems. At the same time, though, the problem of granting access to those discoveries to everyone is not simple at all. The State is called upon for intervening, but the healthcare systems are not always capable of responding to the challenges posed by new needs<sup>665</sup>.

Far from indicating that the right to health is a purely utopian and ideological right that entails that each person has the power of claiming a free access to therapies and drugs, guaranteed by the State (this would be a mere aspiration), and far from a position that considers the right to health as a mere element to be taken into consideration by the State in the financial distribution of resources, my claim<sup>666</sup> is that the right to health cannot be undermined in its “essential core” of being a fundamental and universal right of the person. It is not only a mere economic and social right which should be pursued by the State as a priority in its financial policy, and by all the private actors operating in the field<sup>667</sup>.

In the consideration of the right to access to medicines (that can be considered as a species of the general right to have access and to share the benefits of science<sup>668</sup>), it is necessary to mention the “*Agreement on Trade-Related Aspects of Intellectual Property Rights*” (T.R.I.P.S.). It elaborates a compulsory licence legislation, thereby which ensures that medicines reach their jurisdictions in adequate quantities. So, «*States are required to take effective measures to promote the development and availability of new drugs, vaccines and diagnostic tools [...]. States*

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<sup>665</sup> See R. FERRARA, *Principi di diritto sanitario*, I, Torino, 1995.

<sup>666</sup> It is in line with R. DWORKIN, *Taking Rights Seriously*, cit., and V. LEARY, *The Right to Health in International Human Rights Law*, in *Health & Human Rights*, 1, 2.4, 1994, p. 28-32.

<sup>667</sup> With regards to the State and civil society obligation, see A.E. YAMIN, *Defining Questions: Situating Issues of Power in the Formulation of a Right to Health under International Law*, in *Human Rights Quarterly*, 18, 1996, p. 402.

<sup>668</sup> See H. HOGERZEIL, ET AL., *Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?*, London, 2006. See also U.N. COMMISSION ON HUMAN RIGHTS, Resolutions 2005/23, 2004/26 and 2003/29, at <http://www.ohchr.org/english/> (last visited 28<sup>th</sup> January 2013).

*therefore are required to resort to a variety of economic, financial and commercial incentives in order to influence research and development into specific health needs. In short, States not only have a duty to ensure that existing medicines are available within their borders, they also have a responsibility to take reasonable measures to ensure that much-needed new medicines are developed and thereby become available»<sup>669</sup>. Along with availability, the States should guarantee that medicines become accessible from a geographic and economic points of view, and in a not discriminatory way. This is to ensure that patients and health professionals could take well-informed decisions and use medicines safely. Such a responsibility, though, does not belong only to the State. Other national and international actors have a role to play. The “*Millennium Development Goals*”<sup>670</sup>, for example, recognize that pharmaceutical companies are among those who share this responsibility. This Declaration states that a global partnership for development should be reached «*in cooperation with pharmaceutical companies*», that must contribute in providing access to medicines as well<sup>671</sup>.*

Thus, with respect to the applications of synthetic biology, the right of health entitled in each human being should be protected without discriminations and inequalities. It should pursue a rational distribution of resources for making it effective, by means of health care financing, providing equal access to medical treatments and drugs, and especially through «*the elaboration of new forms of institutional frameworks in which local organizations, state and federal institutions, and perhaps even private medical programs are connected, with the objective of providing individuals and communities a voice in defining their health interests*»<sup>672</sup>.

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<sup>669</sup> P. HUNT, R. KHOSLA, *The Human Right To Medicines*, in *Sur - International Journal On Human Rights*, 5, 8, June 2008, p. 102.

<sup>670</sup> The “*Millennium Development Goals*” are the result of a U.N. initiative. They are eight international development goals to be reached by 2015, and they were officially established, following the adoption of the United Nations Millennium Declaration in 2000 (see at <http://www.un.org/millenniumgoals/>, last visited 28<sup>th</sup> January 2013).

<sup>671</sup> See Goal 8.

<sup>672</sup> A.E. YAMIN, *Defining Questions: Situating Issues of Power*, cit., p. 431.

### 3.3.2. *Synthetic Biology and Public Health: the Link between the Right to Health and the Right to Safety/Security.*

As discussed in the previous sections, it is clear that the right to health can be taken to mean the right both to individual and to public health. This right to public health has a social and collective dimension that transcends the individual dimension of the members of the community. It expresses the positive and negative obligation for the State to supply people with all the means for the best preservation of integrity, life, wellness (through sanitary programs, vaccinations, and so on) and to impede any alteration or threat to such physical integrity of the community. So, in cases of risks to biosafety and biosecurity arising from synthetic biology, the right to public health comes into question. As the U.S. Public Health Service has said, biological warfare and bioterrorism are «*public health in reverse*»<sup>673</sup> because of the potentially devastating effects on populations. Indeed, in the hypothesis of a bioterrorist attack through synthetic elements, «*a public health response may require relaxing an individual's due process protections*»<sup>674</sup> to prevent the disease from spreading. Moreover, in hypothesis of accidental spread of harmful synthetic substance in the environment, public health is posed into peril.

This notion is illustrated in the traditional definition by Wislow<sup>675</sup>, «*Public Health is the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community effort for the sanitation of the environment, the control of communicable infections, the education of the individual in personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of the social machinery to insure everyone a standard of living adequate for the*

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<sup>673</sup> US DEPARTMENT OF HEALTH, EDUCATION AND WELFARE, *Effects of Biological Warfare Agents*. Washington, D.C., 1959.

<sup>674</sup> P.D. JACOBSON, S. SOLIMAN, *Co-opting the Health and Human Rights Movement*, in *Journal of Law, Medicine & Ethics*, 30, 2002, p. 705.

<sup>675</sup> It should be added the definition given by the Institute of Medicine (I.O.M.) in its seminal report *The Future of Public Health*: “Public health is what we, as a society, do collectively to assure the conditions for people to be healthy” (INSTITUTE OF MEDICINE (IOM), *The Future of Public Health*. Washington, D.C., 1988, p. 19). In this view the public health policies entail a narrow intervention in cases of diseases and epidemics and a broader intervention for ameliorating socio-economic conditions.

*maintenance of health, so organizing these benefits as to enable every citizen to realize his birthright of health and longevity»<sup>676</sup>.*

In the context of the protection of public health, a connection between the right to health in its collective facet and the right to life and dignity in their super individual dimensions<sup>677</sup> is set up. It should be noted that, historically, the first examples of the protection of health by the States in Europe and in the United States<sup>678</sup> were concerned with precisely the intervention towards public security and safety. Indeed, the first laws were on sanitation, implementing hygienic assistance, measures of purifying the water supply, creating sewage systems, monitoring the food supply, and encouraging immunization in front of contagious disease. These laws were based on the need to protect public health. So, the right to health was neither an individual right to be claimed nor a collective right. Health was only a public need to guarantee<sup>679</sup>. Then, during the subsequent years, the original sense of “health” as “public health” was recognized not only as a State necessity and duty to pursue, but also as a right upon a collective subject such as the whole society. This is the *ratio* at the basis of the compulsory treatments that are stated, for example, by art. 32 of the Italian Constitution. It is affirmed that such treatments could be allowed, provided that the legality principle is abided by (i.e. the allowed treatments are only the ones that are stated by law), the proportionality principle is implemented (the measures should be temporary and balancing the interests at stake) and the respect of the person is followed<sup>680</sup>. Only in the presence of these conditions, is it possible to

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<sup>676</sup> C.E.A. WINSLOW, *The Untilled Fields of Public Health*, in *Science* 23, 51, 1920, p. 30.

<sup>677</sup> See, for example, the decision n. 444/2005 by the Spanish Constitutional Court, which states that «*public health does not coincide with the individual health (as a legally protected good). It is a valorisation of the health of the whole members of a society*» (see at <http://hj.tribunalconstitucional.es/>, last visited 28<sup>th</sup> January 2013).

<sup>678</sup> For the history of the field of public health, see E. FEE, *The Origins and Development of Public Health in the United States*, in R. DETELS ET AL. (EDS.), *Oxford Textbook Of Public Health*, 1, 3, Oxford, 1991, p. 3-34.

<sup>679</sup> See in the U.K. the Poor Law, which has represented the first legislative intervention in order to protect public health of proletariat categories living in the suburbs of British cities.

<sup>680</sup> In the first years of the application of art. 32, it was perceived as a programmatic norm, referred only to public health (the same view was shared). Then, in Italy, with the laws n. 431/1968 about psychiatric assistance, law n. 194/1978 about the interruption of pregnancy, law n. 833/1978 instituting the National Health System, the right to health starts to be conceived an individual and subjective claim of status of wellness (see V. DURANTE, *Dimensioni della salute: dalla definizione dell'OMS al diritto attuale*, in *La nuova giurisprudenza civile commentata*, 2, March-April 2001, p. 132-148; about the evolution of the interpretation of art. 32 in Italian Constitution see also L.

prevail the community's interest upon the individual's freedom and autonomy. This duty to protect collective public health lies not only upon the Legislator, but also upon administrative and judicial bodies<sup>681</sup>.

Such interpretation of the right to health - as a right upon the community and implying a duty for the State to intervene - is much simpler to be implemented in the European States where positive obligations are part of the notion of social and welfare state. However, it is more difficult in the United States where the tradition is usually the liberal one, which entails that people should be prevented from the governmental intrusion into their persons. This is exemplified in the decision of U.S. Supreme Court pertaining to the case of *Jacobson v. Massachusetts*<sup>682</sup>. It is probably the most important decision about public health in the U.S.. Pursuant to a Massachusetts Statute, the City of Cambridge had adopted an ordinance to provide mandatory smallpox vaccination free of charge for all of the city inhabitants over the age of twenty-one who had not been recently vaccinated. The claimant Jacobson refused to be vaccinated because he saw it as an intrusion into the personal sphere. According to him, the ordinance should be considered unconstitutional as it was a violation of the due process, equal protection, and privileges and immunities (14<sup>th</sup> Amendment)<sup>683</sup>. The Court, despite its initial self restraint in establishing new rights and being against the ones opposing to its "creative" role, on the basis that *«the judicial process is a poor format for the weighing of alternatives and the calculation of costs»*<sup>684</sup>, affirmed that the State has the duty to protect public health and public

CARLASSARE, *L'art. 32 della Costituzione e il suo significato*, in R. ALESSI (ED.), *L'ordinamento sanitario*, vol. *L'Amministrazione sanitaria*, Milano 1967, p. 103 ff.

<sup>681</sup> With regards to sanitary compulsory treatments, it is relevant to consider Italian Constitutional Court rulings about the obligatory controls for the fight to AIDS, such as decisions nn. 218/1994 and n. 210/1994 (see comments and observations by C. CASONATO, *Aids e diritto: un nuovo equilibrio?*, in *Sanità pubblica*, 1994, p. 905 ff.). About obligatory vaccinations, see the decision n. 258/1994.

<sup>682</sup> Case *Jacobson v. Massachusetts*, Supreme Court of the United States, Decided on 20<sup>th</sup> February 1905 (197 U.S. 11, 1905). On an opposite side, see the decision by Supreme Court on the case *De Shaney v. Winnebago County Department of Social Services*, Supreme Court of the United States. Decided on 22<sup>nd</sup> February 1989 (U.S. 189, 1989), in which the Court was reluctant to impose on government an affirmative duty to safeguard the well-being of its citizens, stating that the U.S. Constitution is a "negative" constitution that has to protect individuals rights from interferences, adopting a *laissez faire* approach (differently from the dissenting opinion of Justice Harry A. Blackmun, who conveyed an alternative view of the constitutional obligation for the State to protect vulnerable citizens and citizen's health, seen not in contrast with Fourteenth Amendment's Due Process Clause).

<sup>683</sup> See also S. KING, *Vaccination Policies: Individual Rights and Community Health*, in *British Medical Journal*, 319, 1999, p. 1448-1449.

<sup>684</sup> D.L. HOROWITZ, *The Courts and Social Policy*, Washington, D.C., 1977, p. 357.

safety and, meaningfully, that the liberty secured by the U.S. Constitution does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. It is a liberty regulated by law. Therefore, in cases of real risk for public safety, the individual freedom must be limited for welfare reasons, in accordance to some conditions that express the balance among rights. Indeed, public police powers that apparently infringe with individual freedoms must be exercised only when respecting the “*public health necessity*” condition (the risk should be real and entailing a public harm), the “*reasonable means*” standard which suggests that the methods used must be designed to prevent or ameliorate a health threat, the “*proportionality*” requisite (that pursues the proportion between the burden imposed and the expected benefit), and the “*harm avoidance*” standard which suggests that the control measure should not pose an undue health risk to its subject<sup>685</sup>.

So, with the threat of bioterrorism or high risks to public health through the use of synthetic products used for malevolent purposes, we are facing pandemic risks. In such situations it would be useful that the E.U., the U.S. and the international framework converge in elaborating a shared notion of the right to health in its public facet (thus linked with safety and security). It could remind us of the importance of State intervention in different ways in order to guarantee a high level of protection of health, both as preventative (preparedness) and reactive (response) ways. These ways could be represented, for instance, by:

(a) laws, as categorised by Mariner in «(1) *laws that target individual conduct - requiring or prohibiting specific actions*<sup>686</sup>; (2) *laws that set health and safety standards - regulating products or companies that affect health by reducing health risks arising from products or the social or working environment*<sup>687</sup>; and (3) *laws*

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<sup>685</sup> For further details, see L.O. GOSTIN (ED.), *Public Health Law and Ethics: A Reader*, Berkeley, Los Angeles, London, 2002, p. 215 ff. and p. 377 ff.

<sup>686</sup> See laws that offer a criminal protection, establishing rules that provide sanctions in cases of crimes affecting public health (for example, XVII title, II book, Spanish criminal code, in particular art. 159 about the use of genetic engineering for building biological weapons aiming at killing human species). In this group there also civil laws, that require immunization against certain contagious diseases and authorize the involuntary detention of people who are likely to transmit contagious diseases.

<sup>687</sup> See laws providing safety standards for workplaces, or standards for manufacturing pharmaceuticals, biologics, food, and cosmetics, safeguards for potentially dangerous products.

that affirmatively create benefit programs<sup>688</sup> - offering healthcare, services, or information that individuals are free to accept or refuse”<sup>689</sup>;

(b) administrative means through the establishment of mechanisms of control, protection, vigilance, surveillance of products, according to principles of transparency and good information.

In these cases, a strict connection between health and human security or safety would become tangible, as encouraged by the United Nations Development Programme (U.N.D.P.), which in 1994 shaped a new notion of security. It goes beyond the one conceived as focused on «*external aggression, or as protection of national interests in foreign policy or as global security from the threat of nuclear holocaust*»<sup>690</sup>. Indeed, the Programme underlined the importance of keeping attention to «*the legitimate concerns of ordinary people who sought security in their daily lives*»<sup>691</sup>.

It is relevant here to see that public health policies do not mean to “sacrifice” other liberties and rights in the name of collective security, but to find a proper balance among security, public health and individual rights in a proportioned way<sup>692</sup>.

In public health issues, therefore, it is central the concern «*primarily with prevention rather than treatment, populations rather than individuals, and collective goods rather than personal rights or interests*»<sup>693</sup>. Populations should be the object of attention by the State, but also the populations have a role in choosing the most suitable measures for dealing with pandemic risks (public engagement).

In summary, in cases of bioterrorism or risks to safety generated by synthetic biology the security is not something to pursue through the suspension of human rights (disposing an exception to human rights because of the risk situation), but on the contrary it is a right to recognize and enforce through the connection with the

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<sup>688</sup> Such as laws for water supply, medical care, programs for those without health insurance, funding for public and private health programs, support for biomedical and epidemiologic research and public information programs.

<sup>689</sup> W.K. MARINER, *Law and Public Health: Beyond Emergency Preparedness*, in *Journal of Health Law*, 38, 2, Spring 2005, p. 268.

<sup>690</sup> U.N.D.P., *Human Development Report*, 1994, 22.

<sup>691</sup> *Ibid.* See also COMMISSION ON HUMAN SECURITY, *Human Security Now*, 2003, that has mentioned a «*comprehensive collective security*», indicating the new emerging infectious diseases as a threat to global health.

<sup>692</sup> See N.L.G. EASTMAN, R.A. HOPE, *The Ethics of Enforced Medical Treatment: The Balance Model*, in *Journal of Applied Philosophy*, 5, 1988, p. 49–59.

<sup>693</sup> L.O. GOSTIN (ED.), *Public Health Law and Ethics*, cit., Preface, xxiii.



right to health. So, the connection among human rights (and specifically the right to health) with the security needs has to be recognized while implementing policies to deal with biosafety and biosecurity risks arisen by synthetic biology.

### *3.3.3. Synthetic Biology, Global Health and the Right to Development.*

With regards to international justice concerns, the right to health in synthetic biology shapes in such a way that it intersects with the right to development in a mutual way. In this context, health is conceived as a collective right that has to be pursued to achieve the development, and at the same time as a right that is reached through the right to development. It is meant as «*a vector of rights, [that] offers public health actors an opportunity to work through international development discourses to empower individuals and states to allocate public goods for the public's health, realizing underlying determinants of health through national public health systems*»<sup>694</sup>. Instead of focusing on individual right to health, that is implemented only through health care systems, the right to development asks for the realization of public health purposes. At its turn, public health guarantees the development of society. So, in order to avoid the possibility of disparities between the rich and poor countries with respect to the applications of synthetic biology and the access to discoveries made by synthetic biology, the right to public health and the right to development must be taken into account, respected and promoted.

The right to health is essential for the implementation of the development. On the other hand, the fact of pursuing the right to development, through synthetic products, helps in the amelioration of the health qualities of populations and the improvement of the right to public health helps in creating more developed societies.

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<sup>694</sup> B.M. MEIER, A.M. FOX, *Development as Health: Employing the Collective Right to Development to Achieve the Goals of the Individual Right to Health*, in *Human Rights Quarterly*, 30, 2008, p. 261. See also A. SENGUPTA, *Implementing the Right to Development*, in N. SCHRIJVER, F. WEISS (EDS.), *International Law And Sustainable Development: Principles And Practice*, 2004, p. 341.

Such a right to development is meant as a “third generation right” (linked to the principle of solidarity)<sup>695</sup>. It was formulated by the States of the South of the world, which were convinced that self determination and political independence would have made the people free from hunger and poverty, and thus encouraging their development. «Hence, the right to development is an attempt to articulate more clearly and precisely the violations of human rights caused by poverty and deprivation»<sup>696</sup>. Derived from the U.N. Charter and various international human rights instruments (such as the International Covenant on Economic, Social and Cultural Rights), and underlined by the U.N. General Assemblies as a means for the realisation of human rights<sup>697</sup>, in the 1986 Declaration on the Right to Development<sup>698</sup> the right to development was conceived as a human right «to participate in, and contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realised» (Art. 1). Thus such right is fundamental for the establishment of a new international economic order, essential for the enjoyment of all other human rights and fundamental freedoms, and it can be fulfilled through solidarity and international cooperation<sup>699</sup>.

This right is said to include: full sovereignty over natural resources; self-determination; popular participation in development; equality of opportunity, and the creation of favourable conditions for the enjoyment of other civil, political, economic, social and cultural rights<sup>700</sup>.

The States should undertake, at the national level, all the necessary measures for the realization of the right to development without discrimination, and shall ensure, *inter alia*, the equality of opportunity for all in their access to basic resources,

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<sup>695</sup> See P. ALSTON, *Conjuring up New Human Rights: A Proposal for Quality Control*, in *American Journal International Law*, 78, 607, 1984. See also S.P. MARKS, *The Human Right to Development: Between Rhetoric and Reality*, in *Harvard Human Rights Journal*, 17, 137, 2004.

<sup>696</sup> C. KUPPUSWAMY, *The international legal governance of the human genome*, London/New York, 2009, p. 90.

<sup>697</sup> See U.N. Doc. A/RES/34/46, 1979; UN Doc. A/RES/35/174, 1980; UN Doc. A/RES/36/133, 1981.

<sup>698</sup> U.N. Doc. A/RES/41/128, 1986. See also the 1993 Vienna Declaration and Programme of Action (VDPA), adopted at the World Conference on Human Rights (UN Doc. A/CONF.157/23, 1993).

<sup>699</sup> See art. 3(3) of the Declaration.

<sup>700</sup> OFFICE OF THE COMMISSION ON HUMAN RIGHTS, *The Content of the Right to Development, Human Rights in Development*, at <http://www.unhcr.ch/development/right-02.html> (last visited 28<sup>th</sup> January 2013); see also G. ABI-SAAB, *The Legal Formulation of a Right to Development* in R. DUPUY (ED.), *The Right to Development at the International Level*, The Hague, Workshop 16–18<sup>th</sup> October 1979, The Hague, 1980, p. 163-164.

education, health services, food, housing, employment and the fair distribution of income<sup>701</sup>.

So, with regards to synthetic biology, the States should implement synthetic applications, drugs and medicines so that the individual will be able to attain a minimum standard of living and to promote their development.

If the right to development is interpreted as a «*set of 'basic' rights and a right to a process*»<sup>702</sup>, and thus overcoming the “classical” division among generations of rights in a holistic way<sup>703</sup>, it includes the right to health as a right to be addressed, so that the right to development could be fulfilled. Therefore, if health applications of synthetic biology are made accessible to people without discrimination, such development grows, as asked for by the Declaration of Alma Ata (according to which «*the promotion and protection of the health of all the people is essential to sustain economic and social development and contributes to a better quality of life and world peace*»<sup>704</sup>). This is in line with the World Health Organization resolution in 1979 called the “*Health and the New International Economic Order*”<sup>705</sup>, which urges States to put their efforts into the transfer of appropriate technology, resources and technical cooperation for the implementation of the primary health care approach towards an improved health for all.

The appropriate attention to warrant access to synthetic biology applications in a non discriminatory and equitable way could solve international concerns with regards to the distribution of synthetic biology resources and help promoting an effective worldwide development, and thus ensuring the proper care to the right to health, the right to development and the principle of solidarity and international cooperation.

The 1997 Universal Declaration on the Human Genome and Human Rights and the 2005 Universal Declaration on Bioethics and Human Rights also urge States to foster solidarity and cooperation in the areas of health research, health care, technology and knowledge transfer, and the free exchange of scientific knowledge

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<sup>701</sup> Art. 8 of the Declaration.

<sup>702</sup> A.K. SENGUPTA, *The Right to Development as a Human Right*, Cambridge, M.A., 1999.

<sup>703</sup> M. ROBINSON, *What Rights Can Add to Good Development Practice*, in P. ALSTON, M. ROBINSON (EDS.), *Human Rights And Development: Towards Mutual Reinforcement*, Oxford, 2005, p. 27.

<sup>704</sup> Declaration of Alma-Ata, cit.

<sup>705</sup> W.H.O. Doc. WPR/RC30.R13, 1979.

and information in medicine, on the basis of the fact that human genome is a common heritage of humankind, and in the belief that progress in science and technology contributes to justice, equity and to the interests of humanity<sup>706</sup>.

#### 3.3.4. *Synthetic Biology and the Possible Alteration of the Notion of Health.*

Similar to the case of the right to life and human dignity, the concept of health as a species-norm is put into doubt by synthetic biology. Indeed, as synthetic biology alters the “normal” borders of evolution, it can also affect the “normal” concept of health and disease as associated to human beings (mainly the Boorse’s Bio Statistical Theory (B.S.T.), according to which *«health is normal species functioning, which is the statistically typical contribution of all the organism’s parts and processes to the organism’s overall goals of survival and reproduction»*<sup>707</sup>). So, in the context of synthetic biology, being in the absence of a group with respect to which a contribution is statistically typical, it is arguable that the “traditional” concepts of health and disease referred to possible synthetic humans could still be applicable. These concepts could be extended to synthetic humans thus overcoming the species reference and giving importance to the function that a being pursues, despite its belonging to a particular species, or these notions could be differentiated for “natural” and synthetic humans.

#### 4. *The Freedom of Scientific Research.*

The issue concerning the freedom of scientific research is an important one in the context of biological research (included synthetic biology). In fact, the “instinct” of broadening knowledge and enriching the scientific progress and life conditions has been a part of mankind since time immemorial. It is because of man’s innate sense of

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<sup>706</sup> See Art. 17, Universal Declaration on the Human Genome and Human Rights, UNESCO Doc. C/RES/29/16, 1997. See also Universal Declaration on Bioethics and Human Rights, UNESCO Doc. C/RES/33/36, 2005.

<sup>707</sup> See C. BOORSE, *Health as a theoretical concept*, in *Philosophy of Science*, 44, 1977, p. 542–573.

curiosity and desire to discover and understand the unknown that the science and technology could flourish.

From the legal point of view, the relevance of research as a fundamental freedom to be guaranteed in a democratic system, has constituted the basis for its declaration and enforcement in Constitutions, Declarations as well as in case laws.

In the Seventies it was referred only to the mere academic structure. However, now it shapes in the context of new technologies and its role is very relevant.

Some of the questions with respect to research in the field of synthetic biology are as follows: (1) what does freedom of scientific research mean?, (2) what are the limits for its exercise?, and (3) what are the relationships between such freedom and other constitutional rights, such as the right to health, public security, life? In this section, I am going to address these questions in greater detail.

#### *4.1. Contents and Limits of the Freedom of Scientific Research.*

Formulated as a fundamental freedom, the freedom of scientific research is a clear symbol of democracy, as it touches on the roots of a constitutional framework.

This freedom shows, on the one hand, an (eventual) institutional aspect, in the sense that in order to exercise such freedom the presence of some centres and organizations and structures (such as universities) is likely to be necessary. These institutions should be kept autonomous from political powers, so that they can focus on their research and society can reap the rewards of this research. On the other hand, this freedom entails an individual aspect, in the sense of a right to be recognised upon the single researcher. In this second meaning, the freedom of scientific research usually expresses the following<sup>708</sup>:

(1) Freedom of investigation as part of the content of the freedom of thought and expression (species of the genus “freedom of thought and expression”), so that a right to seek truth and express it is recognized. In this case, “scientific research” essentially means observation and speculation, not manipulation. This interpretation

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<sup>708</sup> For this distinction, see R. RUÍZ LAPEÑA, *Libertad de Investigacion*, in C.M. ROMEO CASABONA (ED.), *Enciclopedia de Bioderecho y Bioética*, cit., vol. II, p. 1047 ff.

of the freedom of research appears in the Constitutions of many countries, for example and not limiting to: art. 19, Universal Declaration of Human Rights (1948); art. 9 and 10 of the E.C.H.R.<sup>709</sup>; I amendment of the U.S. Constitution<sup>710</sup>; art. 2 of the Canadian Constitution; art. 12 of the Chilean Constitution; art. 14 of the Mexican Constitution; art. 11 of the French Declaration of 1789, and subsequently recognized by French Constitution (1958);

(2) Freedom of investigation as having a self content, as seen in the following examples of, but not limiting to, articles in the various Constitutions: art. 13, of the Nice Charter (but through Explanations by Presidium, it is connected to art. 10 of the E.C.H.R.<sup>711</sup>); art. 5 of the German Constitution; art. 33 of the Italian Constitution<sup>712</sup>; art. 42 of the Portuguese Constitution; art. 20 of the Spanish Constitution; art. 59 of the Slovenian Constitution; art. 27 of the Colombian Constitution, in the Preamble of London Treaty instituting in 1945 the U.N. Organization for education, science and culture (U.N.E.S.C.O.), in art. 15 of U.N. Covenant About Economic, Social,

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<sup>709</sup> The E.C.H.R. does not contain a specific norm about the freedom of scientific research, but it can be deduced from the freedom of thought and expression. Art. 9 and 10 E.C.H.R. should be also related to Art. 15 of the European Biomedicine Convention, that justifies the freedom of scientific research in the field of biology and medicine by humanity's right to knowledge and by the considerable progress its results may bring in terms of the health and well-being of patients. In art. 2, though, the primacy of the interest and the welfare of the human being is not meant to be as absolute because, merging the interest of science with some other supreme interests (as the protection of public health), some restrictions could be provided. So, in cases of public safety needs and necessity, the freedom of scientific research could be limited.

<sup>710</sup> With regards to freedom of scientific research within US Constitution, see, among others, D.R. IRWIN, *Freedom of Thought: The First Amendment and the Scientific Method*, in *Wisconsin Law Review*, 2005, p. 1479-1481; B.P. MCDONALD, *Government Regulation or Other "Abridgements" of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, in *Emory Law Journal*, 54, 2005, p. 979-986; S. KEANE, *The Case Against Blanket First Amendment Protection Of Scientific Research: Articulating A More Limited Scope Of Protection*, in *Stanford Law Review*, 59, November 2006, p. 505 ff.; R.C. POST, *Constitutional Restraints on the Regulations of Scientific Speech and Scientific Research*, in *Faculty Scholarship Series, Yale Law School, Yale Law School Legal Scholarship Repository*, Paper 165, 2009. It should be noted that the Supreme Court has never clearly connected the freedom of scientific research to I Amendment: however, the closest the Court has come to this was in the case *Griswold v. Connecticut*, noting: «*The right of freedom of speech and press includes not only the right to utter or to print, but the right to distribute, the right to receive, the right to read and freedom of inquiry, freedom of thought, and freedom to teach*» (381 U.S. 479, 1965).

<sup>711</sup> The limitations to this freedom must be prescribed by law, must be necessary in a democratic society, must be aimed at protecting the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary (art 10, § 2, E.C.H.R.).

<sup>712</sup> With regards to the introduction within Italian Constitution of an article precisely dedicated to scientific research and the debate in the Constitutional Assembly, see L. CHIEFFI, *Ricerca scientifica e tutela della persona: bioetica e garanzie costituzionali*, Napoli, 1993, p. 28 ff.

Cultural Rights that enucleates the duty for States to respect the indispensable freedom of scientific research;

(3) Freedom of investigation connected to a duty for the State. Some Constitutions not only proclaim this freedom, but call for the State of a role of improving and promoting science and research. This is exemplified, but not limiting to, the Italian Constitution (art. 9), the Mexican (art. 27), the Portuguese (art. 77), the Spanish (art. 44), the Greek (art. 16). In the European Union, the latest modifications to Treaties have introduced a similar role for States and for the Union itself: title XIX of T.F.E.U., as introduced by Lisbon Treaty, is dedicated to “Research and technological development and space”. In art. 179 the Union is charged with the objective *«of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties»*. In doing this, the E.U. should cooperate with States in enacting multiannual framework programs.

Thus, in the constitutional panorama, three levels of protection are given to freedom of science: *«at a first basic level, this freedom receives the same protection given to all other fundamental rights included in the genus of freedom of thought and expression; at a second level, we could find a specific and expressed constitutional recognition for such a fundamental freedom; and finally, at a possible third level, the State is engaged in promoting scientific research»*<sup>713</sup>.

It should be noted that in the European Constitutions the necessity of formulating the freedom of scientific research starts after the Second World War when the desire to get rid of the terrible experiences of Nazi experiments on human beings in the name of freedom of science was very strong<sup>714</sup>. In other States (such as

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<sup>713</sup> A. SANTOSUOSSO, V. SELLAROLI, E. FABIO, *What constitutional protection for freedom of scientific research?*, in *Journal of Medical Ethics*, 33, 2007, p. 342.

<sup>714</sup> About Nazi eugenic programs see A. SANTOSUOSSO, *Corpo e Libertà – Una storia tra diritto e scienza*, Milano, 2001. See also A. ORSI BATTAGLINI, *Libertà scientifica, Libertà accademica e valori costituzionali*, in AA.VV., *Nuove dimensioni nei diritti di libertà. Scritti in onore di Paolo Barile*, Padova, 1990. It must be noted that, before the formulation of the freedom of scientific research, there was another legal concept, i.e. the one of academic freedom. It was mentioned firstly in the Prussian Constitution of 1850, which declared that “science and its teaching shall be free”. It is reflected in German Constitution, in which academic freedom is known as *Lehrfreiheit* – the right of faculties to

Canada and the U.S.A.), instead, with a different legal background, the diverse evolution of historical facts and the absence of totalitarian and eugenic experiences led to ensure protection to scientific research in an indirect way, i.e. absorbing it in the freedom of thought and expression.

The content of such freedom includes: the right to choose the object of investigation, the right not to investigate about what the person does not like or is not interested in, the right to freely work and in an independent way, the right not to be sanctioned because of the investigation, the right to be recognized in his intellectual property rights upon the investigation, and the right of having a social protection, with the extension of benefits from results. More precisely, this freedom develops on different levels and has multiple dimensions<sup>715</sup>: on a first level, it entails the researcher's right to investigate on the topic that he/she freely chooses; on a second level there is the right to spread the knowledge to others, to communicate results to other colleagues or community, on a third level there is the check of hypothesis, collecting and testing data according to the scientific method (it includes the right to experiment too), and on a fourth level, the economic exploitation of the products or results of research.

The freedom of scientific research is not an absolute one, but is always limited and balanced by other values/interests/goods at stake<sup>716</sup>: for example, within the biomedical area, this freedom must comply with the respect of other human rights and dignity<sup>717</sup>, the respect of the proportionality principle (without altering the essential content of the freedom of investigation), and the respect of the needs of “*leges artis*” and good practices.

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teach on any subject, and it articulates in (1) *Freiheit der Wissenschaft*, freedom of scientific research, and (2) *Lernfreiheit*, the right of students to attend any lectures. With regards to the freedom of scientific research in German Constitution, see C. STARCK, *Freedom Of Scientific Research And Its Restrictions In German Constitutional Law*, in *Israeli Law Review*, 39, 2, 2006, p. 110-126.

<sup>715</sup> J.A. ROBERTSON, *The scientist's right to research: a constitutional analysis*, in *California Law Review*, 51, 1977-1978, p. 1204 ff.

<sup>716</sup> See Bilbao Declaration (26<sup>th</sup> May 1993): «*the scientific investigation should be free, without any limit except the one self imposed by the researcher himself. The respect of fundamental rights enacted in declarations and international conventions fixes the limit of the actuation and application of genetic techniques to the human being*» (conclusions). The Bilbao Declaration was the first international document to address the human genome. The declaration denounces all uses of genetic information causing or leading to discrimination in work relations, in the insurance domain or in any other sector. See in *Revista Médica de Chile*, 122, 6, 1994, p. 705-708.

<sup>717</sup> See Nuremberg Principles, Oviedo Convention, Directive 2005/28, and U.N.E.S.C.O. Universal Declaration on Bioethics and Human Rights. In German and Spanish Constitutions the limit of human dignity is referred to research in general, not only for the one in biomedical area.



The U.N.E.S.C.O. Declaration on Bioethics specifies the principles that must apply to any kind of investigation which are listed as follows: the research for peace, for improving the quality of life, for progress, the respect for human dignity and fundamental rights and freedoms (dignity here coincides with the informed consent), the priority to interest of the person upon exclusive interest of science and society, the improvement of benefits and minimization of risks, the respect to cultural diversity and pluralism, the principle of solidarity and cooperation, and the principles referred to participants at research projects or patients, such as physical integrity, privacy, confidentiality, equality, justice, equity, non discrimination, and no stigmatization.

The 1997 Universal Declaration on the Human Genome and Human Rights, which forms the basis of “soft law” in the area of human genome governance, states that the research on the human genome and the resulting applications open up vast prospects for progress in the improvement of the health of individuals. However, this research should fully respect human dignity, human rights and protect public health, as well as prohibit all the forms of discrimination based on genetic characteristics. Moreover, it should follow the standards of *«meticulousness, caution, intellectual honesty and integrity»* both during the investigation phase and in the presentation and utilization of findings. States are responsible for facilitating the freedom of research and must ensure that *«research results are not used for non-peaceful purposes»* (art. 15), thus infringing peace and security.

The 1999 U.N.E.S.C.O. Declaration on Science and the use of scientific knowledge states that science must be at the service of knowledge and knowledge at the service of progress, peace, development of society. Thus, scientific research is not entirely free but linked to specific purposes, so that if a research is harmful, it should be banned.

In this context, it is relevant to distinguish between the freedom of scientific research and the free application and diffusion of scientific discoveries. In the first meaning, as said, there is a freedom that is prohibited and limited only when it affects human dignity and fundamental rights. In the second sense, instead, the limits are bigger and broader. In fact, not everything that could technically and theoretically be done must be done (from an ethical and legal point of view). That is why the

public powers tend to limit the spread of discoveries that could damage humanity or put it in peril, or they oppose to attempts of letting the knowledge circulate in a free way. On the other hand, instead, if a discovery could benefit the whole humanity, it is a role and duty of public powers to favor the spread of it, so that to improve humankind.

Other limits of free scientific research are the right to privacy, life, integrity, public security and public health. Moreover, the scientific research is conditioned by private interests (pharmaceutical companies and biotech multinationals), and by the interests of a monopoly that find an expression in the patent system<sup>718</sup>.

With regards to the limits, in Italian Constitution<sup>719</sup>, for instance, scientific research is lawful and protected by the Constitution, if it pursues the aim of incrementing human knowledge and scientific progress, and of improving human life conditions<sup>720</sup>. Thus the freedom of scientific research that is stated in art. 9 and 33 as an individual right must be connected to art. 32 as well. The freedom of inquiry cannot be detached from the “person-centred principle” (“principio personalista”), as it should be at the service of human dignity, life, human rights, physical and psychical integrity. It cannot become a “servant” of economic interests, but the centre of the scientific research must be the human being in any case<sup>721</sup>. Of course,

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<sup>718</sup> Braben advise about the risk of looking for sponsors for conducting research, and this could infringe the freedom itself. Indeed, the risk of an economic influence that alters the freedom of investigation is high, if the financial mechanisms influence the chosen topic and prevail over it. (D. BRABEN, *Scientific Freedom: the Elixir of Civilization*, Hoboken, New Jersey, 2008).

<sup>719</sup> See the Italian Constitution: art. 9 with regards to the role of Republic in promoting the development of scientific research, and art. 33 that guarantees the freedom of research and the free teaching. Art. 9 is a precondition for the exercise of the individual liberty enucleated in art. 33, so that the first article regards the duties upon the State in promoting research and supplying researchers with tolls and means, while art. 33 aims at guaranteeing the effective exercise of the right to research (see S. LABRIOLA, *Libertà di scienza e promozione della ricerca*, Padova, 1979, p. 41 ff.). Moreover, if the scientific research could be qualified as a free economic activity as in art. 41, it should not be in contrast with social utility or in such a way to damage security, freedom and human dignity. It should also be noted that, even if scientific research is object of specific articles, its relationship with the freedom of thought has been recognised by the Constitutional Court (see decision n. 59/1960); though, the limit for the freedom of thought (“public morals”) cannot apply to freedom of research.

<sup>720</sup> See, for example, S. LABRIOLA, *Libertà di scienza e promozione della ricerca*, cit.; F. MERLONI, *Autonomia e libertà nel sistema della ricerca scientifica*, Milano, 1990; A. ORSI BATTAGLINI, *Libertà scientifica, libertà accademica e valori costituzionali*, cit.; R. BIN, *La libertà della ricerca scientifica in campo genetico*, in M. D’AMICO, B. RANDAZZO (EDS.), *Alle frontiere del diritto. Scritti in onore di Valerio Onida*, Milano 2011, p. 215 ff.; L. CHIEFFI, *Ingegneria genetica e valori personalistici*, in L. CHIEFFI, *Bioetica e diritti dell’uomo*, Torino, 2000, p. 87.

<sup>721</sup> See R. ROMBOLI, *La «relatività» dei valori costituzionali per gli aspetti di disposizione del proprio corpo*, in *Politica del Diritto*, 1991, p. 565 ff.

since the attribution of the right to life and the notion of dignity remain ambiguous, it is analogous that the limits of scientific research are ambiguous.

In the U.S. Constitution, however, does clearly not refer to the limits of such freedom. Instead, they can be enucleated by considering the Preamble where the importance of some values like justice, domestic tranquillity, national defence, and general well-being is expressed<sup>722</sup>. The Supreme Court has specifically addressed the issue<sup>723</sup>, by enacting the so-called O'Brien test to draw a threshold between the freedom of speech (within which the freedom of scientific research pertains) and the intervention of Government for societal interests: the state regulation is, indeed, due and justified if «(1) it is within the constitutional power of the government; (2) it furthers an important or substantial governmental interest; (3) the asserted interest is unrelated to the suppression of free expression; (4) the incidental restriction on alleged First Amendment freedoms is no greater than is essential to the furtherance of that interest»<sup>724</sup>. So, limits are accepted in a narrow sense and as exceptional, only if the government exercises its own constitutional powers, if it enacts a content-neutral regulation, and if the interest at stake is general.

Starck specifies that within the freedom of scientific research there are both internal and external limits. Among the latter category, there are the limits that have been mentioned above (right to health, security, human dignity and so on), while the former group concerns itself with the ethical rules of conducting research in a “good” way, i.e. taking into account that «*results are to be documented, outcomes are to be consistently reviewed and strict honesty is to be maintained regarding contributions made by other scientists*»<sup>725</sup>. So, the internal limits of research are the professional and deontological rules of conduct of researchers, which are summarised in the duty of not to manipulate data, of not to incur into plagiarism or theft of ideas, of not to forge contents, and so on.

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<sup>722</sup> For example, the U.S. Supreme Court in the case *Bill Johnson's Rests., Inc. v. NLRB*, 461 U.S. 731, 742, 1983, has stated that public health and safety interests are substantial to be protected by the State.

<sup>723</sup> See case *Chaplinsky v. New Hampshire*, 315 U.S. 568, 571, 1942; case *United States v. O'Brien*, 391 U.S. 367, 1968.

<sup>724</sup> See *United States v. O'Brien*, cit., at 377.

<sup>725</sup> C. STARCK, *Freedom Of Scientific Research*, cit., p. 114.

About the subject of whom the freedom of research is entitled, Díez Picazo states that it is recognizable to everyone<sup>726</sup>. Indeed, everyone can aspire to investigate, although the State has fixed a number of requirements that are needed to be complied in order to belong to scientific community (such as a good professional preparation and education). Nowadays the individual's right of investigation is perceived as a collective one (because of the team working and the birth of a scientific community), and it influences the notion of responsibility and the regulation of activities.

Such freedom of research entails “negative” and “positive” obligations for the State. On the one hand, there is the duty for the State not to interfere in the choice of topics of research and in its developments without any imposition upon researchers (“freedom from”, typical of liberal societies). On the other hand, it should be indicated that the State has the duty to promote and sustain this freedom of scientific research (“freedom to”, typical of welfare states), assuming the responsibility of developing scientific investigation for the benefit of the whole humanity (general interest). Of course, it is important to find a proper balance between these two duties. Indeed, if the State interferes too much in the determination of tools and structures for the realization of research, and thus orienting research, it could infringe the individual's liberty. On the other hand, the State cannot be denied the essentiality of its support and contribution, in order to put the conditions (and resources) for conducting investigations<sup>727</sup>. Furthermore, the States should recognize, as deriving from the freedom of scientific research, the right for the members of community of having access to the benefits of research without any discrimination in terms of geographical, cultural, economic provenience.

So, in the first meaning this freedom entails that an individual right is vested upon the researchers in their protection against interference by the government and the society. In a second meaning, the freedom of scientific research is a claim to civic membership, thus such a right to research embeds science more explicitly within

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<sup>726</sup> L.M. DIEZ PICAZO, *El sistema de derechos fundamentales*, Madrid, 2005.

<sup>727</sup> About the possible conflict among these two duties for the State, see L. CHIEFFI, *Ricerca scientifica e tutela della persona*, cit., p. 87-88.

society and requires that people participate in research, ask for its progress and enjoy its results<sup>728</sup>.

#### 4.2. *The Freedom of Scientific Research and Synthetic Biology.*

When talking about scientific research, it is important to start from the definition, in order to understand what this expression means. Quoting the “*Frascati Manual*” by O.E.C.D.<sup>729</sup>, «*research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications*». This term, therefore, covers three activities: (1) basic research (experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view), (2) applied research (original investigation undertaken in order to acquire new knowledge and directed primarily towards a specific practical aim or objective) and (3) experimental development (systematic work, drawing on existing knowledge gained from research and/or practical experience, which is directed to producing new materials, products or devices, to installing new processes, systems and services, or to improving substantially those already produced or installed).

Synthetic biology, being a rational, intellectual, theoretical and empirical activity, based on investigation, observation, collection of data, experiments, applications, clearly belongs to the “scientific research” category. It shows theoretical aspects, as the knowledge connected to biology, nanoscience, computer sciences, genetics and so on is at stake and increases in the process of research, but it

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<sup>728</sup> With regards to a society’s right to do science, see A. ORSI BATTAGLINI, *Libertà scientifica, libertà accademica e valori costituzionali*, cit., p. 98. See also M. SALVI, *What Responsibility For Science*, in *Law and the Human Genome Review*, 17, July-December 2002, p. 125-134; J.T. EDSALL, *Two aspects of scientific responsibility*, in *Science*, n. 212, 1981, p. 11-14. G. STENT, *The dilemma of science and morals*, in *Genetics*, 1974, p. 41-51. It is worth remembering that in the 20<sup>th</sup> Century, meaningful were the appeals to an ethical compromise of science with society against the perils of the use of scientific results. For example, Einstein and Russell signed the Manifesto of Pugwash (1955), appealing for a nuclear disarm and intending science as a means for peace.

<sup>729</sup> O.E.C.D., *The Measurement of Scientific and Technological Activities*, Frascati Manual 2002, Proposed Standard Practice for Surveys on Research and Experimental Development.

is also an applied research and experimental one, as the theoretical discoveries lead to practical applications (technological facet). In reality, it is difficult to distinguish between the theoretical and experimental phase (followed by technological applications), because the two fields are strictly connected within synthetic biology. Indeed, the activity of research needs evidences of the suggested hypothesis, and these are obtained through experiments. It is impossible to separate “observation” from “manipulation”. It means that, although there are different types of research, within synthetic biology all the levels are inter-related and “merged”. For this reason, it is very hard to argue, in the synthetic biology area, that the freedom of research pertains only to the theoretical phase and not to the other phases (as affirmed in the U.S. Constitutional system, where the I Amendment about the freedom of thought “covers” only the “observation” moment, so that every research implying manipulation would be excluded from constitutional protection)<sup>730</sup>. Indeed, *«even the simple observation is a form of interaction and therefore, after all, a manipulation/construction of the object. Furthermore, the contraposition between observation and manipulation does not stand the test of the facts. In scientific research activity, there is no breaking point between speculative activities and activities that are more likely manipulative, because research in itself looks like a continuum: each phase implies the other phases and vice versa. Each stage of scientific research includes both authentic theoretical–observational and more practical–manipulative aspects in different proportions from time to time»*<sup>731</sup>.

In a nutshell, synthetic biology represents a type of scientific research having theoretical, applied and experimental facets. Being a type of research, the freedom of scientific research plays a meaningful role within synthetic biology activities, that are, therefore, constitutionally protected.

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<sup>730</sup> At this regard, see the U.S. Bioethical Presidential Commission which stated about the freedom of scientific research that *«most currently controversial biological research involves experimental manipulation of living matter, rather than theoretical exploration or mere observation of natural objects [...] Scientists may have the right to pursue knowledge in any way they want cognitively, intellectually, but when it comes to concrete action in the lab, that becomes conduct and the First Amendment protection for that is far, far weaker»* (U.S. PRESIDENT’S COUNCIL ON BIOETHICS, *The monitoring of stem cell research. A Report*, Washington, D.C., 2004, at <http://www.bioethics.gov>, last visited 28<sup>th</sup> January 2013).

<sup>731</sup> A. SANTOSUOSSO, V. SELLAROLI, E. FABIO, *What constitutional protection*, cit., p. 343.

However, such freedom is not entirely free, but finds some limits in the different directions where it shapes. This section aims to consider its role in relationship with security (and health) issues, intellectual property rights and dignity.

#### 4.2.1. *Scientific Research and Security Issues.*

The risk that scientific research could affect public security is not so impossible to conceive. If we consider that until the 19<sup>th</sup> Century research was explicitly reserved for warfare purposes<sup>732</sup>, this connection between research and war still remains in force after the 19<sup>th</sup> Century, as seen in the devastating applications of physics and chemistry during the Second World War, such in the launch of atomic bomb or the usage of toxic gases.

In current times, the implications of life sciences in warfare and also terrorism purposes cannot be excluded from consideration. It is the same with synthetic biology. As it was extensively discussed in the previous sections and chapters, it is clear that synthetic biology has the potential to be used for harmful purposes. It is a viable threat to democracy and even to the survival of humankind rather than for the benefit of it.

The centrality of the right to life, to public health and integrity cannot be undermined by needs of scientific research<sup>733</sup>. These rights fix a limit to the exercise of investigations in the name of the centrality of the person in legal systems<sup>734</sup>. In fact, if a research such as the one in synthetic biology puts into peril the existence of human beings or alters the health and security of them, it cannot be admitted in an absolute way. In the balance between the freedom of scientific research and the right to life or health or security, a prevalence should be given to the latter rights. It is not say that scientific research having possible harmful purposes should be completely

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<sup>732</sup> See M.S. GIANNINI, *L'organizzazione della ricerca scientifica*, in *Rivista trimestrale diritto pubblico*, 1966, p. 3 ff.

<sup>733</sup> See, for example, what has been affirmed by the Italian Constitutional Court in decisions nn. 479/1987, 364/1988.

<sup>734</sup> In Italy the principle based on centrality of the person (*principio personalista*) determines the way of interpreting all the other rights proclaimed by the Constitution (see L. SAPORITO, *La ricerca scientifica*, in G. SANTANIELLO (ED.), *Trattato di diritto amministrativo*, Padova, 2007, p. 12; L. CHIEFFI, *Ricerca scientifica e tutela della persona*, cit., p. 122).

banned, but it should be regulated and controlled. For example, in the case that some scientific publications about pathogens could be used by bioterrorists for reaching their malevolent purposes, it is necessary to implement some measures so as to control the spread of information. This gives rise to the problem whether to opt for censorship or free publication of results in the hypothesis that they could be handled for a bioterrorist purpose.

Moreover, the possession of instruments for conducting research in synthetic biology should need to be controlled, for instance through a license system, so as to supervise “who owns what”.

It is clear that the censorship or the restraint of publications or the control of labs, scientific machineries and other scientific tools represent ways of limiting the freedom of scientific research, but they are all chosen in the light of ensuring a proper protection to constitutional values, interests and rights such as life, integrity and health that must “prevail” over the freedom of inquiry and investigation.

So, an operation of a balance of rights is due. In general, in the theory of constitutional law, the balancing is a common technique that is adopted (a) in the conflict of two non homogeneous rights, or (b) in the contrast between two different claimants of the same right, or (c) in the contrast between one individual right and a collective one. The balance is pursued through three stages: «(a) *the first establishes the degree of interference with one principle or right, (b) the second establishes the importance of satisfying a competing right, and (c) the third determines whether the importance of satisfying the competing right justifies the interference with the first right*»<sup>735</sup>.

The balance is an expression and part of the principle of proportionality that consists of three sub-principles: the principles of suitability, of necessity, and of proportionality in the narrow sense. The principle of suitability provides not to adopt means that obstruct the realisation of at least one principle without promoting any principle or goal for which they were adopted. In other words, the first stage consists of evaluating that the «*relationship between the means chosen and the ends pursued*

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<sup>735</sup> R. ALEXI, *Constitutional Rights, Balancing, and Rationality*, in *Ratio Juris*, 16, 2, June 2003, p. 136. In general, with regards to the balance according to proportionality principle, see also - among the many - A. PACE, *Interpretazione costituzionale e interpretazione per valori*, in G. AZZARITI (ED.), *Interpretazione costituzionale*, Torino, 2007, p. 83 ff.



*is rational and appropriate*»<sup>736</sup>. The principle of necessity requires that of two means promoting one goal that are, broadly speaking, equally suitable, the one that interferes less intensively in another goal ought to be chosen. «*At the core of necessity analysis is a least restrictive-means (LRM) test, through which [...] [it must be ensured] that the measure at issue does not curtail the right more than is necessary for the government to achieve its goals*»<sup>737</sup>. Balancing is the subject of the third sub-principle of the principle of proportionality, i.e. the principle of proportionality in the narrow sense. This one sounds: “The greater the degree of non-satisfaction of, or detriment to, one principle, the greater the importance of satisfying the other”<sup>738</sup>. It means that, if possible, a right cannot be suppressed in the face of the competing one, and its “essential core” must be preserved.

Such balance is clearly expressed by a metaphor put forth by Bin: it must be thought as a pavement crowded with people on a rainy day<sup>739</sup>. There are a lot of umbrellas and under each one there is a person, whose head is well protected by the umbrella itself, but as much as you go further from the head, humidity and wet places appear. So, the “head” of the freedom of scientific research (meant as the freedom of investigation on whatever topic) is protected by Constitution and is absolute, but as soon as you distance yourself from it, you meet other umbrellas and so other interests or rights must be taken into account, such as the right to life, to health, to integrity and security.

This means that the intangible nucleus of the freedom of research is the choice of topics of investigation and the exercise of theoretical speculations. However, when such theory meets the application phase and the results of research are used for specific purposes (such as the use of synthetic biology for developing bioterrorist applications), the freedom of research should be limited, provided that the balance occurs in the respect of the proportionality principle.

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<sup>736</sup> A. STONE SWEET, J. MATHEWS, *Proportionality Balancing and Global Constitutionalism*, in *Columbia Journal of Transnational Law*, 72, 47, 2008, p. 75.

<sup>737</sup> J. MATHEWS, A. STONE SWEET, *All Things In Proportion? American Rights Review And The Problem Of Balancing*, in *Emory Law Journal*, 60, 2011, p. 803.

<sup>738</sup> R. ALEXY, *A Theory of Constitutional Rights*, Oxford, 2002, p. 102.

<sup>739</sup> R. BIN, *La Corte e la scienza*, in A. D'ALOIA (ED.), *Bio-tecnologie e valori costituzionali: il contributo della giustizia costituzionale*, Atti del seminario di Parma, 19<sup>th</sup> March 2004, Torino, 2005, p. 11 ff.

4.2.2. *The Relationship with the Right to Health.*

When we move to biosafety (and also biosecurity) issues, the freedom of scientific research should be balanced with the right to health, as some synthetic application could affect individual and collective health in spreading (accidentally or voluntarily) in the environment. Indeed, «*not all science is good for humanity*»<sup>740</sup>.

In these cases, again, the researcher's freedom should be balanced. Indeed, if the research is able to damage and provoke harmful effects on health, it should be limited in the name of the right to health (by association to the right to integrity and life). This is the underlying rationale of the precautionary principle and the model based on "*prudent vigilance*" too. The principle of "*responsible stewardship*" asks for a responsible care and attention by researchers towards health issues.

However, if a scientific research like synthetic biology increases the conditions of health with its applications, it should be encouraged and promoted. If the benefits for the whole society are much bigger and broader than harms<sup>741</sup>, the freedom of scientific research should prevail on the individual right to health. So, in the balance between this freedom and health, the latter always prevails in some cases limiting the freedom of scientific research, while in others the health needs indicate the road and purposes that scientific research must follow.

In the case of the scientific research that should be boosted for health reasons, the freedom of research could be read as a right vested upon collective people (society) in the further development of research<sup>742</sup>, which could indeed ameliorate their living conditions. So, the right to enjoy the benefits of research and the right to have the research improved and progressed originate from the freedom of scientific research, and it is tied with the right to health (both in the individual and collective dimensions)<sup>743</sup>.

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<sup>740</sup> M.D. KIRBY, *Human Rights. The Challenge of the New Technology*, in *Austin Law Journal*, 60, 170, 1986.

<sup>741</sup> See L. CHIEFFI, *Ricerca scientifica e tutela della persona*, cit., p. 146.

<sup>742</sup> With regards to the right to expectations of research recognised upon society and exercised by associations of consumers/defenders of patients' rights, for example, see R. BIN, *Freedom of Scientific Research in the Field of Genetics*, in R. BIN, S. LORENZON, N. LUCCHI (EDS.), *Biotech Innovations and Fundamental Rights*, Heidelberg, 2012, p. 105-118.

<sup>743</sup> With regards to the link between the right to health and the freedom of scientific research, see Italian Constitutional Court decisions n. 201/1995 (about the existence of a relevant interest to

#### 4.2.3. *Scientific research and Intellectual Property Rights in Synthetic Biology.*

Until the industrial revolution, scientific research was essentially a public activity, promoted and handled by State authorities. At this point, economic and private interests were beginning to shape and were becoming relevant. And progress was starting to be seen as a primary societal interest. Thus, the introduction of patents put the researchers within a network of commercial enterprises.

In the field of IPRs, numerous interests are into conflict: the researchers' right to investigate, publish their results and obtain protection for their discoveries and inventions (as recognized by art 15 Covenant on Economic, Social and Cultural Rights and by art. 27 Universal Declaration of Human Rights), the interests of enterprises in commercial exploitation of applications derived from that research, and the interests of society of having access to the benefits of research.

The individual right vested upon the single researcher entails his/her claim in seeing his/her invention recognised and in his/her right in obtaining economic gains from it. In this case the freedom of scientific research relates to the right to economic enterprise<sup>744</sup>. Also, the balance between the principles of the personal right to property (claimed by researcher) and the advancement of the "common good"<sup>745</sup> must be attained, so as to combine the stimulation of innovation with an equitable distribution of the benefits from synthetic biology to society<sup>746</sup>.

As previously mentioned, the question of whether to adopt an open source model, a "commons" model or a proprietary one with regards to synthetic biology is a "hot problem"<sup>747</sup>.

According to someone<sup>748</sup>, a patent system would limit the innovations and advancement of research. Despite the fact that it would protect the single researchers,

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scientific research, constitutionally protected), n. 500/1993 (research as essential common good) and n. 423/2004 (research as a constitutional value).

<sup>744</sup> In Italian Constitution it is protected by art. 41.

<sup>745</sup> J. RUSSO, *Inventors and innovations: Intellectual Property and the Evolution of its Regulation*, in *Intellectual Property Law Institute*, 14, 1, 18<sup>th</sup> September 2008.

<sup>746</sup> About these issues, see the Manchester Manifesto, enacted by some intellectuals and Nobel winners in 2009 (at <http://www.isei.manchester.ac.uk/TheManchesterManifesto.pdf>, last visited 28<sup>th</sup> January 2013).

<sup>747</sup> See, about IPRs applied to synthetic biology, SYBHEL project, funded by European Commission's Science in Society Program and part of the 7th Research Framework (at <http://www.sybhel.org>, last visited 28<sup>th</sup> January 2013).

the benefits of the whole society would be undermined. Moreover, the first ones to obtain patents would effectively block the later innovators and create a situation of monopoly where the first innovators would avoid the later ones in the pursuit of their research. This is the origin of the so-called “*tragedy of anti-commons*”<sup>749</sup>, i.e. the over-utilisation of privatization and exclusive property rights, which blocks the stimulus to innovation and research, and thus deterring the investments needed to make use of the discoveries. In fact, if the patent landscape is complex (suppose that, for example, any single biobrick is vested with a patent), a multitude of coexisting patents would be necessary to be associated with a single product and it could be very difficult for researchers to obtain materials for developing their studies, and thus resulting in the depletion of the innovation in the long term<sup>750</sup>. It would also in the need for a large investment for the development of a single product (patent thicket), and the waiting of 20 years for the life span of the patent to wane would limit the access to precious information. This thus determines a divide between Poor and Rich countries of the world, i.e. those been granted with patents and those not. As Rutz says, the blockage of a technology could occur «*because one holder of a necessary patent refuses to license*»<sup>751</sup>. In addition, there is the risk where some of the patents that are granted in synthetic biology area could be «*astoundingly basic, the equivalent of patenting Boolean algebra right at the birth of computer science*»<sup>752</sup>, and so they would cover immense areas of research<sup>753</sup>. In this sense, as Boyle states

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<sup>748</sup> A. RAI, J. BOYLE, *Synthetic Biology: Caught Between Property Rights*, cit.; J. HENKEL, S.M. MAURER, *The economics of synthetic biology*, in *Molecular Systems Biology*, 3, 2007, p. 117 ff.; J. CALVERT, *The commodification of emergence: systems biology, synthetic biology and intellectual property*, in *Biosocieties*, 3, 2008, p. 383–398.

<sup>749</sup> The expression was used for the first time by Michael Heller (M. HELLER, *The Tragedy of the Anticommons*, in *Harvard Law Review*, January 1998). About the “tragedy of anti-commons” in synthetic biology, see K. OYE, R. WELLHAUSEN, *The Intellectual Commons and Property in Synthetic Biology*, in M. SCHMIDT (ED.), *Synthetic Biology: The technoscience and its societal consequences*, cit., p. 121-140.

<sup>750</sup> Consider the US Patent Application 20070269862 on “Installation of Genomes or Partial Genomes into Cells or Cell-like Systems”. It was filed by Glass and others in 2007. It covers methods of introducing a genome into a cell or cell like system, with extraordinarily broad claims covering the production of medicines and biofuels. If granted, a lot of researchers would be in trouble, since the patent would cover most of the current field of synthetic biology.

<sup>751</sup> B. RUTZ, *Synthetic biology and patents. A European perspective*, in *European Molecular Biology Organization Reports*, 10, 2009, p. S14-S19.

<sup>752</sup> A. RAI, J. BOYLE, *Synthetic Biology: Caught Between Property Rights*, cit, p. 390.

<sup>753</sup> It can be noted that similar observations have been given with regards to the patentability of single genes: indeed, being a gene potentially multi-coding, the fact of allowing the patentability of an isolated one without any other human intervention but the isolation would mean granting the right to exploit all the possible future applications of the gene itself.

succinctly: «*The danger isn't that Craig Venter has become God, it is that he might become Bill Gates. We do not want a monopolist over the code of life*»<sup>754</sup>. Furthermore, the problem of “patent sharks” or “patent trolls”, defined as «*patent owners who do not intend to exploit a patent but who enforce their patent rights against purported infringers*»<sup>755</sup> could arise. Indeed, they would hide their patents, and sue the ones that infringe them, and in a field like synthetic biology that is globally spread and fragmented, it may be hard to identify all the patents released. The fear of being sued could, of course, slow down the innovation.

As seen, «*one major part of the technological terrain into which synthetic biology must fit – biotechnology - has already proven difficult for intellectual property law to manage*»<sup>756</sup>. However, the flip side is, apart from patent considerations, there are copyright difficulties for software.

In general, copyright covers original works of expression and excludes works that are functional, while patent law covers inventions that are useful, novel, and non obvious, i.e. functionality is a requirement (but algorithms are excluded from patentability). On the basis of these conditions, historically, it seemed that software did not fit into either copyright or the patent box, as it was too functional for copyright, and too close to a collection of algorithms and ideas for a patent. Only after the span of a few years, software came to be recognized as to be covered by both copyright and patent<sup>757</sup>. Within the software regime, it appears that two models of protection have mainly been elaborated: a proprietary one and an open-source one.

Currently, it has been affirmed that synthetic biology is similar to a software<sup>758</sup>. In synthetic biology programs are based on a genetic code formed by 4 bases (A, T, C, G), while the software systems works with a binary code (0, 1). Therefore, if the analogy between software and synthetic biology is valid, it would result in an open model, inspired by the open software movement in information and communication

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<sup>754</sup> J. BOYLE, *Monopolist of the Genetic Code?*, 28<sup>th</sup> May 2010, at <http://www.thepublicdomain.org/2010/05/28/monopolist-of-the-genetic-code/> (last visited 28<sup>th</sup> January 2013).

<sup>755</sup> See. J. HENKEL, M. REITZIG, *Patent Sharks*, in *Harvard Business Review*, 1<sup>st</sup> June 2008, p. 129-133.

<sup>756</sup> S. KUMAR, A. RAI, *Synthetic Biology: The Intellectual Property Puzzle*, cit., p. 1749.

<sup>757</sup> See U.S. Computer Software Copyright Act of 1980, Pub. L. n. 96-517, 94 Stat. 3028.

<sup>758</sup> The first proposals to assimilate genetic sequences to software can be found in I. KAYTON, *Copyright in Living Genetically Engineered Works*, in *George Washington Law Review*, 50, 1982, p. 191-192.

technology<sup>759</sup>. However, the source code remains linked to a property right (upon the holder of copyright), despite the fact that the licenses are open to developers, and thus the connection with property schemes would recreate the same problems of a patent system.

An opposite system against any property claim would be that of the “commons”, such as the one chosen by the aforementioned BioBricks Foundation with the institution of the Registry of Standard Biological Parts and applied in iGEM competition. Indeed, «*placing parts into the public domain not only makes parts unpatentable, but it undermines the possibility of patents on trivial improvements*»<sup>760</sup>, and it would reduce the costs of patentability. In addition, «*extending platforms like the Registry of Standard Biological Parts to include ownership information would help boost open parts usage*»<sup>761</sup>, and push for the cooperation between researchers and reciprocity. So, «*proponents of the ‘open access to research’ concept believe that it will not only increase the transparency in research, thereby promoting only those scientists who really seek to use such information productively and simultaneously aid in subduing the misuse of synthetic biology. It shall also create a common consortium wherein there is free exchange of information without any hindrance as to access or the need to pay royalty*»<sup>762</sup>.

Such a model is contested by scholars<sup>763</sup> who think that a system of commons would not ensure a proper protection to researchers and would undervalue research itself, by rendering it a “chattel” in the hands of everyone. Moreover, a researcher could also be reluctant to disclose his/her invention and leave it at the discretion of the whole public domain. So, the monopoly determined by patents would be necessary and justified because it could really serve the benefit of society<sup>764</sup>. Patents on synthetic products could only advance the state of technology to the public, in the sense that they would, indeed, be intended as a tool for ensuring commutative justice

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<sup>759</sup> In general about the creation and use of open-source software, see B. PERENS, *The Open Source Definition*, at <http://perens.com/OSD.html> (last visited 28<sup>th</sup> January 2013).

<sup>760</sup> A. RAI, J. BOYLE, *Synthetic biology: caught between property rights*, cit., p. 392.

<sup>761</sup> J. HENKEL, S.M. MAURER, *Parts, property and sarin*, in *Nature Biotechnology*, 27, 12, December 2009, p. 1096.

<sup>762</sup> T. SAUKSHMYA, A. CHUGH, *Intellectual property rights in synthetic biology: an anti-thesis to open access to research?*, in *System Synthetic Biology*, 4, 2010, p. 242.

<sup>763</sup> T. SAUKSHMYA, A. CHUGH, *Securing the benefits and implications of synthetic biology*, in *Journal of Commercial Biotechnology*, 16, 2010, p. 135-158.

<sup>764</sup> Case *Graham v. John Deere Co*, 383 US 1, 7-10 (1966).

in the long term and they would represent the proper balance between the incentives given to the inventor and the benefits deriving to community.

If a patent model is chosen, the aforementioned exclusions of patentability grounded on public order and moral reasons should be taken into account. They challenge the freedom of research as well. In fact, it is of common opinion that excluding patentability means the slowing down or impediment of research. In this context it is proper to take in consideration *Brüstle* case again. One of the questions asked by the Federal Court to E.C.J. was whether the concept of “uses of human embryos for industrial or commercial purposes” covered also the use of human embryos for purposes of scientific research.

The Court points out that the purpose of the Directive is not to regulate the use of human embryos in the context of scientific research, as it is limited to the patentability of biotechnological inventions. Even if the purpose of scientific research must be distinguished from industrial or commercial purposes, the use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attached to it. So the exclusion from patentability refers to the use of human embryos for purposes of scientific research as well, because it is not possible to distinguish from industrial and commercial use. Only the use of human embryos for therapeutic or diagnostic purposes could be object of a patent.

Thus, in this ruling the term “use” is adopted in a broad sense, by referring to both commercial, industrial and research purposes, and including prior events on which an invention is based. Thus, any invention, which requires either the prior destruction of human embryos or their use as base material, is excluded from patentability.

This decision has been strongly criticized, as it is thought that it would provoke negative effects on the whole of the European research, by impeding patents and the developments of investigations on human embryos. In reality, the interpretation of the decision, as the Court repeatedly says, should be referred only to the purposes and object of Directive 98/44 (therefore, only for the patentability field and, more precisely, for impeding the patentability of researches entailing the destruction of human embryos), and so it is possible that in other fields the E.C.J.

could offer a diverse definition of “embryo” and “use”. Moreover, the patentability of human genetic material derived from stem cells that did not require the destruction of embryo is admitted<sup>765</sup>. However, there are commentators who claim that the considerations offered by E.C.J. are more general. The ban of patentability could be referring to the whole research involving embryo cells, regardless of the patent aim. Even if researches not pursuing patentability are admitted (and also the researches not entailing the destruction of human embryos), they could hardly survive in the competition with the other (especially U.S.) enterprises<sup>766</sup>. As a result, the research on embryos would be completely forbidden, and not only the one connected to patent purposes.

In my view, and with a more positive interpretation of the ruling, what the Court is trying to do, although not explicitly declared, is to promote other ways of fostering research rather than through patents. Indeed, if the use of scientific research purposes linked to patents is banned, the use of that material for investigation but protected by other means could be admitted. In other words, the Court would be inviting us to re-think the patentability system and the association of it with innovation, thus substituting it with other tools or reframing it in the light of the relevance of other values/interests/rights over the economic gains that patents bring.

In stressing the importance of dignity and human rights, the E.C.J. could mean to reshape patents, in order to stop the prevalence of the monopolies and of financial, and private interests over the social and public role that patents could have for the benefit of the whole society. In this sense, a possible solution, for synthetic products as well, could be to maintain patents but mould them as “human rights”<sup>767</sup>, or to introduce new patterns, such as the “commons” one<sup>768</sup> or the open source one,

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<sup>765</sup> For comments on the ruling, see A. SPADARO, *La sentenza Brüstle sugli embrioni: molti pregi e... altrettanti difetti*, in *Forum di Quaderni costituzionali* (3<sup>th</sup> May 2012); V. ALTAMORE, *La tutela dell'embrione, tra interpretazione giudiziale e sviluppi della ricerca scientifica, in una recente sentenza della Corte di Giustizia europea (C-34/10 Olivier Brüstle contro Greenpeace e V.)*, in *Forum di Quaderni costituzionali*, 2<sup>nd</sup> December 2011.

<sup>766</sup> For this consideration, see C. CASONATO, *Introduzione al Biodiritto*, cit., p. 45 ff.

<sup>767</sup> See N. BOSCHIERO (ED.), *Bioetica e biotecnologie nel diritto internazionale e comunitario: questioni generali e tutela della proprietà intellettuale*, Torino, 2006.

<sup>768</sup> In defense of the BioBricks Foundation model, see A.W. TORRANCE, *Synthesizing Law for Synthetic Biology*, in *Minnesota Journal of Law, Science & Technology*, 11, 2, 2010, p. 629-665. The Author states that: «the BioBrick Agreement, a licensing framework intended to govern the legal relationships between the BBF, BioBricks contributors, and BioBricks users has the potential to be more than a mere license. In fact, like a constitution, it could help define some of the foundational



that is used for software<sup>769</sup> (but this model is still linked to property rights, like patents, and so it needs to be reshaped like them).

The first idea poses to “save” patents and thus recreate the balance between private and public interests, among companies, scientists and society, thus reframing more equal relations, and even allowing the intervention of the State or public bodies (so that to impede the monopolization of private interests). This would also favour the cooperation between enterprises, and thus re-giving importance to public and social interests behind the mere economic expectations of patents.

The second idea poses to boost the sharing of knowledge between enterprises and researchers, and would make discoveries transparent, free and available to everyone without any limitation. In this way the role of research as a way of “serving” public and benefit humankind would become concrete and visible<sup>770</sup>.

In conclusion, with regards to the relationship between synthetic biology and IPRs, it could be said that when “common heritage of mankind” issues are at stake the patentability should be excluded (on the basis of the “moral clause”). When synthetic products are created, one of the choices could be to opt for patents but in a revised form, revised so as to create a proper balance between the researcher’s rights, the enterprises’ interests and the benefits to the whole society, or to choose to adhere to an open source model (provided that the analogy between synthetic sequences and source code in software is accepted, and this is more visible in the *in silico* synthetic biology, where genetic sequences are designed through computers). Another choice would be to introduce a model of commons, leaving synthetic discoveries in the public domain<sup>771</sup>. In my opinion, the patent system could work in the cases of when synthetic biology products are more similar to biotechnological products, i.e. when

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*values and principles that synthetic biology might espouse to ensure that its social contributions prove beneficial to a degree commensurate with its scientific potential»* (p. 665).

<sup>769</sup> In defense of a copyright system to be applied to synthetic biology, see C.M. HOLMAN, *Copyright For Engineered DNA: An Idea Whose Time Has Come?*, in *West Virginia Law Review*, 113, 2011, p. 699-738.

<sup>770</sup> D. ENDY, *Open source biology*, 2005, at <http://itc.conversationsnetwork.org/shows/detail663.html> (last visited 28<sup>th</sup> January 2013).

<sup>771</sup> For further details on this conclusion, see A. FALCONE, *La Tutela Del Patrimonio Genetico Umano fra Costituzione e Diritti. Verso La Formazione di un Corpus Iuris sul Genoma Umano*, in print, p. 158 ff. In reality, Falcone creates an intermediate category between the “common heritage” issues and synthetic products, i.e. the category of biotech innovations having particular importance such as medicines or vaccines, and Biobricks too, for which a system of open licenses and public funding should be introduced.

synthetic biology shapes as an evolution of genetic engineering. The software model could be adopted when synthetic biology is closer to the engineering approach, i.e. when biobricks and the standardized parts look like the “pieces” of the source codes.

#### 4.2.4. *Abuses of Scientific Research Affecting Human Dignity.*

Another limit to the freedom of scientific research could be represented by human dignity. As established previously, this concept is vague and ambiguous.

Human dignity plays a role in blocking research when research consists of going beyond the theoretical dimension and it shows itself in actions which could affect the “core” essence of humankind.

Examples of abuses of scientific research that affect human dignity have been quoted with regards to eugenics, linked not only to the experience of Nazi countries or to the totalitarian countries, such as the Tuskegee experiment shows<sup>772</sup>.

In the field of synthetic biology, it could be argued that the creation of synthetic humans could alter the inherent dignity and uniqueness recognised to human beings (as affirmed by 1997 U.N.E.S.C.O. Universal Declaration on the Human Genome and Human Rights). So the research in this direction such as the ones affecting the common heritage of humankind (included future generations), i.e. the human genome, should be stopped. Analogously, the purpose of cloning achieved through synthetic biology should be avoided, as cloning would undermine human life. As such, scientific research should be limited by ethical principles<sup>773</sup>.

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<sup>772</sup> The “Tuskegee Study of Untreated Syphilis in the Negro Male” was a study pursued in the U.S.A., concerning 616 African American males, who were given blood tests in 1932. More than half of them were diagnosed with syphilis. The test subjects were not told they had syphilis and were not treated for it, despite the fact that after 1943 penicillin was available as a cure. The purpose of the research was to study the long term effects of untreated syphilis. After the Tuskegee case came to light in 1972 the US Congress created a National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research which published ethical principles generally known as the “Belmont Report” in 1979.

<sup>773</sup> See NATIONAL BIOETHICS ADVISORY COMMISSION, *Cloning Human Beings: Report And Recommendations Of The National Bioethics Advisory Commission*, 6, 1997. See C.R. SUNSTEIN, *Is There a Constitutional Right to Clone?*, in *Hastings Law Journal*, 53, 987, 2002, and J.A. ROBERTSON, *Procreative Liberty in the Era of Genomics*, in *American Journal of Law and Medicine*, 29, 439, 2003.

Moreover, the exceptions to patentability for moral reasons are based on human dignity for limiting patents and, as a consequence, scientific research as well.

Of course, individuating an offense to human dignity in the pursuit of some kind of research is not simple, and opposite positions are confronted. What appears to someone as a threat to dignity can be seen by others as a benefit for humanity to be improved.

The relationship between scientific research and human dignity is also shaped by the fact that the latter orients research and indicates in which direction research should go, such as for the benefit of humanity. If research is oriented in such way, dignity vested upon society is respected. Indeed, «*complementary to the notion of respect to human dignity so that to ensure individual subjective rights is that of dignity that is essential to the humanity of society*»<sup>774</sup>.

#### *4.2.5. The Freedom of Scientific Research, and the Interests of Current and Future Society.*

The freedom of scientific research entails that the benefits of it should be available to humankind and be equally distributed (according to solidarity principle). It is valid for results and applications of synthetic biology as well. It is, therefore, possible to individuate, as deriving from the freedom of scientific research, an interest upon society in obtaining positive results from research, as enshrined in human rights documents at international level (such as the aforementioned U.N.E.S.C.O. Declaration on Human Genetic Data (art. 19), U.N.E.S.C.O. Declaration on Bioethics and Human Rights (art. 2 lett. f), Universal Declaration of Human Rights (art. 27)<sup>775</sup> and Covenant on Economic, Social, Cultural Rights (art.

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<sup>774</sup> Translation from B.M. KNOPPERS, *Integrità del patrimonio genetico: diritto soggettivo o diritto dell'umanità?*, in *Politica del Diritto*, 2/1990, p. 352.

<sup>775</sup> About the origin of drafting, history and evolution of art. 27 of the Universal Declaration and its relationship with T.R.I.P.S. Agreement and IPRs, see A. PLOMER, *The Right to Access the Benefits of Science and Intellectual Property Rights*, in R. BIN, S. LORENZON, N. LUCCHI (EDS.), *work cit.*, p. 45-68.

15). As well as in the field of IPRs, the so-called «*human rights paradox*»<sup>776</sup> between the individual rights of researchers in their discoveries and the society's right to benefit from science is apparent. Indeed, the researcher's right and the society's one are not in contrast one to each other, but they integrate and complement each other.

Thus, the research in the area of synthetic biology should take into account the common interests of society in the scientific progress and the importance of pursuing it as a means of a way to see the recognition and the enforcement of the right to development. The solidarity principle, read in connection with the right to development, indicates for scientific research a road to follow, and it entails that each researchers has the duty<sup>777</sup>, to contribute to the development of science for the benefit of the others.

Such solidarity should be meant as “symmetric”<sup>778</sup>, thus belonging to the researcher and to the beneficiaries of research, so that the positive results which are derived from synthetic biology should be spread among the scientific community (in order to increase the set of knowledge and make the progress develop and grow), and among the whole society that could gain from them. This society refers to the current one (and in this sense, the solidarity principle is at the basis of an intra-generational responsibility), but it could be even the future society (meant as a subject of rights), which could take advantage of the evolution of discoveries and science (intergenerational responsibility).

The link between the freedom of scientific research, the right to development and the solidarity principle<sup>779</sup> determines, therefore, that synthetic biology research and the application of its results must be shared around the world. This is because only the circulation of results and benefits can produce much more development and growth in quality of life. It is towards these interests that research should be oriented.

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<sup>776</sup> See L. HELFER, *Human Rights and Intellectual Property: Conflict or Coexistence?*, in *Minnesota Intellectual Property Review*, 5, 43, 2003; L. HELFER, *Toward a Human Rights Framework for Intellectual Property*, in *University of California Davis Law Review*, 40, 2007, p. 971-1020 and P. TORREMANS, *Intellectual Property and Human Rights*, New York, 2008.

<sup>777</sup> With regards to research as a moral obligation for researchers and for participants to studies, see J. HARRIS, *Scientific Research is a Moral Duty*, in *Journal of Medical Ethics*, 31, 2005, p. 242-248.

<sup>778</sup> See C. CASONATO, *Derechos de la persona y Lógicas de la investigación clínica*, in *Teoría y Derecho*, n. 11/2012, p. 27-39.

<sup>779</sup> See also L. BUSATTA, *First Observations on the Right to Development Approach to Informed Consent in Medical and Genetic Research*, in R. BIN, S. LORENZON, N. LUCCHI (EDS.), *work cit.*, p. 323-333.

## 5. *The Right to Environment.*

Looking at the rights involved in the legal landscape of synthetic biology, a final mention must be given to the right to environment. This is because some references have been made to it in terms of the right to health (interpreted as a right to healthy environment as well), the right to development and, in particular, about the precautionary principle, as is one of the most quoted principles for the environmental protection. In this section I offer a deeper analysis of the content of this right to environment and the importance that it assumes within the field of synthetic biology, as numerous applications of synthetic biology concern the environment and have the potential to affect it.

### *5.1. Environment: a Prerequisite for Other Rights, an Object to Be Cared of in the Enactment of Other Rights, or a Right in Itself?*

The importance attributed to the environment and its connection with human rights started in the Seventies, when the first set of environmental damages drew the attention of States and the discussions about giving a particular legal relevance to the concept began to take shape. However, the road to formulate a specific right to environment is long and even now the existence of it as a right in itself (a “third generation” right) is questionable.

The current debate<sup>780</sup> focuses on whether the environment should be recognised as: (1) a pre-requisite for the enjoyment and realisation of human rights<sup>781</sup>, (2) an object to be cared of in the enactment of other rights, and (3) a right in itself, thus a right to a safe, healthy, sustainable environment.

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<sup>780</sup> See M.R. ANDERSON, *Human Rights Approaches to Environmental Protection: An Overview*, in A.E. BOYLE, M.R. ANDERSON (EDS.), *Human Rights Approaches to Environmental Protection*, New York, 1996, p. 1-4; J.G. MERRILLS, *Environmental Rights*, in D. BODANSKY, J. BRUNNÉE, E. HEY (EDS.), *Oxford Handbook of International Environmental Law*, Oxford, 2007, p. 663 ff.

<sup>781</sup> About this position, see J.A. DOWNS, *A Healthy and Ecologically Balanced Environment: An Argument for a Third Generation Right*, in *Duke Journal of Comparative and International Law*, 3, 1993, p. 351-385.

If the environment is a pre-requisite for the enjoyment and realisation of other rights, the human remains central, and the environment has to be protected only because it serves to the exercise of other rights. It is analogous to the right to life or integrity, in the sense that the States have the duty to ensure a good environmental protection, so that people could exercise their rights. Under this perspective, the Stockholm Declaration should be mentioned. At the United Nations Conference on the Human Environment held in Stockholm in 1972 a link among health, environment and human right was highlighted. It was stated that «*Man has the fundamental right to freedom, equality and adequate conditions of life, in an environment of a quality that permits a life of dignity and well-being, and he bears a solemn responsibility to protect and improve the environment for present and future generations*»<sup>782</sup>. Moreover, man was defined as the “*moulder of his environment*” and two aspects of environment, the natural and the man-made, were defined as «*essential to his well-being and to the enjoyment of basic human rights*»<sup>783</sup>. Thus, in this context, environmental protection was seen as a pre-condition to the enjoyment of other human rights, especially the rights to life and health<sup>784</sup>. In the same direction, the 1981 African Charter on Human and Peoples’ Rights proclaims environmental rights in qualitative terms, protecting the right of peoples to the «*best attainable standard of health*» (art. 16) and their right to «*a general satisfactory environment favourable to their development*» (art. 24).

If the environment is an object to be cared of in the enactment of other rights, the focus is on environmental impacts on human lives. This is to ensure that some civil and political rights are “greened” and used as a means for (a) ensuring environmental protection, (b) facilitating the right to access to information, participation in decision-making, and access to justice in environmental matters, and (c) pushing States to fix minimum standards of protection for life, private life and property from environmental harm. In this view, the rights to access, to participation, to fair trial and so on (i.e. mostly procedural rights) are recognised to people faced

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<sup>782</sup> Principle 1, Stockholm Declaration on the Human Environment, *Report of the United Nations Conference on the Human Environment*, New York, 1973, UN Doc. A/CONF.48/14/Rev.1.

<sup>783</sup> See Concluding Session.

<sup>784</sup> When the Universal Declaration of Human Rights (art. 25), the International Covenant on Civil and Political Rights (art. 6) and the International Covenant on Economic, Social and Cultural Rights (art. 12) refer to the right to health and life, they leave for implicit that environment was a prerequisite for the enjoyment of those rights.

with environment as a way for protecting them from environmental damages. Under this second perspective, it is central what is stated in the Rio Declaration (1992). Here, the right to environment is conceived as a «*right to a healthy and productive life in harmony with nature*»<sup>785</sup> and certain human rights are underlined as important elements to achieving environmental protection. This has as a principal aim the protection of human health. For example, principle 10 regards right to access and participation of people to environmental issues, and in the same line goes Aarhus Convention<sup>786</sup>.

If environment is a right in itself, i.e. a right to a safe, healthy and sustainable environment, it goes out from anthropocentrism to ecological “lens”<sup>787</sup>. Thus, it moulds the right to environment either as an individual social or economic right that must be promoted by other rights, similarly to the right to development, and as a collective or solidarity right, giving communities rather than individuals a right to determine how their environment and natural resources should be protected and managed<sup>788</sup>. The notion of environment here is read as a specific good to be protected and preserved by human beings. This perspective is the most innovative. However, as argued by Cullet, we must be careful to «*categorize this new right as, either a civil and political right, or an economic, social and cultural right, or a solidarity right because it transcends the distinctions and embodies elements found in each of the three categories*»<sup>789</sup>. Indeed, it «*requires States to refrain from activities harmful to the environment, and to adopt and enforce policies promoting conservation and improvement of the quality of the environment. Secondly, it appears on several counts that the right is not purely an individual right: one may*

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<sup>785</sup> Principle 1, Declaration on Environment and Development, *Report of the United Nations Conference on Environment and Development*, I, New York, 1992, UN Doc.A/CONF.151/26/Rev.1.

<sup>786</sup> Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters, 1998.

<sup>787</sup> From a philosophical and ethical point of view such change from anthropocentrism to ecologic theories is fixed starting with the works of A. LEOPOLD, *A Sound Country Almanac*, Oxford, 1949 and R. CARSON, *Silent Spring*, Boston, 1962, patrons of environmental ethics. See generally M.C. TALLACCHINI, *Law for Nature: Ecology and Philosophy of Law*, Torino, 1996; H. ROLSTON, *Environmental Ethics: Duties to and Values in the Natural World*, Philadelphia, 1988.

<sup>788</sup> See U.N. Declaration on the Rights of Indigenous Peoples, which in art. 29 proclaims: «*Indigenous peoples have the right to the conservation and protection of the environment*», and 1966 International Covenant on Civil and Political Rights, art. 27, under which minorities have the right to enjoy their own culture, including the exploitation of natural resources.

<sup>789</sup> P. CULLET, *Definition Of An Environmental Right In A Human Rights Context*, in *Netherlands Quarterly of Human Rights*, 13, 1995, p. 25-40.

*single out the rights of future generations whose interests must be taken into account but whose individual members cannot be identified, or focus on more precise claims relating in particular to displaced indigenous peoples facing the total loss of their cultural, social and physical environment»*<sup>790</sup>. The environment is no longer something “submitted” to human interests or something to be exploited or manipulated in an arbitrary way. The environment now is a good to be respected, and whose protection can ameliorate human life and could make even the future generations live better. So, the environment is more than a right. It is a value to be protected through a right that entails both the claim towards the States in preserving and promoting the environment, and the duty vested upon everyone (individually and collectively) in respecting it. Under this perspective, examples of the environment (a) becoming an object of a substantive right linked to the right to health and development (but not coinciding with them), and (b) being taken as a good as such towards which human beings have specific responsibilities and duties, linked to the principle of solidarity, can be found now in most of the regional human rights declarations<sup>791</sup>, treaties<sup>792</sup>, national laws and constitutions<sup>793</sup>.

In the past few years, thanks to the concept of sustainability, the concept of environment has broadened. For example, Johannesburg Declaration on Sustainable

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<sup>790</sup> Ibid.

<sup>791</sup> See Bangkok Declaration (1990) about the rights of individuals, groups, and organizations to obtain, publish and distribute information on environmental issues in Asia and the Pacific. Similarly, the Arab Declaration on Environment and Development and Future Perspectives (1991). See also Dublin Declaration on “The Environmental Imperative” (by the Council of Europe, 1990). One of the most meaningful non binding declarations is the Draft Declaration of Principles on Human Rights and the Environment (1994), presented in the Report of the U.N. Special Rapporteur on Human Rights and the Environment (U.N. Doc, E/CN.4/Sub.2/1994/9). It sets out general principles, including the human right to a secure and healthy environment, the right to non-discrimination and the right to an environment adequate to meet the needs of the present and future generations, and a lot of substantive rights (the human right to protection of the environment, the right to safe and healthy water, the right to preservation of unique sites and the rights of indigenous peoples to land and environmental security, and so on).

<sup>792</sup> See Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (1988), which in art. 11 refers to the “Right to a healthy environment” recognised to everyone and entailing the duty for the State to promote protection, preservation and improvement of the environment.

<sup>793</sup> See, for example, German Constitution (art. 20a), Greek (art. 24), Dutch (art. 21), Slovenian (art. 72), Spanish (art. 45), Portuguese (art. 66); South African (art. 24); Brazilian (art 225); Argentina (art. 41). The French Constitution, amended to add a Charter of the Environment in 2005, affords French citizens the right to live in a *«balanced environment, favourable to human health»*.



Development (2002)<sup>794</sup> fosters the assumption of a collective responsibility to make sustainable development concrete. This is meant as the fusion of socio-economic development and environmental protection. In addition, the principles of precaution, prevention, “the polluter pays” and rectification of environmental harm at the source<sup>795</sup> have been shaped as a means to protect environment as well.

In Italian Constitution, the modification of Constitution occurred in 2001<sup>796</sup> has added the protection of environment to the State powers<sup>797</sup> and the Constitutional Court has repeatedly considered it as a value to be protected at all levels<sup>798</sup>.

In the U.S., numerous State Constitutions mention rights and duties connected with environment<sup>799</sup>, but no prevision has been given at Federal level, despite the attempts to introduce it.

At the European Union level, the Charter of Fundamental Rights states the right to environment in art. 37 in the chapter about solidarity, thus shaping the environment as a good towards which the duties of solidarity must be exercised. Moreover, the protection of environment should be implemented in any policy of E.U. (as stated in art. 3 T.F.E.U.) and the main principles of environmental protection are stated in art. 174 T.E.U..

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<sup>794</sup> In reality in Rio Declaration there was also a reference to sustainability, in the statement that environmental protection must be tied together with development processes and cannot be considered as isolate from it.

<sup>795</sup> See P. SANDS, *Principles of International environmental law*, I, 1995.

<sup>796</sup> Constitutional Law n. 3/2001, Gazz. Uff., 24<sup>th</sup> October 2001, n. 248 (It.)

<sup>797</sup> Before 2001, and on the basis of Massimo Severio Giannini’s conception, environment was protected through pollution law, planning law and “natural beauty” law, finding a constitutional protection to environment in art. 117 (about planning law which was a competence vested at the regional level), art. 32 (health) and art. 9 (preservation of natural beauty which must be promoted by the Republic). About Giannini’s formulation, see M.S. GIANNINI, “Ambiente”: *saggio sui suoi diversi aspetti giuridici*, in *Rivista Trimestrale di Diritto Pubblico*, 23, 1973.

<sup>798</sup> See, for example, ruling n. 407/2002, in which the Court has affirmed that, being environment a widespread value, both State and Regions are vested with the power to regulate the topic. Previously, the Court derived the right to healthy environment – meant as a right to be recognised for the formation of the personality of human beings – from art. 32 Const. about the right to health (see ruling n. 127/1990). In further rulings, the Court links the right to environment to protection of future generations (see decisions nn. 246/2009 and 142/2010).

<sup>799</sup> See, for example, Alaska, art. VIII, § 16 (right not to be divested of use of water); Hawaii, art. XI § 9 (right to a clean and healthful environment); Illinois, art. 11, § 1 (duties to provide and maintain a healthy environment) and § 2 (right to a healthy environment); Montana, art. 2, § 3 (right to a clean and healthy environment); Pennsylvania, art. 1, § 27 (right to clean air, pure water, and to the preservation of natural, scenic, historic and aesthetic values of environment); Rhode Island, art. 1, § 17 (right to the use and enjoyment of natural resources with due regard for the preservation of their values); Texas, art. XVI, § 59 (conservation and development of all natural resources are declared “public rights and duties”).

In the context of the Council of Europe, an expressed formulation of the right to environment is not present<sup>800</sup>. However, the European Court of Human Rights has exercised art. 8 E.C.H.R. about the right to private life, so as to entail the right to live in a healthy environment and enjoy peaceful conditions of life<sup>801</sup> or to individuate State's failure to enforce national environmental rights or rights having environmental nuisances (such as the right to health)<sup>802</sup>. Art. 2 about the right to life, art. 6 about the right to fair hearing, art. 10 about the right to information, art. 1 of the Protocol 1 about the right to peaceful enjoyment of possessions and property have also been shaped for hypothesis of environmental damage that affected human lives<sup>803</sup> and for allowing access to environmental information and to justice in environmental cases.

In the U.K. the elaboration of the right to environment comes from judicial interpretations as well<sup>804</sup>.

From these observations, it is clear that nowadays the most accepted idea of the right to environment is the one that conceives it as a right and at the same time as a duty vested upon individuals and populations (even minorities and indigenous groups) to preserve and promote environment<sup>805</sup>. This idea is twofold. On the one hand, it entails that people can claim towards States the enactment of measures and actions so that to protect it and, on the other one, it has as the consequence the duty to treat it in a responsible manner<sup>806</sup>.

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<sup>800</sup> There are, indeed, no references to this right in the European Convention of Human Rights, despite the attempts to introduce it (lastly in June 2010, the Committee of Ministers of the Council of Europe has refused to take into consideration Recommendation n. 1885/2009 by the Parliament about this issue).

<sup>801</sup> See case *Arrondelle v. UK* 26 D.R. 5 (1982); *Lopez Ostra v. Spain* 16798/90 [1994] E.C.H.R. 46 (9<sup>th</sup> December 1994); *Guerra v. Italy* 14967/89 [1998] E.C.H.R. 7 (19<sup>th</sup> February 1998). For further details about the jurisprudence of the European Court of Human Rights about environmental issues, see A. BOYLE, *Human Rights and Environment: a Reassessment*, in *Fordham Environmental Law Review*, 18, 2008, p. 471-511.

<sup>802</sup> See case *Taşkin and Others v. Turkey*, 46117/99 [2004] E.C.H.R. 621 (10<sup>th</sup> November 2004); *Giacomelli v. Italy*, 59909/00 [2006] (2<sup>nd</sup> November 2006); *Di Sarno and others v. Italy*, 30765/08 (10<sup>th</sup> January 2012).

<sup>803</sup> See case *Oneriyildiz v. Turkey*, 48939/99 [2004] E.C.H.R. 657 (30<sup>th</sup> November 2004).

<sup>804</sup> See C. STEPHENS, S. BULLOCK, A. SCOTT, *Environmental justice. Rights and means to a healthy environment for all*, Special Briefing n. 7, November 2001, at [http://www.foe.co.uk/resource/reports/environmental\\_justice.pdf](http://www.foe.co.uk/resource/reports/environmental_justice.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>805</sup> See D.R. BOYD, *Environmental Rights Revolution: A Global Study Of Constitutions, Human Rights, And The Environment*, Vancouver, 2012.

<sup>806</sup> It can be highlighted a similarity between the environmental ethics discourse and the one developed in the field of animal rights: indeed, the same responsibility and respect that men should express towards nature should also be shown towards animal, thus rendering them subjects of rights

So, if at the beginning of its history, the right to environment was considered a condition for enjoying other rights and as a right of people claiming towards public powers to be safeguarded from harms and to be ensured in their healthy living and working conditions, in an anthropological sense, then it has been shaped as a good to be defended, because from it the survival of human beings in current and future generations depend<sup>807</sup>.

## 5.2. *Environment and Future Generations.*

It is worth noting that the reflection about the responsibility towards future generations has found the capability of coming at stake with regards to the freedom of scientific research. In the context of genetic interventions on human genome, for example, it finds its birth precisely in the environmental area. Indeed, after the 2<sup>nd</sup> World War only a few instruments mentioned the rights of future generations<sup>808</sup>. The real discussions of this issue started in the seat of Drafting of the 1982 World Charter of Nature. The issue of future generations found a great formulation in the 1997 U.N.E.S.C.O. Declaration regarding the responsibility to future generations<sup>809</sup>, where the values of biodiversity, earth life, cultural heritage, genome, peace, development, education are pursued in the name of protecting interests of future generations and constitute a duty upon the current people.

Against the positions affirming that future generations do not yet exist and thus cannot be a subject of rights (and so, as a consequence of this reasoning, any

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too.: See, for example, P. SINGER (ED.), *In defence of Animals*, London, 2005; P. SINGER, T. REGAN (EDS.), *Animal Rights and Human Obligations*, Prentice Hall, N.J., 1989.

<sup>807</sup> With regards to the link among rights and duties in the environmental field, see F. FRACCIA, *The Legal Definition of Environment: From Rights to Duties*, in *Bocconi University Institute of Comparative Law "Angelo Sraffa" (I.D.C.), Legal Studies Research Paper Series*, Paper n. 06/09.

<sup>808</sup> See Declaration of Francisco (1945) that aimed that future generations should be preserved from the cruelty of wars; see U.N.E.S.C.O. Declaration of the principles about the international cultural cooperation (1966) about the cultural cooperation among States for favouring the professional education of new generations (art. X). See also U.N.E.S.C.O. Convention about the cultural and natural endowment (1972), that mentioned the State duty to ensure the identification, protection, conservation and recognition of the value and transmission of cultural and natural endowment to future generations (art. 4).

<sup>809</sup> U.N.E.S.C.O. Declaration on the Responsibilities of the Present Generations Towards Future Generations, 12<sup>th</sup> November 1997.

environmental issue would be addressing a non-existing target<sup>810</sup>), the recognition of group rights and generational rights has occurred. Future people do not need to be indicated in each singular components, but it is sufficient to shape them as a group. In this way the legal claims of future people are grounded. With the formulation of this category of rights, the Constitutions now show their strength and value beyond the time when they were drafted. As an example, in the Italian Constitution, although no norms are dedicated to future generations, yet some articles show the capacity of providing for future generations' protection, such as art. 1 about sovereignty that links current and future people, art. 2 about human rights and duties vested in everyone (future people included), and art. 9 about environmental protection.

The first meaningful ruling that shake the principle of intergenerational justice, precisely with regards to the right to environment, is the *Minors Oposa v. Secretary of Department of Environment and Natural Resources* (1993)<sup>811</sup> in the Philippines. A group of children sued the Ministry for having granted some licenses of exploiting wood, thus ruining the Filipino forests. The Court admitted that the right is embedded in art. 16 of the Constitution, which asks the State to protect the individual right to a healthy environment, and this right belongs to future generations as well. The preservation of environment is connected to the essential needs of humankind and is even linked to its existence. So, an “*actio popularis*” is recognised upon minors that represent themselves and future generations not born yet.

If in the ambit of genome the issue of future generations is quoted to impede to develop some actions (as the modification of human genome or cloning), in the area of environment it entails positive obligations of intervention for a proper care to it. It ties with the principle of solidarity that reminds us that we are dependent on the keeping of life on earth for our survival and that we are also linked to the coming generations in a responsible way<sup>812</sup>.

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<sup>810</sup> These positions start from Parfit's one. (D. PARFIT, *Future Generations: Further Problems*, in *Philosophy and Public Affairs*, 11, 2, Spring 1982, p. 113-172).

<sup>811</sup> Case of *Minors Oposa v. Secretary of Department of Environment and Natural Resources*, Supreme Court of the Philippines, 30<sup>th</sup> July 1993.

<sup>812</sup> See A.E. PEREZ LUÑO, *Le generazioni dei diritti umani*, in F. RICCOBONO (ED.), *Nuovi diritti dell'età tecnologica*, Milano 1991, p. 147.

### 5.3. *The Protection of the Environment and Synthetic Biology.*

The relationship between synthetic biology and environment is undeniable. Many synthetic applications could have an impact on the environment, such as biofuels or methods for bioremediation. On the other hand, though, synthetic biology could provoke harms to environment and biodiversity, and in this sense the right to environment could play a role. The risk of an accidental escape of products and substances have been repeatedly mentioned (biosafety risks) and the method based on risk assessment, management and communication, as per “*prudent vigilance*” model is the most suitable method for dealing with it. This method takes into account the importance of the environment, health and other interests so as to protect the environment from the escape of harmful products.

The relevance of environment, though, is at stake in other directions as well. The concept of biodiversity is a central one. In a comprehensive sense, biodiversity is «*the variety of life at all levels of biological organization*»<sup>813</sup>. It occurs at the level of genes (genetic diversity which refers to the totality of the genetic characteristics of each species), at the level of organisms (species diversity which refers to the totality of species in an ecosystem or an area), and, at the level of ecosystems (ecological diversity, all the different ecosystems of a given area).

Synthetic biology aims at creating new life forms, by going beyond the recombination of genetic material. «*1. Unlike naturally occurring species, they have no evolutionary history; 2. Unlike naturally occurring species, they have no*

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<sup>813</sup> K.J. GASTON, J.I. SPICER, *Biodiversity: an introduction*, Oxford, 2004. See also the Convention on Biological Diversity, which was the product of the 1992 United Nations Conference for the Environment and Development at Rio de Janeiro. It defines “biodiversity” as «*the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; [biodiversity] includes diversity within species, between species and of ecosystems*». See also Protocol on Biosafety (Cartagena, 2000), annexed to the Convention. Other Conventions in this area are: the Convention on the protection of wetlands of international importance (Ramsar Convention 1971), the Convention on the protection of world cultural and natural heritage (Paris Convention 1972), the Convention on the protection of plants (Rome Convention 1951), the Convention on trade in endangered species of wild fauna and flora (Washington Convention 1973), the Convention on the conservation of European wildlife and natural habitats (Berne Convention 1979), the Convention on the conservation of migratory birds of wild fauna (Bonn Convention 1979). In the E.U. see the Council Directive 92/43/EEC of 21<sup>st</sup> May 1992 on the conservation of natural habitats and of wild fauna and flora, in *O.J. L 206/1992*.

*ecological history; 3. Synthetic life forms have the potential to confound our traditional taxonomic categories, including the classification of species itself*<sup>814</sup>.

Synthetic biology life forms alter the landscape of species, because they alter the “normal” process of evolution, and they alter the taxonomy of species to which we assign typical features<sup>815</sup>. For these reasons biodiversity could be affected.

In the light of this, there are positions that claim that synthetic biology could alter biodiversity by reducing the difference among species, by crossing them and, perhaps in future, making some of them disappear. On the other hand, there are thinkers who are afraid that there could be a misunderstanding idea of the role that synthetic biology could take with regards to biodiversity. The idea that synthetic forms would be capable of intervening to substitute disappeared species is essentially wrong and in this sense, while used for the improvement of biodiversity, synthetic biology in reality has nothing to do with it<sup>816</sup>.

Moreover, synthetic biology could affect the value given to the environment (meant as “nature”). With reference to the previous section on dignity, it is questionable whether nature is something that does not have to be touched and altered, and thus owning an intrinsic value that entails its “untouchableness”, or whether it can be modified by the human hand. In some views, the preservation of the environment and biodiversity coincides precisely with a conservative view. Artificial “creatures” would be distinct from naturally occurring ones and they would undermine environment in its (moral) value. In other viewpoints, the preservation of biodiversity is precisely for the benefit of mankind<sup>817</sup>, in the sense that the diversity of organism is positive for the discovery of new medicines, new industrial products and so on. For this reason the more there is a diversity of species, the more chances there are to discover “exploitable” properties among them and the more chances to ensure the survival of human species. In this perspective, there would be no difference between “natural” or “artificial” life forms, as all of them can contribute to such “exploitation”.

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<sup>814</sup> B.G. NORTON, *Synthetic Biology: Some Concerns of a Biodiversity Advocate. Remarks on Synthetic Biology to the Presidential Commission on Bioethics*, 13<sup>th</sup> September 2010, p. 2.

<sup>815</sup> See S.J. GOULD, *What is a Species?*, in D. VAN DE VEER, C. PIERCE (EDS.), *The Environmental Ethics and Policy Book*, 1994, Belmont CA, p. 473-477.

<sup>816</sup> For this position see B.G. NORTON, *op. cit.*

<sup>817</sup> E.O. WILSON, *Biodiversity*, Washington, D.C., 1988.

It seems to me that the right to environment as enucleated above, and the linked concepts of sustainability and biodiversity, indicate neither the stopping of any kind of activity towards environment (meant as something to be left untouched) nor the use of it as a instrument for exploitation (rendering it a “servant” of human interests). However, at first sight, there seems to be a contradiction between the preservation of natural resources and development of research. This is because the former would entail to conserve nature in its state and the latter to “work” on it. Thus, the right to environment and the need to protect environment as a good in itself solves the apparent oxymoron. This means that synthetic biology, whether or not related to biodiversity, cannot be slowed down, and thus is not impeded in its development and progress (even altering species boundaries). It must be oriented in a way that respects biodiversity and does not undermine the value of environment for current and future generations. The right to environment, indeed, does not exclude from taking advantage of environment for the benefit of humanity, but at the same time it must be respected and valued as a good, i.e. treated in a responsible way in the light of the principle of solidarity and intergenerational justice.

### *Conclusion.*

The long examination conducted in this chapter with regards to the human rights coming into question in the field of synthetic biology served a dual purpose of demonstrating the possibility and the way that the “classical” human rights could be shaped in the presence of new technologies such as synthetic biology. This chapter also aim to demonstrate how human rights could constitute the basis for a constitutional framework that should, in my opinion, ground the regulation and governance of the whole subject. Indeed, the model of “*prudent governance*” that I have described thus far should be taken as the “horizon” on the basis of which to enact regulations with regards to the different risks coming out from the field of synthetic biology. In addition, such regulations should also have a constitutional frame in which to examine them. Such “frame” is represented by human rights, as moulded in my discourse. So, the right to life, health, dignity, as well as the freedom

### CHAPTER III

of scientific research, and the right to environment should not be neglected. Instead, it must be properly considered in the enactment of any model of governance and of any regulation of this emerging technology.



## CHAPTER IV

### A CASE STUDY: SYNTHETIC BIOLOGY, BIOSECURITY AND BIOTERRORISM

*“Knowledge without conscience is simply the ruin of the soul”*

*(F. Rabelais)*

As it has been established thus far, synthetic biology gives rise to several risks. The approach for dealing with them as delineated in the previous chapters needs to be “tested” and checked, in order to see if it works or not and how to shape it in a concrete applicative sense. For the purpose of this thesis, the approach will be verified against the risk of biosecurity and bioterrorism.

In this chapter, I aim to (1) focus on the notions of biosecurity and bioterrorism, (2) consider the regulations adopted so far in this area at international, European and national level (considering only three legal systems: the U.K., the U.S.A., Italy), (3) evaluate these regulations on the basis of the constitutional frame of human rights, and finally (4) formulate the most suitable frame for future policies for dealing with biosecurity risk in the field of synthetic biology, i.e. verify how the “*prudent vigilance*” approach could be applied to manage the risk of biosecurity and bioterrorism that could come out from synthetic biology.

#### *1. Biosecurity and Bioterrorism.*

Biosecurity has become a central and challenging part of any global policy-making agenda in the 21<sup>st</sup> Century, due to the rapid advancement of science and

technology. Synthetic biology represents a further source of threat to biosecurity<sup>818</sup>. Indeed, the possibility of creating synthetic viruses having harmful purposes has already been mentioned. It is not a mere hypothesis, but a concrete reality as demonstrated, for example, by the *de novo* synthesis of poliovirus<sup>819</sup>. So, synthetic biology could become a weapon in the hands of bioterrorists, by enriching them with biological weapons. These weapons represent the latest development in the series of weapons of mass destruction<sup>820</sup> after the chemical ones (toxic gases), that proliferated during the World War I, and nuclear weapons, adopted through aerial bombardment (Hiroshima and Nagasaki) in the World War II.

### 1.1. Definition of Bioterrorism.

Starting from the consideration that «*the search for means aimed at fighting against and winning over the enemies is a consubstantial phenomenon to human history*»<sup>821</sup>, Romeo Casabona further elaborates on this by stating that «*in many occasions it is possible to argue that these actions respond, in a weaker form, to Darwin's evolutionist theories with regards to the strong's fight for surviving and exercising power over the weak*»<sup>822</sup>. However, it cannot be forgotten that «*the Darwinian concept of biological strength has been substituted by human beings, time after time, with the one of technical superiority, meant as a projection of his development and intelligence*»<sup>823</sup>.

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<sup>818</sup> As McLeish and Nightingale specify, biosecurity is a broad umbrella, that covers different areas: bio-terrorism (the threat or use of disease by non-state actors for political ends); bio-defence (the development of responses to biological warfare attack, including bioterrorism); dual-use controls (controls on technologies with legitimate and prohibited applications) and non-proliferation (controls on the diffusion of technologies to prevent their (illegal) hostile use). See C. MCLEISH, P. NIGHTINGALE, *Biosecurity, bioterrorism and the governance of science: The increasing convergence of science and security policy*, in *Research Policy*, 36, 2007, p. 1635–1654.

<sup>819</sup> See J. CELLO, A.V. PAUL, E. WIMMER, *op. cit.*

<sup>820</sup> See M.C. BASSIOUNI, *International Humanitarian Law and Arms Control Agreements*, New York, 2000, p. 4 ff.

<sup>821</sup> C.M. ROMEO CASABONA, *Riesgo y prevención en la moderna biotecnología no humana: la limitada función del derecho penal*, in C.M. ROMEO CASABONA (ED.), *Genética, biotecnología y ciencias penales*, Bogotá, 2009, p. 343.

<sup>822</sup> Ibid.

<sup>823</sup> Ibid.

The knowledge of living beings, of DNA, of techniques of intervention on genomes through genetic engineering has opened the doors to the creation of more sophisticated biological weapons and so the phenomenon of bioterrorism has appeared in all its force<sup>824</sup>.

The term “bioterrorism”<sup>825</sup> is usually associated with a specific type of terrorism that is identified with the intentional criminal release of germs or biological agents (pathogenic microorganisms such as bacteria, virus...) or toxins, capable of causing diseases, harming or death of human beings or vegetables and animals (“agroterrorism”) by introducing them into natural elements, environment or food, with the intent to intimidate or coerce a government or civilian population to further political or social objectives<sup>826</sup>. As such, biological agents or toxins are used as munitions or projectiles against human, animal or vegetal targets. These materials can be modified in order to implement their capabilities and lethal functions, and it appears to be possible to clone them in a selective way, in the sense of programming them to attack specific ethnic groups that are susceptible to a particular disease (this behaviour sounds very close to genocide). Like conventional terrorism in the general sense, the bioterrorists aim to generate terror within the population by altering the functioning of powers and public institutions and subverting the legitimate and established public order, up to the point of aiming to eliminate the whole humanity, thus threatening the survival of the world itself.

The preparation of these weapons does not take much time and it does not need very qualified people. The access is relatively simple and the preparation could be done in small laboratories and with minimal costs<sup>827</sup>. The clandestine manufacture and distribution of effective biological weapons is certainly possible today, because

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<sup>824</sup> See J.B. PETRO, T.R. PLASSE, J.A. MCNULTY, *Biotechnology: Impact on Biological Warfare and Biodefense*, in *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science*, 1, 3, 2003, p. 161-168.

<sup>825</sup> For a complete analysis of bioterrorism in all its aspects, see R. KATZ, R.A. ZILINKAS (EDS.), *Encyclopaedia of Bioterrorism Defense*, Hoboken, N.J., 2010.

<sup>826</sup> For this definition, see INTERPOL, *Bioterrorism Incident Pre-Planning and Response Guide*, ICPO-Interpol, 2007.

<sup>827</sup> See, for example, the case published in the *Guardian* newspaper in June 2006 about its science correspondent, James Randerson, who had purchased “a short sequence of smallpox DNA” and had it delivered it to a residential London address. He aimed at demonstrating the easiness of obtaining DNA of viruses (see J. RANDERSON, *Did anyone order smallpox?*, in *Guardian Weekly*, 23<sup>rd</sup> June 2006, at <http://www.guardian.co.uk/science/2006/jun/23/weaponstechnology.guardianweekly>, last visited 28<sup>th</sup> January 2013).

of the easy availability of and access to genetics and synthetic biology<sup>828</sup>. However, the possibilities of success in a bioterrorist attack are not very high, as it is dependent on many factors, such as the type and amount of agent used, the manner in which it is delivered, the conditions at the target site, and the rapidity and effectiveness of the responses to an attack<sup>829</sup>.

The bioterrorism is a type of terrorism. However, it has an asymmetric shape, as it is a way of fighting the States without a conventional war, and without having the intent of territorial occupation<sup>830</sup>. It has an indiscriminate nature and could be categorized as a «*dread risk*»<sup>831</sup>, because it is uncontrollable, catastrophic, hard to prevent, fatal, inequitable, and involuntary. Furthermore, it evokes a fundamental feeling of dread<sup>832</sup>. Indeed, «*in addition to being a deliberate act that is indiscriminate and unpredictable in nature yet potentially catastrophic and fatal in form, it is also an invisible one that challenges our essence of being*»<sup>833</sup>. In particular, the fact of being invisible and being able to spread everywhere, without a specific geographical location allows to affirm that «*the deliberate release of a biological agent has more in common with naturally occurring infectious diseases than the threat from terrorism using conventional weapons or weapons of mass destruction*»<sup>834</sup>.

Biological weapons, as underlined by Mordini, quoting Zanders, produce unnecessary suffering, as these weapons do not distinguish between civil and

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<sup>828</sup> It should be noted, though, that not all the scientists agree about the facility of producing synthetic DNA: see, for example, U.K. ROYAL SOCIETY, Policy Document 38, *Science and Technology Developments Relevant to the Biological and Toxin Weapons Conventions*, 2006, p. 6.

<sup>829</sup> See G. LINDSTROM, *Protecting the European Homeland: The CBR Dimension*, Chaillot Paper n. 69, Paris, 2004, p. 17.

<sup>830</sup> See M. MARTINEZ, *El marco jurídico de bioterrorismo*, in *Anuario jurídico y económico escorialense*, 2004, p. 24.

<sup>831</sup> J. STERN, *Dreaded Risks and the Control of Biological Weapons*, in *International Security* 27, 3, 2002/2003, p. 89–123.

<sup>832</sup> See P. SLOVIC, B. FISCHOFF, S. LICHTENSTEIN, *Facts and Fears: Understanding Perceived Risk*, in R.C. SCHWING, W.A. ALBERS, JR (EDS.), *Societal Risk Assessment: How Safe Is Safe Enough?*, New York, London, 1980, p. 199.

<sup>833</sup> S. KITTELSEN, *Conceptualizing Biorisk: Dread Risk and the Threat of Bioterrorism in Europe*, in *Security Dialogue*, 40, 1, 2009, p. 52.

<sup>834</sup> C. ENEMARK, *Disease and Security: Natural Plagues and Biological Weapons in East Asia*, London, New York, 2007, p. 79.

military objectives, and violate the principles of protection of neutral States (being the weapons easy to spread out of the borders)<sup>835</sup>.

### 1.2. Biological Agents.

The term “biological agent” refers to «*microorganisms that provoke an infirmity to human beings, animals, plants or that produce a deterioration of materials*»<sup>836</sup>. Biological agents are also the natural substances produced by those organisms, and the products of them (such as toxins). The development and creation of these agents by genetic engineering and currently synthetic biology should be included as well.

The World Health Organization has classified those agents into three categories:

(1) category A: microorganisms that can generate risks for national security. They are very simple to transmit from person to person, easily disseminated, and thus creating high ranges of mortality and attacks to public health, together with panic in the society. Included in this category are: anthrax, carbuncle, botulism, plague, big pox, tularaemia and those causing hemorrhagic viral fever;

(2) category B: agents having a moderate propagation. They do not result in high mortality, but they need to be constantly watched over. Agents in this category include: brucellosis, toxin epsilon from *Clostridium perfringens*, melioidosis, psittacosis, Q fever, the toxin from *Ricinus communis*, staphylococcal enterotoxin B, tífus exantemático, and those causing viral encephalitis;

(3) category C: emerging pathogenic agents, which are susceptible of genetic modification. They have massive propagation, and a capacity of determining high mortality and disease. Included in this category are viruses such as the virus from Nipah and hantavirus.

The fears connected with bioterrorism are due to the fact that biological weapons are less controllable than nuclear weapons, simpler to be produced, easily

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<sup>835</sup> For these considerations, see V. MORDINI, *Conclusions of the International Conference on ethical Implications of Research into Prevention of Bioterrorism*, 2004, at <http://www.istitutobioetica.org/Bioetica%20generale/ricerca/Mordini%20Bioterrorism.htm> (last visited 28<sup>th</sup> January 2013), p. 6.

<sup>836</sup> P. BINDER, O. LEPICK, *Les armes biologique*, Paris, 2001, p. 7.

spread out, transported and hidden. Indeed, biological agents are invisible, odourless, and imperceptible to humans, and their effects are delayed. Dormant biological agents such as anthrax spores can persist undetected for years in the environment, while others like smallpox have the potential for a person-to-person transmission of contagion.

### *1.3. Brief History about the Use of Biological Weapons: Biowarfare and Bioterrorism.*

The history of the use of biological weapons is a long one<sup>837</sup>. It is a misconception to believe that the birth of bioweapons is a recent invention.

The Romans were first ones to contaminate food and water using dead animals, with the sole purpose of weakening enemies from both the physical and psychological viewpoint.

Later, in 1347, the Tartars while besieging the Genoese city of Kaffa in the Black Sea catapulted contaminated corpses over the walls. When Genoese ships abandoned Kaffa and returned to Europe, they brought with them the plague. The disease spread everywhere and caused, in the subsequent years, the deaths of over 20 million of people.

In the U.S., in 1763, during the Seven-Year War the British, in order to kill Indians who were thought to be allies of the French, gave them some blankets as an apparent sign of friendship. Unbeknownst to the Indians, they contained smallpox. This results in disastrous effects on the populations.

The period between the two World Wars was characterized by the development of biological warfare programs in countries like the U.R.S.S., Italy and Germany. During the World War I, under the Baron Otto Karl von Rosen, Germany produced a biological weapon encapsulated in sugar. In 1930 Japan developed an

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<sup>837</sup> For the historical basis of bioterrorism, see F. URBANO, *Alle basi del Bioterrorismo: un approccio storico alla Guerra Biologica*, in *Caleidoscopio letterario*, 2005, at <http://www.medicalsystems.it>. See also <http://www.npr.org/news/specials/response/anthrax/features/2001/oct/011018.bioterrorism.history.html>, [http://www.pbs.org/wgbh/nova/bioterror/hist\\_nf.html](http://www.pbs.org/wgbh/nova/bioterror/hist_nf.html) (last visited 28<sup>th</sup> January 2013); C.D. MALLOY, *A history of biological and chemical warfare and terrorism*, in *Journal of Public Health Management and Practice*, 6, 4, July 2000, p. 30 ff.; D.H. JOYNER, *International Law and the Proliferation of Weapons of Mass Destruction*, Oxford. 2009.

offensive program, instituting the special section of army, called “Unit 731”<sup>838</sup>, aimed at experimenting the potentialities of biological agents. Crude anthrax bombs were produced by this Unit, which were used in the attack of villages in Manchuria. Anthrax, contagious causing plague, and typhoid were used during the Sino-Japanese war in the 1930s and 1940s.

During the same period, the U.K. had started its program of biological warfare. The Gruinard Isles (near Scotland) were chosen as a place to conduct experiments. The British people thought that the place was isolated enough not to spread the contaminations, but in 1943 a serious epidemic occurred among the cattle, and the contagion rapidly diffused into water, air, soil.

In the U.S., biological warfare programs began in 1942, in line with the Japanese and the British. The research was located in Fort Detrick, Maryland<sup>839</sup>.

During Cold War, both the U.S.A. and the U.R.S.S. produced bacteriological weapons. In the U.S. the experiments were conducted in San Francisco. The release of *Serratia marcescens* for experimental reasons occurred in San Francisco and of *Bacillus subtilis* in New York<sup>840</sup>, while in the U.R.S.S. the city of Sverdlovsk was one of the main seats for the production of these bacteriological weapons.

It was only in 1969 when President Nixon expressed the will to destroy the arsenals of biological weapons and its production, as well as to limit the research only for defensive purposes<sup>841</sup>.

However, in the U.R.S.S. in 1973 a secret program called “Biopreparat” for biological warfare was prepared, despite it being officially to be aimed at biotechnological research of a peaceful nature<sup>842</sup>.

During the war against Vietnam, soviet helicopters spread over the population coloured aerosol, which was suspected of containing micotoxin T-2<sup>843</sup>.

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<sup>838</sup> See H. GOLD, *Unit 731 Testimony*, Tutlant, 1996.

<sup>839</sup> See N.M. COVERT, *A History of Fort Detrick, Maryland*, 2000, at [http://www.detrick.army.mil/cutting\\_edge/index.cfm?chapter=contents](http://www.detrick.army.mil/cutting_edge/index.cfm?chapter=contents) (last visited 28<sup>th</sup> June 2013).

<sup>840</sup> See J. CARLTON, *Of Microbes and Mock Attacks. 51 Years Ago, The Military Sprayed Germs on U.S. Cities*, in *Wall Street Journal*, 26<sup>th</sup> October 2001.

<sup>841</sup> J.B. TUCKER, E.R. MAHAN, *President Nixon’s Decision to Renounce the U.S. Offensive Biological Weapons Program*, Washington, D.C., October 2009, at [http://www.ndu.edu/press/lib/pdf/CSWMD-CaseStudy/CSWMD\\_CaseStudy-1.pdf](http://www.ndu.edu/press/lib/pdf/CSWMD-CaseStudy/CSWMD_CaseStudy-1.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>842</sup> See at <http://www.fas.org/nuke/guide/russia/agency/bw.htm> (last visited 28<sup>th</sup> January 2013).

<sup>843</sup> J.B. TUCKER, *The “Yellow Rain” controversy: Lessons for Arms Control Compliance*, in *The Non proliferation Review*, Spring 2011, p. 25-42.

In 1979, spores of *Bacillus anthracis* were freed accidentally from Sverdlovsk microbiological military system<sup>844</sup>.

In the Nineties, the search for bacteriological and biological weapons started again, because of the new discoveries in genetics. In 1991, the suspicion that Iraq possessed biological weapons led the U.S. to begin the Gulf War and the U.N. to create a Commission (U.N.S.C.O.M.: United Nation Special Commission) with the sole purpose of supervising the destruction of Iraqi biological arsenal<sup>845</sup>.

In 1995 Iraq confessed to have developed a specific program for realization and diffusion of biological agents<sup>846</sup>.

Following South Africa's apartheid era, in 1998 the Truth and Reconciliation Commission investigated the Project Coast, a chemical and biological weapons program run under the apartheid regime<sup>847</sup>.

The use of biological weapons is not only a prerogative of States, as shown until now, but also that of single people, individually or collectively considered, who can make use of this material. Thus, this led to the development of bioterrorism, along with biowarfare<sup>848</sup>. The first examples were found in 1978, when in London underground a Bulgarian refugee and Soviet dissident, Georgi Markov, journalist for the B.B.C., was wounded with the point of an umbrella, that had been modified by the Russian secret service, so as to inject the ricin-toxin. Markov died a few days later<sup>849</sup>.

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<sup>844</sup> M. MESELSON, J. GUILLEMIN, M. HUGH-JONES, A. LANGMUIR, I. POPOVA, A. SHELOKOV, O. YAMPOLSKAYA, *The Sverdlovsk Anthrax Outbreak of 1979*, in *Science*, 266, 1994, p. 1202-1208 (Official publication of the American Association for the Advancement of Science).

<sup>845</sup> See at <http://www.un.org/Depts/unscom/> (last visited 28<sup>th</sup> January 2013).

<sup>846</sup> R.A. ZILINSKAS, *Iraq's Biological Weapons. The Past as Future?*, in *The Journal of American Medical Association*, 278, 5, 6<sup>th</sup> August 1997, p. 418-424.

<sup>847</sup> See C. GOULD, P. FOLB, *Project Coast: Apartheid's Chemical and Biological Warfare Programme*, publication of the United Nations, 2002, at <http://www.unidir.org/pdf/ouvrages/pdf-1-92-9045-144-0-en.pdf> (last visited 28th January 2013).

<sup>848</sup> The difference among biowarfare and bioterrorism lies in the fact that the former refers to "the deliberate release of microorganisms or toxins of biological origin against armed forces in a time of war", while the latter "is the deliberate release of microorganisms or toxins of biological origin against civilian populations for the purposes of destabilization of social and political structures" (see L. GOSTIN (ED.), *Public Health Law and Ethics. A Reader*, cit., p. 460).

<sup>849</sup> See N. PATON WALSH, *Markov's umbrella assassin revealed. After 26 years, police hope to bring killer to justice*, in *The Guardian*, 6<sup>th</sup> June 2005, at <http://www.guardian.co.uk/world/2005/jun/06/nickpatonwalsh> (last visited 28th January 2013).



In 1984, the members of the religious cult, “Bhagwan Shree Rajneesh”, contaminated food in restaurants located in Oregon with *Salmonella typhimurium*, provoking an epidemic which resulted in 751 infected people<sup>850</sup>.

From 1990 until 1995, the religious group “Aum Shinrikyo” or “Supreme Truth” spread, several times, aerosols containing anthrax and botulinum toxin in Tokyo. On the 21<sup>st</sup> March 1995, it released Sarin in the Tokyo underground, causing the death of 12 people and intoxication of 5000<sup>851</sup>.

In the U.S.A., Larry Wayne Harris, a microbiologist in Ohio who was linked to the extremist group “Arian Nation”, was arrested in 1998 for having threatened to spread carbuncle *bacillus* in Las Vegas<sup>852</sup>.

The most famous cases of bioterrorism are the ones which occurred in 2001 in U.S.A. through the sending of some envelopes contaminated with spores of anthrax to U.S. Senators and media organizations located in New York City and Boca Raton, Florida. It caused the death of 5 people (because of inhalation) and contaminated a further 22 people due to inhalation and the absorption of anthrax through the skin between the months of September through October of 2001<sup>853</sup>.

Initially, Al-Qaeda terrorists were suspected to be the ones who distributed the anthrax, but these suspicions were dismissed when it was discovered that anthrax came from a strain held at Fort Detrick. After a seven-year investigation, the Federal Bureau of Investigation (F.B.I.) presented evidence that the crime was perpetrated by Bruce E. Ivins, a U.S. Army microbiologist, who committed suicide before criminal charges were filed against him<sup>854</sup>.

Al-Qaeda connections with bioterrorism were, however, found in 2001 in Afghanistan<sup>855</sup>, where the coalition forces discovered Al-Qaeda training manuals with formulas for producing the botulinum toxin and ricin as bioweapons.

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<sup>850</sup> See B.C. BERNETT, *U.S. Biodefense And Homeland Security: Toward Detection And Attribution*, Monterey, C.A., 2008, p. 13-35.

<sup>851</sup> See S. BONINO, *Il caso Aum Shinrikyo. Società, religione e terrorismo nel Giappone contemporaneo*, Chieti, 2010.

<sup>852</sup> See at <http://archive.adl.org/learn/anthrax/Harris.asp?xpicked=3&item=5> (last visited 28<sup>th</sup> January 2013).

<sup>853</sup> See, among the others, P. SARASIN, *Anthrax: Bioterror as Fact and Fantasy*, Cambridge, M.A., 2006.

<sup>854</sup> See U.S. DEPARTMENT OF JUSTICE, *Amerithrax Investigative Summary*, Washington, D.C., 2010.

<sup>855</sup> See J.J. LUMPKIN, *Al Qaeda's Bio Weapons*, in *C.B.S. News*, 11<sup>th</sup> February 2009.

So, in the 20<sup>th</sup> Century in particular, «*three generations of offensive biological warfare programs*»<sup>856</sup> have been individuated: bacteriology, aerobiology, and genetic engineering. It is of my belief that synthetic biology should be added to these three categories, as I aim to show further.

#### 1.4. What Does “Dual use” Mean?

“Dual use” is an expression that usually refers to all the different kinds of technology that can be used both for civil and military purposes, for example, drugs development, in medical treatment (i.e. civil) and in the production of bioweapons (i.e. military). Certainly, “dual use” is an aspect that pertains not only to the technological application of a research, but to the research itself<sup>857</sup>, which could be used for malevolent and benevolent purposes<sup>858</sup>. Taken in itself, science and technology are “neutral”, but it is their use that determines their function and that confers them a quality<sup>859</sup>.

Selgelid brings the example of machete, which is an instrument for farming but in Rwanda was used for killing other people, or the case where the physicists who discovered atomic fission realized that the discovery could «*have beneficial applications in medicine and the generation of energy, but [...] the same discoveries might lead to the development of new, monstrously devastating weapons*»<sup>860</sup>.

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<sup>856</sup> See M.R. DANDO, *The Impact of the Development of Modern Biology and Medicine on the Evolution of Offensive Biological Warfare Programs in the Twentieth Century*, in *Defense Analysis*, 15, 1, 1999, p. 51.

<sup>857</sup> See the reference of “dual use” to research, technology and artifacts, i.e. the products of technology, by J. FORGE, *A Note on the Definition of “Dual Use”*, in *Science of Engineering Ethics*, 16, 2010, p. 111–118. An example of the dual-use as intrinsic to research could be the experiments conducted by Nazis doctors during the World War II or the Tuskegee study on Negro males (see footnotes 625, 633, 714 and 772). An example of the dual-use with reference to the purposes of research and to applications of research could be the dynamite, which could be used for digging water wells in Poor countries or for killing people.

<sup>858</sup> About the multiple meanings of “dual use”, see R.M. ATLAS, M.R. DANDO. *The Dual-use Dilemma for the Life Sciences: Perspectives, Conundrums, and Global Solutions*, in *Biosecurity Bioterrorism*, 4, 2006, p. 276–286.

<sup>859</sup> See W.H.O. definition of “dual use”: W.H.O., *Life Science Research: Opportunities and Risks for Public Health*, Geneva, 2005.

<sup>860</sup> M.J. SELGELID, *Dual-Use Research Codes of Conduct: Lessons from the Life Sciences*, in *Nanoethics*, 3, 2009, p. 176. See also S. SCHWEBER, *In the shadow of the bomb: Bethe, Oppenheimer, and the moral responsibility of the scientist*, Princeton, N.J., 2000; B. RAPPERT, *Defining the*

A very powerful metaphor is the one that compares technologies to the Greek myth of Persephone, an innocent woman who was used to pick beautiful flowers, but one day was attracted by Hades and kidnapped by him, who carried her off to the Underworld, and as a compromise between her mother and Zeus, she was allowed to spend six months on earth (meaning Spring) and six months in Hades's world (representing Winter)<sup>861</sup>. Thus, sciences and technology could suffer from "Persephone effect", being aimed for good, but being able to fall into evil's temptations as well.

Such issues of "dual use" were born in the years of nuclear energy and atomic weapons research, as demonstrated by Feynman's speech: *«Once in Hawaii I was taken to see a Buddhist temple. In the temple a man said, "I am going to tell you something that you will never forget". And then he said: "To every man is given the key to the gates of heaven. The same key opens the gate of hell". And so it is with science. In a way it is a key to the gates of heaven, and the same key opens the gate of hell, and we do not have any instructions as to which is which gate»*<sup>862</sup>.

### 1.5. Synthetic Biology as a Threat to Biosecurity.

Bostrom affirms that what worries the most is the fact that new technologies, such as synthetic biology, could affect the existence of humanity as we know it, by creating risks of extinction of human species<sup>863</sup>. Indeed, nowadays new pathogens can be designed and built rather easily. Their basic component could be downloaded from the Internet, digitally represented and printed out to create new strains of viruses. The case of poliovirus in 2002 is a case in point. Some researchers obtained from a scientific mail-order house the chemical basis used to create a laboratory-synthesized virus, that was virtually identical to the naturally occurring one causing

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*Emerging Concern with Biosecurity: For Who? From What? What now?*, in *Japan Journal for Science, Technology and Society*, 17, 2008, p. 95-116.

<sup>861</sup> For this metaphor, see G. KWIK, J. FITZGERALD, T.V. INGLESBY, T. O'TOOLE, *Biosecurity: Responsible Stewardship of Bioscience in an Age of Catastrophic Terrorism*, in *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science*, 1, 1, 2003, p. 28.

<sup>862</sup> Quoted by S. SCHWEBER, *In the Shadow of the Bomb: Bethe, Oppenheimer, and the Moral Responsibility of the Scientist*, Princeton, N.J., 2000, p. 64.

<sup>863</sup> See also EDITORIAL, *Life from Scratch. Promise, Peril, and Pathogens: Breakthroughs in Synthetic Biology*, in *New Atlantis*, Spring 2004, p. 101-103.

polio. The scientists modelled it on the genetic sequence for the poliovirus, which could be obtained from a public database on the Internet. They ordered short stretches of DNA in the proper chemical order from a commercial company, stitched those chunks together and transformed them into a poliovirus that could reproduce itself and paralyze mice.

Schmidt and Giersch<sup>864</sup> underline that these experiments are actually the most worrying concerns: «*Non-intentionally enhancing the virulence of the mousepox virus by inserting an IL-4 gene into the mousepox genome*<sup>865</sup> [...]; *Synthesis of the poliovirus genome* [...]; *The [reconstructed] 1918 Spanish Flu* [...]; *Transfer of the virulence factor of variola major (which causes smallpox) into the vaccinia virus, which is of much lower virulence and usually used for vaccinations against smallpox*»<sup>866</sup>.

It is clear that synthetic biology owns the potentiality of recreating and creating old or new pathogenic viruses. Thus, its capacity for threat and risk is evident.

Moreover, it should not be neglected that synthetic biology has the potential to be handled in “garage laboratories”, and with that symbols of the D.I.Y. (do-it-yourself) movement that are spreading everywhere<sup>867</sup>. As such, the abuse of synthetic biology in order to create biological weapons could occur by side of governments and by single terrorists. These threats are becoming of global size.

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<sup>864</sup> M. SCHMIDT, G. GIERSCH, *DNA Synthesis And Security*, in M.J. CAMPBELL (ED.), *DNA Microarrays, Synthesis and Synthetic DNA*, New York, 2011, p. 285-300.

<sup>865</sup> R.J. JACKSON ET AL., *Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox*, in *Journal of Virology*, 75, 2001, p.1205-1210.

<sup>866</sup> A.M. ROSENGARD ET.AL., *Variola virus immune evasion design: expression of a highly efficient inhibitor of human complement*, in *Proceedings of the National Academy of Sciences of the U.S.A.*, 99, 2002, p. 8808-8813.

<sup>867</sup> See J. ALPER, *Biotech in the basement*, in *Nature Biotechnology*, 27, 12, December 2009, p. 1077-1078.

## 2. *Where Are We Now? A Summary of the Main Regulations against Bioterrorism.*

### 2.1. *At the International Level.*

At the international level, the starting point for biosecurity rules can be found in 1925 Geneva Protocol<sup>868</sup>, which prohibited the deployment of chemical and biological weapons following the horrible impact of chemical warfare during the World War I. However, this Protocol mentioned only the ban of developing biological weapons, and no reference was made with regards to their production, storage, and transfer<sup>869</sup>.

After this Protocol, the Geneva Conventions related to Humanitarian Law were drafted (1949)<sup>870</sup>.

With the development of science and the birth of the first biological weapons programs, the need for more specific rules was perceived as a urgency, and this led to the enactment of the 1972 Biological and Toxins Weapons Convention (B.W.C.)<sup>871</sup>, which is still the main instrument in this field, despite it lacking relevant elements.

Considered as a complement of Geneva Protocol, it contains a lot of provisions, starting with a list of specific biological agents (art. 1), and more specifically: «*live agents capable of reproducing themselves (bacteria, fungi); live agents capable of reproducing themselves only in a host cell (virus); agents that are not alive and are incapable of reproducing themselves, but that are secreted by living organisms (peptides, toxins);and agents that are not alive, are incapable of*

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<sup>868</sup> 1925 Geneva Protocol, Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare. The Protocol was drawn up and signed at a conference which was held in Geneva under the auspices of the League of Nations from 4<sup>th</sup> May to 17<sup>th</sup> June 1925, and it entered into force on 8<sup>th</sup> February 1928.

<sup>869</sup> In reality, the Protocol was anticipated by some Declarations and conventions, such as the Paris Declaration (1856), followed by some conventions and other declarations, such as the Convention of Red Cross (Geneva 1864), Saint Petersburg Declaration (1868), Bruxelles Declaration (1874), Le Hague Conventions (1899 and 1907).

<sup>870</sup> The 4 Geneva Conventions, at the core of humanitarian law, were enacted on 12<sup>th</sup> August 1949, and were followed by 3 Protocols (see at <http://www.icrc.org/eng/war-and-law/treaties-customary-law/geneva-conventions/index.jsp>, last visited 28<sup>th</sup> January 2013).

<sup>871</sup> U.N., *International Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, 10<sup>th</sup> April 1972, entered into effect in 1975. Currently, there are 165 States Parties, 12 signatories, 19 states that neither signed nor ratified.

*reproducing themselves and are obtained by chemical synthesis, but with a structure that is identical to, or similar to the above».*

The following are the three obligations that the States have to fulfil:

(1) not to develop, reproduce, stockpile, acquire or retain microbial or biological agents or toxins or weapons, equipment or the means of disseminating such agents for non-peaceful purposes (art. 1);

(2) not to transfer biological weapons to third party states or international organisations or assist them, encourage them or induce them to manufacture or acquire such weapons (art. 3);

(3) to prohibit and impede these activities in their territory (art. 4).

The Convention requires the destruction of existing inventories and delivery devices and it encourages the cooperation among States when they are called for the solving of the problems of consultation and the carrying out of the investigation required by U.N. Security Council. In addition, it fosters mutual assistance in case a State is attacked by biological weapons.

It should be noted that there are no references to specific agents or pathogens. This leaves the freedom to the States to decide which ones are the addressed agents. Furthermore, there is no ban for the use of those biological agents for therapeutic and civil purposes.

The States are called upon to implement the issues about (1) the definitions (of toxins, agents, etc.), (2) the prohibitions and the penalties (pertaining to the preparation, development, production, acquisition, stockpiling, retention, direct or indirect transfers, and use of biological weapons), (3) the jurisdiction (extraterritoriality), (4) the enforcement (through national authorities, laboratories, surveillance bodies, international cooperation), (5) the export control (through licenses, border controls, and so on), and (6) the biosafety and biosecurity measures.

This Convention has an unlimited duration, but a series of review conferences were conducted and have been held in order to establish (a) compliance procedures (through an organisation or implementing body or any other effective means), (b) measures for monitoring national implementation, and (c) mechanisms for investigating the alleged violations, since all these aspects were not indicated in the original treaty and the provisions of the B.W.C. are so general that they do not

provide specific guidance. Yet, these conferences (the last one, the 7<sup>th</sup>, occurred in 2011<sup>872</sup>) have failed in resolving the accountability and enforcement procedures. In fact, there is a strong resistance (especially within the U.S.A.) against the intrusion of an international convention upon national activities. So, a system of verification of B.W.C. and of control of application is still lacking, along with excessive vagueness of some dispositions.

Other weaknesses of the Convention are represented by the fact that its *«focus on state-based B.W. programs does not adequately reflect the growing role of private (non-state) actors in relevant research activities or the potential threat of bioterrorism»*<sup>873</sup> and the States' obligation to take all the necessary measures to prevent any of the prohibited activities within their territories (art. 4) does not explicitly state what these measures actually would be. So, the Convention refers only to prevention of biological weapons among the States, and forgetting the usage of them by bioterrorists, criminal bands, groups.

Other relevant regulations on the international level are the following ones: (a) the Convention about the prohibition of military use of techniques of modification of environment (Geneva 1977)<sup>874</sup>, (b) the Convention about the prohibition and restriction of using conventional weapons that could be considered as dangerous and having indiscriminate effects (Geneva 1980)<sup>875</sup>, (c) the Chemical Weapons Convention (C.W.C. 1993) about the prohibition of chemical weapons<sup>876</sup>,

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<sup>872</sup> In the last review conference, States were called to adopt measures designed to “ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins”, in particular through implementing voluntary management standards on biosafety and biosecurity, promoting the development of training and education programmes for scientists, encouraging a culture of responsibility amongst relevant national professionals and the voluntary promulgation of codes of conduct. The 8<sup>th</sup> Review Conference will be taken in 2016. For more information, see <http://www.unog.ch/bwc> (last visited 28<sup>th</sup> January 2013).

<sup>873</sup> M. SCHMIDT, G. GIERSCH, *DNA Synthesis And Security*, cit., p.

<sup>874</sup> The Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques was adopted by Resolution 31/72 of the United Nations General Assembly on 10<sup>th</sup> December 1976. The Convention was opened for signature at Geneva on 18<sup>th</sup> May 1977.

<sup>875</sup> The Convention on Prohibitions or Restrictions on the Use of Certain Conventional Weapons Which May be Deemed to be Excessively Injurious or to Have Indiscriminate Effects was adopted in 1980 and entered into force in 1983.

<sup>876</sup> The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction was adopted on 13<sup>th</sup> January 1993 and entered into force on 29<sup>th</sup> April 1997.

and (d) the Convention on the prohibition, usage, production, transport of antiperson mines (Oslo 1997)<sup>877</sup>.

In general, the international regulation, as Bassiouni says<sup>878</sup>, has followed two roads, namely:

(1) the way of international humanitarian law (Geneva Conventions), stating a ban for the use of belligerency methods producing high damages to environment and people, and

(2) the way of multilateral agreements about the control of weapons. In the second category, three types of instruments can be found:

(a) agreements that have a general character, namely the banning of the use of weapons of mass destruction weapons (1968 treaty of non proliferation of nuclear weapons<sup>879</sup>; 1972 B.W.C; 1980 Geneva Convention on conventional weapons having a discriminate effects, and 1993 C.W.C.);

(b) treaties which ban the weapons of mass destruction in certain areas: the Antarctic Treaty (Washington 1959)<sup>880</sup>, the treaty on the prohibition of proofs of nuclear weapons in the atmosphere and submarine territories (Moscow 1963)<sup>881</sup>, the Treaty on the activities of States about the exploration of space (Washington, London, Moscow 1967)<sup>882</sup>, the treaty on the use of nuclear weapons in the depth of sea and ocean (Washington, London, Moscow 1971)<sup>883</sup>, and the agreement on the activities of States on the Moon (New York 1979)<sup>884</sup>;

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<sup>877</sup> The 1997 Convention on the Prohibition of the Use, Stockpiling, Production and Transfer or Anti-Personnel Mines and on their Destruction was adopted on 18<sup>th</sup> September 1997 and entered into force on 1<sup>st</sup> March 1999.

<sup>878</sup> M.C. BASSIOUNI, *work cit.*, p. 17 ss.

<sup>879</sup> The Treaty on the Non-Proliferation of Nuclear Weapons, commonly known as the Non-Proliferation Treaty or N.P.T. was adopted on 1<sup>st</sup> July 1968 and entered into force on 5<sup>th</sup> March 1970.

<sup>880</sup> The Antarctic Treaty and related agreements, collectively called the Antarctic Treaty System or ATS, was adopted on 1<sup>st</sup> December 1959 and entered into force on 23<sup>rd</sup> June 1961.

<sup>881</sup> The Limited Test Ban Treaty was adopted on 5<sup>th</sup> August 1963 and entered into force on 10<sup>th</sup> October 1963.

<sup>882</sup> The Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies (Outer Space Treaty) was adopted on 27<sup>th</sup> January 1967 and entered into force on 10<sup>th</sup> October 1967.

<sup>883</sup> The Treaty on the Prohibition of the Emplacement of Nuclear Weapons and Other Weapons of Mass Destruction on the Seabed and Ocean Floor and in the Subsoil Thereof (Seabed Treaty) was adopted on 11<sup>th</sup> February 1971 and entered into force on 18<sup>th</sup> May 1972.

<sup>884</sup> The Agreement Governing the Activities of States on the Moon and Other Celestial Bodies was adopted on 18<sup>th</sup> December 1979 and entered into force on 11<sup>th</sup> July 1984.



(c) the agreements which establish the zones of atomic exclusion (1968 Tlatelolco Treaty<sup>885</sup>; 1985 Raratonga Treaty<sup>886</sup>; 1995 South-Eastern Asia Treaty<sup>887</sup>, and the 1996 Pelindaba Treaty<sup>888</sup>).

The main principles underlying these conventions are that the weapons that generate indiscriminate and useless suffering, which are not proportional and not necessary, must be prohibited. These principles usually contain a list of prohibited behaviours, which state the ban of use and possession of forbidden weapons, and ask the State to develop policies of prevention and to sanction the violations. The rules of proportionality and discrimination between the fighters and innocents in the use of weapons are also established.

In the U.N. system, since 2001, the Security Council within the National Organization focuses its attention on terrorism, as its role is central in cases «*overwhelming outbreak of infectious disease that threatens international peace and security*»<sup>889</sup>. With the Resolution 1453/2003<sup>890</sup>, the U.N. makes reference to the possibility that terrorists could have access and to detain biological materials having lethal functions. The main resolution is the n. 1540/2004<sup>891</sup>, where it is stated that all the States of the International Community should introduce national controls in order to prevent the proliferation of nuclear, chemical and biological weapons and of connected materials, thus intensifying international cooperation against fabrication, construction, transport and diffusion of those weapons. The focus is posed particularly on non State use of bioweapons. The Resolution also establishes the

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<sup>885</sup> The Treaty of Tlatelolco is the conventional name given to the Treaty for the Prohibition of Nuclear Weapons in Latin America and the Caribbean. It was adopted on 14<sup>th</sup> February 1967 and entered into force on 22<sup>nd</sup> April 1968.

<sup>886</sup> The Treaty of Raratonga is the common name for the South Pacific Nuclear Free Zone Treaty, it was adopted on 6<sup>th</sup> August 1985.

<sup>887</sup> The Treaty of Bangkok is the common name for the Treaty on the Southeast Asia Nuclear-Weapon-Free Zone. It was adopted on 15<sup>th</sup> December 1995 and entered into force on 27<sup>th</sup> March 1997.

<sup>888</sup> The Treaty of Pelindaba is the common name for the African Nuclear-Weapon-Free Zone Treaty. It was adopted on 11<sup>th</sup> April 1996, but is not entered into force yet.

<sup>889</sup> See Kofi Annan, about U.N. Reform Project, U.N.G.A., *In Larger Freedom: Toward Development, Security and Human Rights for All*, Report of the Secretary-General, U.N. Doc. A/59/2005, 21<sup>st</sup> March 2005, p. 29.

<sup>890</sup> The U.N. Security Council resolution 1453 was adopted unanimously on 24<sup>th</sup> December 2002.

<sup>891</sup> The U.N. Security Council resolution 1540 was adopted unanimously on 28<sup>th</sup> April 2004.

creation of the Committee 1540, which is voted to control the effective application of the Resolution<sup>892</sup>.

At the international level the initiative of G7 members is relevant as well. In 2001 in Ottawa the G7 Ministries of Health (together with the Mexican Secretary of Health and one Member of the European Commission, responsible for health and protection of the consumers) created the Global Group of Sanitary Action and Security<sup>893</sup>, which aims to organize a coordinate response in cases of bioterrorism.

Interpol (International Police) also plays a meaningful role here. In 2006, Interpol established a specific programme about bioterrorism detailing the implementation of security education, and the legislative norms about cooperation. The programme was called “Bio-criminalization” and, through the support of Sloan Foundation and the Government of Canada, a Guide on the anticipatory measures and response to bioterrorist incidents was published<sup>894</sup>.

Furthermore, “Australia Group” (A.G.) is *«an informal forum of countries which, through the harmonisation of export controls, seeks to ensure that exports do not contribute to the development of chemical or biological weapons»*<sup>895</sup>. The A.G. maintains Common Control Lists that require controls on the export of certain biological agents or parts thereof. The control list refers to: genetic elements that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list; genetic elements that contain nucleic acid sequences coding for any of the toxins in the list, or for their sub-units; genetically-modified organisms that contain nucleic acid sequences associated with the pathogenicity of any of the microorganisms in the list; and genetically-modified organisms that contain nucleic acid sequences coding for any of the toxins in the list or for their sub-

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<sup>892</sup> The Committee has been extended in its role through Resolution 1673/2006 and Resolution 1840/2008.

<sup>893</sup> The 7<sup>th</sup> G7 Summit was called the Ottawa Summit, and was held in Montebello, Quebec, Canada and nearby Ottawa between 20<sup>th</sup> and 21<sup>st</sup> July 2001.

<sup>894</sup> See at <https://secure.interpol.int/public/BioTerrorism/bioC/default.asp> (last visited 28th January 2013).

<sup>895</sup> See <http://www.australiagroup.net> (last visited 28<sup>th</sup> January 2013). Chaired by Australia, the “Australia Group” was formed as an informal arrangement, found in 1984 as a result of C.W. use in the Iran-Iraq War. The members of the Group are presently: Argentina, Australia, Austria, Belgium, Bulgaria, Canada, Czech Republic, Croatia, Cyprus, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, South Korea, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, United States of America, and the European Community Commission (Observer).

units<sup>896</sup>. The list is being implemented through national laws and regulations, but it clearly requires the States within the A.G. to regulate exports of such material, and not domestic transfers. The additional biosecurity screening of domestic orders and customers by DNA synthesis companies is *de facto* done on a voluntary basis, following company guidelines.

In 2005 the World Health Assembly, the highest decision-making body of W.H.O., adopted a revised set of International Health Regulations<sup>897</sup>, which is in force from 2007, and it binds the W.H.O. Member States on an opt-out basis. It adopted an “all risk” approach, which includes any emergency with repercussions for international health security (outbreaks of epidemic diseases, outbreaks of food, natural disasters, accidental or deliberate release of pathogens). It has the purposes of protecting against public health threats, controlling and providing adequate response in cases of spread of diseases. The States have to notify W.H.O. of events within their territories that may constitute a “public health emergency of international concern” and they have to intervene without being invasive or intrusive to people’s lives.

In the Council of Europe, bioterrorism has been contemplated in Resolution 1367/2004<sup>898</sup>, in which the Parliamentary Assembly<sup>899</sup> asks the States to inform and educate the public about the inherent dangers of bioterrorism, to draw up an objective assessment of the potential sources of bioterrorist danger, and elaborate an efficient and effective surveillance and warning systems, to devise emergency intervention and public-health relief plans, to frame a suitable public vaccination policy; to control the purchase and movement of dangerous substances, and to establish strict control over activities based on the use of modern biotechnologies in order to avoid their misuse for bioterrorism.

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<sup>896</sup> Australia Group, List of Biological Agents for Export Control, July 2006, <http://www.australiagroup.net/en/biologicalagents.html> (last visited 28<sup>th</sup> January 2013).

<sup>897</sup> International Health Regulations (2005), W.H.A. Res. 58.3, 23<sup>rd</sup> May 2005.

<sup>898</sup> Resolution 1367 (2004), adopted by the Standing Committee, acting on behalf of the Assembly, on 2<sup>nd</sup> March 2004.

<sup>899</sup> See also the Doc. 10095, 17<sup>th</sup> February 2004, *Bio-terrorism: a serious threat for citizens’ health*, Opinion by the Committee on the Environment, Agriculture and Local and Regional Affairs, where the possibility of terrorist use, not only of known natural pathogens but also of synthetic biological agents produced for peaceful purposes, is mentioned. Moreover, see the Report by Social, Health and Family Affairs Committee (9<sup>th</sup> February 2004).

The O.E.C.D. has, over the years, had a relevant role in the development of a culture of biosecurity both on the governmental and scientific community level. Indeed, it has indicated the importance of common standards of safety in labs<sup>900</sup> and established a Group of Experts on Biosecurity to the Task Force on Biological Resource Centres (2002). Moreover, in 2004 the O.E.C.D. International Futures Programme (I.F.P.)<sup>901</sup>, which has been working on risk management issues since 2000, conducted a workshop on “*Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources*” in Frascati, Italy<sup>902</sup>.

## 2.2. *At the European level.*

The first list of biological agents enacted by the E.U. goes back to 1990 in the Directive 90/679<sup>903</sup> (followed by a Decision 18<sup>th</sup> July 1994).

Regarding the export of technological material of “double use”, the Regulation n. 1334/2000 established a regime of control of exports, transfer, brokering and transit<sup>904</sup>. It contains a list of biological and chemical agents which are to be subjected to strict measures of check and authorization by Member states before export (as indicated in Annex I).

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<sup>900</sup> See the publication of the reports: *Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology*, 2001, and *Best Practices for Biosecurity in Biological Resource Centres*, 2007.

<sup>901</sup> See at <http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/33855561.pdf> (last visited 28th January 2013).

<sup>902</sup> For deepening the role of O.E.C.D. in biosecurity, see D.B. SAWAYA, *Biosecurity at the OECD*, in B. RAPPERT, C. GOULD (EDS.), *Biosecurity Origins, Transformations and Practices*, England, 2009, p. 79 ff.

<sup>903</sup> Council Directive 90/679/EEC of 26<sup>th</sup> November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), in *O.J. L* 374/1990.

<sup>904</sup> See Regulation 1334/2000 of 22<sup>nd</sup> June 2000 setting up a Community regime for the control of exports of dual-use items and technology in *O.J. L* 159/2000, modified by Regulation 2432/2001 of 20<sup>th</sup> November 2001 in *O.J. L* 338/2001, and by Regulation 428/2009 of 5<sup>th</sup> May 2009 in *O.J. L* 134/2009.

Since 2001, the European Union started worrying about anthrax cases after the events which happened in the United States in the aftermath of 9/11<sup>905</sup>. Such events generated the necessity of adopting preventative measures in the sanitary field, in order to protect the people from the risks to their health and security. It also instituted a network of information for a rapid response to threats, a policy of vaccination, and a cooperation in management of risks<sup>906</sup>. In 2001 the Committee of Sanitary Security was established (formed of the highest members of health coming from different E.U. States), with the duty to ensure the adequate coordination between security and health agencies within the E.U., to share knowledge and information, to cooperate and approve a programme of preparedness and response in case of attacks with chemical and biological agents (BICHAT)<sup>907</sup>. This programme contained four main lines of action:

- (1) the establishment of an alert mechanism and exchange of information;
- (2) the warranty of capacities of detection and identification of chemical and biological agents, susceptible to be adopted for attacks;
- (3) the creation of a database including medical, sanitary and pharmaceutical data that could be useful in case of attack, a proposed list of national reservation of antibiotics and vaccines (currently not yet in existence), and a list of medical experts in the hypothesis of an attack, and
- (4) the elaboration of norms and codes of conduct to be adopted in case of threat.

A system of rapid alarm for signalling cases of propagation of harmful biological agents became operative since 2002 (called RAS-BICHAT, Rapid Alert System for Biological and Chemical Attacks and Threats). It connected the members of the Committee of Sanitary Security and the contact points at national level, and it was aimed at ensuring controls and emergency responses.

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<sup>905</sup> About the summary of all the initiatives of the E.U. in the field of bioterrorism, see at [http://ec.europa.eu/health-eu/my\\_environment/bio\\_terrorism/index\\_en.htm](http://ec.europa.eu/health-eu/my_environment/bio_terrorism/index_en.htm) (last visited 28th January 2013).

<sup>906</sup> In reality since 1998, Decision 2119/98 (24<sup>th</sup> September 1998 in *O.J.* L 268/1998) focused on the surveillance of transmissible diseases, stressing the importance of monitoring infective diseases and activating rapid responses all over Europe, also creating an EU network of communicable diseases.

<sup>907</sup> See Communication from the Commission to the Council and the European Parliament, "On Cooperation in the European Union on Preparedness and Response to Biological and Chemical Attacks", COM (2003) 320, 2<sup>nd</sup> June 2003.

Interventions in the sector of civil protection are also relevant as a means for ensuring sanitary security and protection from threats<sup>908</sup>, in a cooperative way among the States.

Moreover, a “*Guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism*”<sup>909</sup> was enacted by the European Medical Agency and its Committee for Proprietary Medicinal Products (C.P.M.P.), on the E.U. Commission’s request, to describe the most used agents of bioterrorism and list the possible drugs that might be useful in the case of an attack.

The Working Group on Bioterrorism was created as well (2002), together with the establishment of (a) a Task Force with Commission and States members about C.B.R.N. (Chemical, Biological, Radiological, Nuclear) protection, (b) a Task Force Commission-Pharmaceutical Industries, (c) a Task Force Commission-Research chiefs, and (d) a Research and Development Expert Group on Countering the Effects of Biological and Chemical Terrorism. Again in 2002 the Council and Commission, jointly, elaborated on a C.B.R.N. Terrorism Programme<sup>910</sup> in order to improve the cooperation in the E.U. for the prevention and limitation of the consequences of terrorist threats. On the basis of C.B.R.N. Programme, a E.U. Subgroup on Lists, which focused on establishment of a list of high-risk C.B.R.N. material to be revised periodically, was created.

In 2003 the Commission drafted a Communication to the Council and Parliament about the cooperation within the E.U. regarding the preparation and response in case of attacks with chemical and biological agents<sup>911</sup>, including all the measures to be adopted (in pharmaceutical, public health, surveillance areas).

In the same year, the E.U. Strategy against proliferation of weapons of mass destruction and their means of delivery, known as the E.U. W.M.D. strategy, was

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<sup>908</sup> See Communications of the Commission COM (2001) 707 def. and COM (2002) 302 def.; Council Decision 2007/779/EC, establishing a Community Civil Protection Mechanism and Council Decision establishing a Civil Protection Financial Instrument (2007/162/EC).

<sup>909</sup> EMEA/CPMP/4048/01, *Guidance document on use of medicinal products for treatment and prophylaxis of biological agents that might be used as weapons of bioterrorism*, London, 25<sup>th</sup> July 2002.

<sup>910</sup> 14627/02, C.B.R.N. Programme to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats.

<sup>911</sup> See footnote 907.

adopted by the European Council<sup>912</sup>. The European Council reviewed it through the adoption of “*New lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems*” (December 2008)<sup>913</sup>. In addition, since 2003, W.M.D. clauses were inserted in all new or renewed mixed agreements with third countries.

Then, in 2005 a Communication<sup>914</sup> about the coordination of sanitary emergency intervention and one about the establishment of a general rapid alert system called “ARGUS”<sup>915</sup> for multisector crisis were enacted.

In 2007 a Green Book on Biopreparedness about the preparation in case of biological attack<sup>916</sup> was released, in order to introduce a process of consultation for the reduction of biological risks, and thus underlining the need to build up a strong culture of awareness among scientific community. The Green Book received over 80 responses, all of which agreed with the importance of tackling the issue of biosecurity at the European level. Thus this indicates the E.U.’s central role in coordinating the biopreparedness of its Member States according to an “all hazards” approach, which involves the police and judicial bodies, health and civil protection services<sup>917</sup>.

The Commission also elaborated on a system of medical information (called “MediSys”) that assembles information about sanitation and methods for treating epidemics, even in emergency contexts. With a White Book on health policies for the period 2008-2013<sup>918</sup>, the Commission clarifies the need for a consideration of the benefits of new technologies on health and, at the same time, a need for progressing

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<sup>912</sup> 15708/03 and SN 400/03, n. 68, E.U. Strategy against proliferation of weapons of mass destruction (W.M.D.) adopted by the European Council on 12<sup>th</sup> December 2003.

<sup>913</sup> 17172/08, 17<sup>th</sup> December 2008, Council Conclusions and new lines for action by the European Union in combating the proliferation of weapons of mass destruction and their delivery systems.

<sup>914</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on strengthening coordination on generic preparedness planning for public health emergencies at the E.U. level, COM 605/2005, 28<sup>th</sup> November 2005.

<sup>915</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Commission provisions on “ARGUS” general rapid alert system, COM 662/2005, 23<sup>rd</sup> December 2005.

<sup>916</sup> Green book n. 11951/07 containing the Communication COM 399/2007 of 11<sup>th</sup> July 2007.

<sup>917</sup> See Commission, Synthesis of the replies to the Green paper on bio-preparedness, SEC(2008) 2374, 4<sup>th</sup> August 2008.

<sup>918</sup> White paper - Together for Health: A Strategic Approach for the EU 2008-2013 {SEC(2007) 1374} {SEC(2007) 1375} {SEC(2007) 1376}, COM 630/2007, 23<sup>rd</sup> October 2007.

in the development of measures to respond to health pandemic risks, such as bioterrorism.

In 2006 a Council Joint Action in support of the Biological and Toxin Weapons Convention was adopted<sup>919</sup>. This is in order to promote the universality of B.W.C. and support for implementation of the B.W.C. by States Parties.

In 2009 the Action Plan, which was put in force to strengthen the C.B.R.N. Programme, was enucleated by the Commission<sup>920</sup>. It presented an “all hazard” approach, focusing on the prevention, preparation, detection and response against threats, which is to be applied through cooperation among the States, and the use of E.U. mechanisms (such as contacting E.U. civil protection, the Committee of Sanitary Security, the European Centre for Disease Prevention and Control, located in Stockholm and instituted by Regulation 851/2004). However, such C.B.R.N. Action Plan is not a legal instrument, and so the implementation of it would be required by future instruments. The E.U. also established a C.B.R.N. Advisory Group in order to support the implementation of the Action Plan.

### *2.3. In the United States of America.*

The attention by the U.S.A. towards biosecurity as threatened by new technologies can be seen since the years 1974 and 1975, when the concerns over the safe and ethical manipulation of genetic material using recombinant DNA techniques emerged at the Asilomar Conference<sup>921</sup>.

As mentioned in chapter II, in Asilomar the members of scientific community claimed self-governance for biotechnology, and drafted a set of voluntary guidelines that restricted recombinant DNA research to the K12 strain of *E. coli*, which was

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<sup>919</sup> Council Joint Action 2006/184/CFSP of 27<sup>th</sup> February 2006 in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction, in O.J. L 65/2006.

<sup>920</sup> 273/2009, 24<sup>th</sup> June 2009. See also SEC (2009) 874, Commission Staff Working Document, entitled “Bridging Security and Health: Towards the identification of good practices in the response to CBRN incidents and the security of CBR substances”, accompanying the Communication of Commission “Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union”.

<sup>921</sup> See footnote 437.



believed to be disabled from generations of use in the laboratory and to be not likely to survive in the environment.

In response to the same fears, the National Institute of Health established the Recombinant DNA Advisory Committee (R.A.C.) in 1974<sup>922</sup>. The R.A.C. was first charged by the N.I.H. to develop a set of guidelines for the safe conduct of recombinant DNA research, which were issued in 1976 as the “*N.I.H. Guidelines for Research Involving Recombinant DNA Molecules*”. The N.I.H. also required the creation of an Institutional Biosafety Committee (I.B.C.) at each funded research institution.

Concerns were also raised with respect to academic freedom and the freedom of research, and in this regard the 1982 Corson Report was enacted, followed in 1985 by the National Security Decision Directive n. 189 (N.S.D.D. n.189). The Corson report<sup>923</sup> was drafted by the National Academy of Sciences, headed by Professor Corson, and it stated that it was not necessary to restrict research and international scientific communication, as the censorship or secrecy would have weakened U.S. technological development. Directive 189<sup>924</sup>, then, fixed the national policy for controlling the flow of scientific and technology information generated in universities and laboratories, by supporting the openness of scientific inquiry, including the right to pursue and publish, without government restrictions, all the research and placing the onus on the scientific community to regulate itself.

In 1989, the B.W.C. was implemented in the national system through the United States Biological Weapons Anti-Terrorism Act<sup>925</sup>.

After the anthrax attacks of October 2001, Congress took a series of legislative actions<sup>926</sup> directed at securing potentially dangerous biological agents, including the 2001 Patriot Act, and the 2002 Public Health Security and Bioterrorism Preparedness and Response Act.

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<sup>922</sup> See footnote 460.

<sup>923</sup> PANEL ON SCIENTIFIC COMMUNICATION AND NATIONAL SECURITY, NATIONAL ACADEMY OF SCIENCES, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, *Scientific Communication and National Security*, Washington, D.C., 1982.

<sup>924</sup> NSDD-189. 21<sup>st</sup> September 1985, *National Policy On The Transfer Of Scientific, Technical And Engineering Information*.

<sup>925</sup> On the basis of this Act, for example, a man from Illinois was sentenced on 24<sup>th</sup> September 2012 to 7 years and 8 months for possession of a toxin (Tetrodotoxin) with intent to use it as a weapon.

<sup>926</sup> For a review of all the legislative framework about bioterrorism in the U.S.A., see E.P. RICHARDS, T. O'BRIEN, K.C. RATHBUN, *Bioterrorism and the Use of Fear in Public Health*, in *The Urban Lawyer*, 34, 3, 2002, p. 685-726.

The Patriot Act<sup>927</sup> determines the case of “possession” of select agents for the first time (Section 817), establishing the possession standards for *bona fide* research and requiring assurances from research institutions that no “restricted persons” could have access to such select agent research. The Patriot Act makes it illegal for anyone in the United States to possess any biological agent, including any genetically engineered organism, for any inappropriate reason<sup>928</sup>.

The second law, the Public Health Security and Bioterrorism Preparedness and Response Act<sup>929</sup>, adds new requirements for the listing of potentially dangerous biological agents and the prevention of unlawful access to agents during transfers. It requires that all persons possessing biological agents or toxins deemed a threat to public health to notify the Secretary, Department of Health and Human Services (D.H.H.S.). The U.S. Department of Agriculture is called for regulating toxins and biological agents posing threats to plants and animals. The Act also establishes penalties for those failing to notify the proper authorities about the possession of select agents (registered in the National Select Agents Registry)<sup>930</sup>.

In 2004, in addition to prohibiting possession and transportation of material, the U.S. restricted the use of synthesis technology to produce one specific pathogen. The Intelligence Reform and Terrorism Prevention Act contains, in fact, an amendment that «*imposes severe penalties for attempts to engineer or synthesize the smallpox virus*», defined as «*any virus that contains more than 85 percent of the gene sequence of variola major or variola minor*»<sup>931</sup>.

In the same years (2004-2005), the U.S. Congress passed the Project Bioshield Act<sup>932</sup>, which provided \$5 billion for vaccines in case of a bioterror event,

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<sup>927</sup> 115 Stat. 272 (2001), signed on 26<sup>th</sup> October 2001 and effective since 1<sup>st</sup> February 2002.

<sup>928</sup> Two meaningful applications of the Patriot Act were in (a) the case of a graduate student in Connecticut, who was charged with violations of the Patriot Act because he did not possess the anthrax for *bona fide* research (he was found to own two vials of anthrax from a 1960 cow necropsy) and (b) the case of a researcher at Texas Tech University (Dr. Thomas Butler), who was convicted of mislabelling plague samples being shipped from overseas.

<sup>929</sup> The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) was signed into law on 12<sup>th</sup> June 2002.

<sup>930</sup> About the U.S. legislation, see L.L. BUCHSBAUM, *The U.S. Public Health Response To Bioterrorism: Need For A Stronger Legislative Approach*, in *Journal Of Medicine And Law* 1, 7, 2002, p. 2-36.

<sup>931</sup> The Intelligence Reform and Terrorism Prevention Act of 2004 (I.R.T.P.A.), 118 Stat. 3638, was enacted on 17<sup>th</sup> December 2004.

<sup>932</sup> The Project Bioshield Act, whose full name is “An Act To amend the Public Health Service Act to provide protections and countermeasures against chemical, radiological, or nuclear agents that may be

and the Biodefense and Pandemic Vaccine and Drug Development Act (“Bioshield 2”)<sup>933</sup> cut the approval time for new drugs to hit the market in the case of a pandemic<sup>934</sup>.

With regards to the control of movement of pathogenic biological agents, the main regulation is the Export Administration Regulations (E.A.R.)<sup>935</sup>. It was enacted to implement the 1979 Export Administration Act which confers legal authority to the President for controlling the U.S. exports for reasons of public national security. The U.S. Department for Commerce is the actor called for implementing E.A.R., and since then it has provided a list of substances to be controlled (such as microorganisms, viruses, bacteria, toxins) and license requirements, which differ from each State of the U.S..

While the international orders are regulated by E.A.R., the internal ones follow Select Agent Regulation (S.A.R.)<sup>936</sup>, which was endorsed in 2005 for implementing the Public Health Security and Bioterrorism Preparedness and Response Act. This results in the notification required by people possessing those agents to be more specified, the deepening the role of D.H.H.S. in listing biological agents and toxins, and the approval of the safety measures, the containment and response plan to accidents developed by labs, in order to confer the certificate of registration that has three years validity.

Regarding the preparedness and response against bioterrorism, the Centre for Disease Control and Prevention (C.D.C.) has a meaningful role in alerting the emergency<sup>937</sup>. In 2001, it drafted a Model State Emergency Health Powers Act (M.S.E.H.P.A.)<sup>938</sup> and, in 2009, the United States developed their first National

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used in a terrorist attack against the United States by giving the National Institutes of Health contracting flexibility, infrastructure improvements, and expediting the scientific peer review process, and streamlining the Food and Drug Administration approval process of countermeasures” (118 Stat. 835–864), was signed on 21<sup>st</sup> July 2004.

<sup>933</sup> The Biodefense and Pandemic Vaccine and Drug Development Act of 2005, nicknamed “Bioshield Two”, is the Act S. 1873/2005.

<sup>934</sup> About the Project Bioshield I and II, see L. MAYER, *Immunity For Immunizations: Tort Liability, Biodefense, And Bioshield II*, in *Stanford Law Review*, 59, 2007, p. 1753-1790.

<sup>935</sup> See at <http://www.bis.doc.gov/policiesandregulations/ear/index.htm> (last visited 28th January 2013).

<sup>936</sup> See at <http://www.selectagents.gov/Regulations.html> (last visited 28th January 2013).

<sup>937</sup> See at <http://www.cdc.gov/> (last visited 28<sup>th</sup> January 2013).

<sup>938</sup> The Model State Emergency Health Powers Act (M.S.E.H.P.A.) is a proposal (21<sup>st</sup> December 2001) by the Center for Law and the Public’s Health, a joint venture of Georgetown University and Johns Hopkins University, to aid America’s state legislatures in revising their public health laws to

Health Security Strategy<sup>939</sup>, which offers a response for cases of natural disasters, naturally-occurring infectious disease epidemics and bioterrorism, and focuses on the preparedness, planning, surveillance, management of property, protection of persons, communication and public information. Coercive public health powers can be exercised only after the governor has declared a state of emergency, and public health officials can carry out examinations necessary for diagnosis and treatment, and conduct isolation and quarantine when they aim to prevent a substantial risk of transmission of infection. However, they must adhere to human rights principles, adopting the least restrictive alternative, and safe measures. Moreover, the C.D.C. has the authority to control and monitor the possession, use and transfer of select agents and toxins.

The Pandemic and All Hazards Preparedness Act<sup>940</sup>, enacted in 2006 to improve the organization, direction, and utility of preparedness efforts, has centralised federal responsibilities, and proposed new national surveillance methods, by placing the Department of Health and Human Services (D.H.H.S.) as the lead agency for federal public health and medical response to public health emergencies covered by the National Response Plan. It also focuses on volunteers for the oversight, through the Emergency System for Advance Registration of Volunteer Health Professionals (E.S.A.R.-V.H.P.) and Medical Reserve Corps (M.R.C.). The Act establishes a new Biomedical Advanced Research and Development Authority (B.A.R.D.A.) within the D.H.H.S. which is charged with fostering collaboration, supporting research, and encouraging innovation.

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respond to bioterrorism. For the text of the proposal, see at <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf> (last visited 28th January 2013). About M.S.E.H.P.A. and bioethical issues linked to bioterrorism, with reference to the U.S, see J.D. MORENO, *Bioethics And Bioterrorism*, in B. STEINBOCK (ED.), *The Oxford Handbook Of Bioethics*, New York, 2007, p. 721 ff.

<sup>939</sup> See at <http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Pages/default.aspx> (last visited 29th January 2013).

<sup>940</sup> The Pandemic and All-Hazards Preparedness Act (P.A.H.P.A.), Public Law No. 109-417, was signed on 29<sup>th</sup> December 2006.

#### 2.4. In the United Kingdom.

The U.K.'s attention on bioterrorism began in 2001 and intensified after London bombings on 7<sup>th</sup> July 2005.

In general, the current legislation in the U.K. in relation to terrorism is represented by the 2000 Regulation of Investigatory Powers Act<sup>941</sup>, the 2000 Terrorism Act<sup>942</sup>, the 2001 Anti-Terrorism, Crime and Security Act<sup>943</sup>, the 2005 Prevention of Terrorism Act<sup>944</sup>, the 2006 Terrorism Act<sup>945</sup>, and the 2008 Counter Terrorism Act<sup>946</sup>. With regards to emergency response to health threats, the 1984 Public Health (Control of Diseases) Act<sup>947</sup> and the 2004 Civil Contingencies Act<sup>948</sup> and could be applied.

In response to the threat of bioterrorism, section 113 of the 2001 Anti-terrorism, Crime and Security Act, concerning the “Use of noxious substances or things to cause harm and intimidate”, indicates that *«a person who takes any action which involves the use of a noxious substance or other noxious thing; has or is likely to have an effect falling within subsection (2); and is designed to influence the government or to intimidate the public or a section of the public»* is charged with a crime. Subsection (2) refers to action that *«causes serious violence against a person anywhere in the world; causes serious damage to real or personal property anywhere in the world; endangers human life or creates a serious risk to the health or safety of the public or a section of the public; or induces in members of the public the fear that the action is likely to endanger their lives or create a serious risk to their health or safety»*.

Part 6 of the same 2001 Anti-terrorism, Crime and Security Act amends the Biological Weapons Act 1974, which gave application to B.W.C.. Section 43 states that *«a person shall not transfer any biological agent or toxin to another person or*

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<sup>941</sup> With regards to the U.K. legislations, see at <http://www.legislation.gov.uk> (last visited 28<sup>th</sup> January 2013). The Regulation of Investigatory Powers Act 2000 (R.I.P. or R.I.P.A.) was approved on 28<sup>th</sup> July 2000.

<sup>942</sup> The Terrorism Act was approved on 20<sup>th</sup> July 2000.

<sup>943</sup> The Anti-terrorism, Crime and Security Act came into force on 14<sup>th</sup> December 2001.

<sup>944</sup> The Prevention of Terrorism Act was approved on 11<sup>th</sup> March 2005.

<sup>945</sup> The Terrorism Act was approved on 30<sup>th</sup> March 2006.

<sup>946</sup> The Counter Terrorism Act was approved on 26<sup>th</sup> November 2008.

<sup>947</sup> The Public Health (Control of Diseases) Act was approved on 26<sup>th</sup> June 1984.

<sup>948</sup> The Civil Contingencies Act was approved on 18<sup>th</sup> November 2004.

*enter into an agreement to do so, or make arrangements under which another person transfers any biological agent or toxin or enters into an agreement with a third person to do so*», if these biological agents are not used for peaceful purposes. Part 7 concerns the security of pathogens and toxins which could be used for «*an act of terrorism to endanger life or cause serious harm to human health (section 58)*». For those who keep or use such substances, the following duties are provided: (1) the duty of notification to the Secretary of State before any dangerous substance is kept or used, (2) the duty of notifying, on demand, the police about the security provisions for those substances, (3) the duty to identify, within one month of the service of the notice, those having access to such substances, where the substances are kept or the building and site where are located, and (4) the duty to give directions to disposal of such substances by others. These measures are accompanied by powers of entry and search warrants, and offences relating to the security of pathogens and toxins. Schedule 5 of the Act sets out a list of pathogens and toxins that are covered by the Act<sup>949</sup>. The Secretary of State has the possibility to extend the list to include further pathogens or toxins if suspected of being used for bioterrorism<sup>950</sup>. He could also specify the manner and time in which the substances must be disposed of (sec. 63), and prevent a particular individual from having access to the substance (sec. 64).

The 2002 Export Control Act<sup>951</sup> also allows the Secretary of State to make provision for the imposition of transfer controls in relation to suspected technology, but he cannot make a control order which has the effect of interfering with the communication of information in the ordinary course of scientific research.

With regards to preparedness and response to bioterrorism, the Cabinet Office (aimed at co-ordinating the operation of government departments<sup>952</sup>) deals with the so-called “U.K. Resilience” by indicating two areas within it: the “Emergency Preparedness” and the “Emergency Response and Recovery”<sup>953</sup>, which are governed in part by the 2004 Civil Contingencies Act.

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<sup>949</sup> About the list, see at <http://www.nactso.gov.uk/AreaOfRisks/PathogensToxins.aspx> (last visited 28<sup>th</sup> January 2013).

<sup>950</sup> See also The Security of Pathogens and Toxins (Exceptions to Dangerous Substances) Regulations 2002 (S.I. 2002/1281).

<sup>951</sup> The Export Control Act was approved on 24<sup>th</sup> July 2002.

<sup>952</sup> See at <http://www.cabinetoffice.gov.uk/about-cabinet-office.aspx> (last visited 28<sup>th</sup> January 2013).

<sup>953</sup> See at <http://www.cabinetoffice.gov.uk/ukresilience.aspx> (last visited 28<sup>th</sup> January 2013).

The general responsibility of counter-terrorism and planning and organization in emergencies is vested on the Home Office<sup>954</sup>. The U.K. Government has published its strategy for countering international terrorism (named CONSENT) in the document “*Pursue Prevent Protect Prepare: The United Kingdom’s Strategy for Countering International Terrorism*”<sup>955</sup>, where a reference to “Chemical, biological, radiological and nuclear weapons, and explosives” is given in Part 2. The CONSENT strategy is overseen at a Ministerial level by the Cabinet Committee on National Security, International Relations and Development (N.S.I.D.), chaired by the Prime Minister, and by the Home Secretary as the lead Minister for counter-terrorism, and it involves the heads of the security and intelligence agencies, the police, and Armed Forces. Other public authorities are also involved, such as the Cabinet Office, the Joint Terrorism Analysis Centre, the Association of Chief Police Officers and Local Authorities.

In relation to health implications, the Health Protection Agency<sup>956</sup>, created under the 2004 Health Protection Agency Act<sup>957</sup>, plays a role in bioterrorism responses<sup>958</sup>. The Agency is articulated into three research centres: the Centre for Emergency Preparedness and Response, the Centre for Infections, and the Centre for Radiation, Chemical and Environmental Hazards. Physicians are also under a general duty to report incidences of communicable or infectious diseases (under the 1984 Public Health (Control of Disease) Act<sup>959</sup>). A surveillance strategy is also in place which provides the examination, hospitalization and detention of an individual who

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<sup>954</sup> See at <http://www.homeoffice.gov.uk/counter-terrorism/> (last visited 28<sup>th</sup> January 2013).

<sup>955</sup> See at <http://webarchive.nationalarchives.gov.uk/20100418065544/http://security.homeoffice.gov.uk/news-publications/publication-search/contest/contest-strategy/contest-strategy-2009?view=Binary> (last visited 28<sup>th</sup> January 2013).

<sup>956</sup> See at <http://www.hpa.org.uk/> (last visited 28<sup>th</sup> January 2013).

<sup>957</sup> The Health Protection Agency Act was approved on 22<sup>nd</sup> July 2004.

<sup>958</sup> See *C.B.R.N. Incidents: Clinical Management and Health Protection* (at [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1194947377166](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947377166), last visited 28<sup>th</sup> January 2013). See also *C.B.R.N. incidents: clinical management & health protection Biological incident action guide*, at ([http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1194947377166](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947377166), last visited 28<sup>th</sup> January 2013). About vaccination against smallpox, see [http://www.dh.gov.uk/dr\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4083964.pdf](http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4083964.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>959</sup> See also now the Health Protection (Notification) Regulations 2010.

has or is suspected to have a listed disease, and the regulations extend to measures to be taken when dealing with people who have died from such diseases<sup>960</sup>.

### 2.5. In Italy.

In Italy, specific norms are not in place with regards to bioterrorism attack, except the Law that ratifies the B.W.C.<sup>961</sup>. There are only references to terrorism (such as in the Law n. 438/2001 and Law n. 155/2005, coming from the Law Decree n. 144/2005 and giving application to the Council Framework Decision 2002/475/JHA on combating terrorism) and single pieces of legislation and administrative acts dealing with the issue.

With regards to the criminal area, it should be noted that new norms are provided in Criminal Code about the possession and misuse of biological agents, and it is aimed at prosecuting those who give instructions about the preparation and utilization of dangerous chemical or bacteriological substances (art. 270 *quinquies*, Criminal Code).

With reference to the handling and use of dual use materials, a general system of authorization is chosen<sup>962</sup>: the control of the import, export and transit is left upon the Ministry of Productive Activities (Department for the Internationalization). A Decree of Ministry for Productive Activities (4<sup>th</sup> August 2003) has classified and listed the kind of dual use products exportable and the State to which the export is allowed, through a general national authorization.

Furthermore, the National Committee for Biosafety, Biotechnology and Life Sciences has been created and, within it, a Working Group for Biosafety and Bioterrorism, which has the purpose of enacting a “*Code of conduct for the dual use products*”<sup>963</sup>. Such Code has been released in 2010, and it recommends that (1) a

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<sup>960</sup> See A. MCCORMICK, *The Notification of Infectious Diseases in England and Wales*, Communicable Diseases Report, 3, 2, R19-R25, at [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1205310733613](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1205310733613) (last visited 28<sup>th</sup> January 2013).

<sup>961</sup> See Law 618/1974 that ratifies B.W.C..

<sup>962</sup> See Law 185/1990, as integrated by the Legislative Decree 96/2003.

<sup>963</sup> COMITATO NAZIONALE PER LA BIOSICUREZZA, LE BIOTECNOLOGIE E LE SCIENZE DELLA VITA, *Codice di Condotta per la Biosicurezza*, 15<sup>th</sup> June 2010, at 286



culture of responsibility and awareness should be developed among scientists about the risks connected with their research, (2) laboratories of high risk should be monitored and controlled, (3) the Ministry of Health and Agriculture should authorize detention and importation of agents, (4) programmes of formation and education of scientists should be pursued, and (5) participation at international networks for biosecurity is essential.

The control of laboratories has a central importance, in order to ensure the safety of research. laboratories that respect the “Labs Good Practice” will receive a certificate of conformity by the Ministry of Health<sup>964</sup>. Moreover, a system of control and inspection of those centres has been shaped<sup>965</sup>. In each centre the level of risk should be determined (from 1 to 4) and, on the basis of it, the type of containment is taken.

Specific norms related to food protection<sup>966</sup>, water protection<sup>967</sup>, environmental protection<sup>968</sup>, all establishing systems of traceability, control and compliance.

With reference to response measures, in 2001 a set of guidelines as “*Emergency National Plan against biological, chemical and radiological terrorist attacks*” has been drafted by Ministry of Health and Ministry of Inner Affairs. In the light of a bioterrorist attack, a Crisis Unity should intervene, along with some Centres for Counselling and Support in all national territory. Regional and local entities should be involved as well. For the Rapid Alert System, a Police Unity for Health Protection (within the police body of “Carabinieri”) has been chosen as the National Contact Point. Military Specialized forces must intervene in case of attack and work in collaboration with civilian Authorities. Then, police, civilian authorities

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[http://www.governo.it/biotecnologie/documenti/Codici\\_condotta\\_biosicurezza.pdf](http://www.governo.it/biotecnologie/documenti/Codici_condotta_biosicurezza.pdf) (last visited 28th January 2013).

<sup>964</sup> See Decree 4<sup>th</sup> July 1997 and Legislative Decree n. 206/2001. About dangerous substances and how to treat them in labs, see Legislative Decree n. 81/2008.

<sup>965</sup> See Legislative Decree n. 50/2007.

<sup>966</sup> In line with the E.U. Directives 2004/1/CE, 2004/13/CE and 2004/19/CE, a system of notification, traceability and labelling of food (with the role of the Ministry of Health and Local Sanitary Agencies for the compliance) has been articulated.

<sup>967</sup> See Document of the National Institute of Health, Rapporti ISTISAN, 05/4, 2005, on Safety of water system.

<sup>968</sup> The National Institute of Health (Istituto Nazionale di Sanità) has the function of evaluating the risk for human health and the environment, indicating measures to take for the management and reduction of risks and also controlling and inspecting the respect of them.

and health bodies are involved in response to bioterrorism, and they are coordinated and supported by the National Centre for Diseases Prevention and Control<sup>969</sup>.

Moreover, according to the “*National Defence Program - Health Sector*”, measures of risk contention are presented. Two Centres have to deal with clinic management of the crisis and for coordination of measures: the “Spallanzani” Hospital in Rome and the “Sacco” Hospital in Milan, while the Institute of Health must deal with the assessment of the prophylactic therapeutic measures and the rapid identification of the relevant biological agents.

### 3. A Constitutional Frame for Dealing with Biosecurity and Bioterrorism.

It has been demonstrated thus far that various nations have, at different levels, put in place some regulations against bioterrorism. The aforementioned legal rules pertain to the following fields<sup>970</sup>:

(1) Criminal law: bioterrorism as a crime and the formulation of sanctions against bioterrorists for possession, manufacture, or distribution of bioweapons; the “goods” that are protected by this type of norms are physical integrity, life, health, public security, constitutional (national and international) order and economic goods as well<sup>971</sup>;

(2) Public health (and medical) law: norms for preparedness in case of bioterrorist act and response, addressed to public health community such as hospitals, laboratory network, medical doctors, health professionals, forensic scientists (norms concerning data collection, control of people, such as for quarantines, and control of property, such as for decontamination of facilities);

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<sup>969</sup> See Law n. 138/2004 (for the National Centre for Diseases Prevention and Control, see <http://www.ccm-network.it>).

<sup>970</sup> See D.P. FIDLER, *Legal Issues Surrounding Public Health Emergencies*, in *Public Health Reports*, 2, 116, 2001, p. 79-86.

<sup>971</sup> For instance, Spanish criminal code is very meaningful in this regard, presenting, beyond crimes about genetic sphere, specific crimes against the production of biological weapons through genetic engineering (see art. 160.1 which refers only to biological elements that have genetically manipulated material, and are used as bioweapons). See also art. 566 and 567 about fabrication, commercialization and traffic of biological and chemical weapons. For further details, see J.L. DE LA CUESTA ARZAMENDI, *Armas biológicas o exterminadoras e ingeniería genética: perspectiva juridico-penal*, in C.M. ROMEO CASABONA (ED.), *Genética e Derecho Penal. Previsiones en el Código Penal Español de 1995*, Granada, 2001, p. 239-265.

(3) Emergency management law: norms for preparedness and response to emergency situations;

(4) National security law: rules for law enforcement communities, such as police, customs agents, governments, and so on, with regards to the controlling of transfer and movements of dangerous biological agents and toxins, the prevention and the response to bioterrorist attacks.

In order to evaluate the regulatory landscape of bioterrorism and, in particular, its applicability to synthetic biology and risks to biosecurity, it is necessary to consider the constitutional frame that should be taken into account by any regulation. For developing a proper set of rules, I support the idea that the Constitutions (meant, in a broad sense, as all the bills of fundamental rights that are settled at the highest level of the hierarchy of sources of law, or as the set of human rights that are part of the constitutional – even non written- tradition) ought to be at the basis of any other regulation, from the statutory level up to the level of the codes of conduct.

### *3.1. The Right to Security and its Relationship with Other Rights and Freedoms: Proportionality and Reasonableness.*

When discussing about bioterrorism and biosecurity, the question lies in the type of rights that needed to be considered and the method in which to shape a constitutional frame to address them.

Fundamentally, the regulation against bioterrorism aims to protect human health of populations (in the form of life and integrity of single individuals belonging to the community), to the point that it could be rational to conceive the existence of a “right to security”<sup>972</sup>, which entails that all these aspects of public health are to be safeguarded. In this area, it is evident that the right to security acquires a legal status

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<sup>972</sup> It is worth mentioning that after Hobbes’s works the notion of security and the State’s role of ensuring it had a meaningful value. In the French Declaration of the Rights of Men and Citizen (1789), the right to security was mentioned as a natural and inalienable right, together with freedom, property and resistance to oppression (art. 2). For these aspects, see T. FROSINI, *Il diritto costituzionale alla sicurezza*, in T. FROSINI (ED.), *Teoremi e problemi di diritto costituzionale*, Milano, 2008, p. 495 ff.

that is «*in part autonomous – as a right to a protected existence, indispensable for the enjoyment of other rights vested into the subject – and in part indirect, in the sense that it is complementary to other rights, i.e. as a need rooted in the notion of quality and wellbeing of individual and collective life. Therefore, security can be qualified as a good intrinsically linked to life, physical integrity, well being, quality of existence and dignity of person. From this, it comes out that it can be recognised as a right vested upon the State, in the form of interest to guarantee a situation of social peace, and as a right vested upon each individual as a right to a protected existence, indispensable for enjoying other rights [...]*»<sup>973</sup>.

So, in deciding how to regulate bioterrorism, public health and security needs are central in both the prevention and response phases, but the very core issue is whether such rights to health and security should prevail over other rights and the need to “suspend” them for security reasons. Indeed, in the light of a bioterrorist attack, the tendency to make security overcome any other rights is strong. The relationship between security and other rights in “normal” conditions would be one of “cohabitation” among the rights. Here, security would have to promote other rights and be at the basis of the enjoyment of them or at least be complementary to them. In “emergency” conditions, instead, like the one of bioterrorism, such a relationship risks becoming one in which only security survives and other rights are suppressed.

For instance, the imposition of vaccines and quarantine for bioterrorism prevention risks to suppress the individual right to refusal of treatments. The manner in which to manage to relate public health needs and individual right to health (whose protection entails self-determination and the right to refusal of treatments)

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<sup>973</sup> T. FROSINI, *work cit.*, p. 1. Such right is mentioned in Latin American Constitutions and in some European ones, such as Finnish, Spanish, Swiss, Portuguese ones, where the right to security is linked to freedom. Symptomatic is also E.C.H.R., art. 5, stating the same connection between freedom and security. Moreover, the reference to the right to security can be found in some judicial decisions, such as the decision n. 15/1982 of the Italian Constitutional Court, and the decisions of the U.S. Supreme Court in the case of *Korematsu v. United States* (323 U.S. 214 (1944)) where the Executive Order 9066, which ordered Japanese Americans into internment camps during World War II regardless of citizenship, was considered constitutional for security reasons; case of *Hirabayashi v. United States* (320 U.S. 81 (1943)), together with the ruling in the case of *Yasui v. United States* (320 U.S. 115 (1943)), where the Court stated that the application of curfews against members of a minority group were constitutional when the nation was at war with the country from which that group originated.

must be dealt with, while keeping in mind that, as Jonathan Mann says, human rights and health are not conflicting goals are *«inextricably linked»*<sup>974</sup>.

Moreover, security reasons could be used to stifle the freedom of scientific research. Indeed, the freedom to investigate some issues that could provoke a malevolent use (even for bioterrorism, such as research about synthetic biology) could be suppressed in the name of protecting security.

So, in presence of the risks of bioterrorism, the trend would be for security to be the dominant value that justifies the “sacrifices” of other human rights and freedoms. In fact, *«there is reason to think that as a general matter in times of crisis, we will overestimate our security needs and discount the value of liberty»*<sup>975</sup>. This view, though, would alter the set of human rights and, in my opinion, as affirmed by more authoritative authors<sup>976</sup>, even in emergency situations, human rights cannot be suppressed. Eventual limitations of rights could be admitted because of security, but not up to the point of “deleting” some rights and, however, on the basis of some rules. The principle of proportionality and of reasonableness seem the most suitable ones to be recalled here. They should be used for drawing the balance between security and other rights, such as the individual right to health and the freedom of scientific research that are at stake in cases of bioterrorism. The principle of proportionality allows a limitation of rights for temporary periods, for necessity reasons, and using the least restrictive means for doing it. In this way, the “core nucleus” of rights is never suppressed and its limitations are established in a way that is proportionate to the aim to be pursued (i.e., protecting security). The reasonableness, then, must guide the balance between purposes and means, tools, time, methods to adopt<sup>977</sup>.

In doing so, security cannot become an instrument for legitimising public powers to suppress any right. Instead, it should be meant as a right that is not merely limited to integrity (as a right to *habeas corpus*) but as a pre-condition of other rights

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<sup>974</sup> J. MANN ET AL., *Health and Human Rights. A reader*, New York, 1999, quoted by G.J. ANNAS, *Bioterrorism, Public Health and Human Rights*, in *Health Affairs*, 21, 6, p. 94-97.

<sup>975</sup> D. COLE, *Enemy Aliens*, in *Stanford Law Review*, 54, 2002, p. 953-955.

<sup>976</sup> See, among the many, P. BONETTI, *Terrorismo, emergenza e costituzioni democratiche*, Bologna, 2006, p. 79 ff; V. BALDINI (ED.), *Sicurezza e stato di diritto: problematiche costituzionali*, Cassino, 2005.

<sup>977</sup> About proportionality and reasonableness, see R. BIN, *Diritti e argomenti. Il bilanciamento degli interessi nella giurisprudenza costituzionale*, Milano, 1992; F. MODUGNO, *I «nuovi diritti» nella giurisprudenza costituzionale*, Torino, 1995.

or a complementary one, which must proceed together with others. Even in conditions of emergency it can never annul other rights, but only limit them for short periods of time in a proportioned and balanced manner<sup>978</sup>. As Ridola says, the growing needs of security, in relationship to new technologies as well, must find «*orienting lines in the constitutional frame*»<sup>979</sup>. «*Rather than being competing goals, human rights and national security are in fact complementary*»<sup>980</sup>.

### 3.2. *The Balance between Security and the Individual Right to Health.*

In a concrete sense, the balance between security/public health and the individual right to refusal of treatments (included vaccines for contagious diseases determined by biological agents) ought to be done in such a way to «*permit public health officials to quarantine individuals who have a serious communicable disease who either cannot or will not accept treatment for it or agree to stay in their home, and who threaten to infect others with it [...]. Even then, however, we require public officials to use the “least restrictive alternative” and resort to quarantine only after other interventions, such as directly observed therapy, have failed*»<sup>981</sup>. In this way, individual consent to treatments should always be asked in principle, but when compulsory treatments are required, they should follow the principle of proportionality, so that the absence of asking consent can be imposed only in a state of necessity and emergency, to people that are really dangerous (i.e., pose a significant risk of transmission of disease), for a temporary time and provided that it

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<sup>978</sup> About the balance of security right with others, see M. RUOTOLO, *La sicurezza nel gioco del bilanciamento*, text of the paper presented at the Conference «I diversi volti della sicurezza», Università degli Studi di Milano – Bicocca, 4<sup>th</sup> June 2009. See also, A. BARAK, *Lectio magistralis. I diritti umani in tempi di terrorismo. Il punto di vista del giudice*, in S. MOCCIA (ED.), *I diritti fondamentali della persona alla prova dell'emergenza*, Atti del Convegno tenutosi presso l'Università di Roma “La Sapienza”, 6<sup>th</sup> December 2007, Napoli, 2009, p. 39 ff.

<sup>979</sup> P. RIDOLA, *Libertà e diritti nello sviluppo storico del costituzionalismo*, in P. RIDOLA, R. NANIA (EDS.), *I diritti costituzionali*, Torino, 2006, vol. I, p. 143.

<sup>980</sup> W.W. BURKE-WHITE, *Human Rights and National Security: The Strategic Correlation*, in *Harvard Human Rights Journal*, 17, 2004, p. 249-280, here p. 254.

<sup>981</sup> G.J. ANNAS, *Legal Aspects of Bioterrorism*, in S. SANDY SANBAR (ED.), *Legal Medicine*, Philadelphia, 2007, p. 684.

is shaped as the least restrictive possibility<sup>982</sup>. Moreover, they should never trump the respect of human dignity, as stated in the Italian Constitution.

In the situation of bioterrorism, therefore, public health powers should be exercised without suppressing civil liberties, and the principle of proportionality is very apt for indicating how to balance the different rights at stake.

### *3.3. Security and the Freedom of Scientific Research: Censorship or Publication?, and Other Means for a Balance.*

Looking at the relationship between public health/security and the freedom of scientific research, in this case the principle of proportionality and reasonableness should be adopted as well.

Scientific research and discoveries could have harmful effects, because they could be used for bioterrorist purposes. Therefore, the need to find how and where to draw the line among admitted research must be fixed. As previously mentioned, theoretically the research as such cannot be limited, but the spread of it (so, the issue of communication and publication of the results of research) should be confronted with security needs. In the case of bioterrorism, however, the distinction between research and its products is not so clear because even a “mere” discovery could be interesting for a bioterrorist<sup>983</sup>. This touches the core of “dual use dilemma”. Indeed, considering that science could be used for malevolent or benevolent purposes, the question now lies in the method to control its diffusion. Is there a need to apply censorship or open access, in the light that the same discoveries that could generate bioweapons could also produce drugs and medicines?

For instance, in the case of the accidental production of a superstrain of mousepox by Australian scientists, they decided to publish their research in the

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<sup>982</sup> See L.O. GOSTIN, *Public Health Law: Power, Duty, Restraint*, Berkeley, 2000, p. 213-216. See also J.G. HODGE, *Bioterrorism Law and Policy: Critical Choices in Public Health*, in *The Journal of Law, Medicine & Ethics*, 30, 2002, p. 254-261.

<sup>983</sup> See E. RINDSKOPF PARKER, L. GIELOW JACOBS, *Government Controls of Information and Scientific Inquiry*, in *Biosecurity And Bioterrorism: Biodefense Strategy, Practice, And Science*, 1, 2, 2003, p. 92.

*Journal of Virology*<sup>984</sup> and later in the *U.S. New Scientist*<sup>985</sup> reported the same experiment. This was just one case that gave rise to the issue of the regulation of scientific research in comparison to security needs. The same happened with the publication of polio virus strain and 1918 influenza virus strain, and more recently with the case of the possible publication of 5 variations to the virus of influenza H5N1, that have been produced at the Erasmus Medical Center in Rotterdam, and with analogous research conducted by Yoshihiro Kawaoka at the University of Wisconsin<sup>986</sup>.

According to one position, the publication could be useful in order to make the people know of the existence of bioweapons and their risks, and in order to prepare an adequate response to bioterrorism. In this view, censorship would limit research and would represent an infringement to the freedom of research<sup>987</sup>. On others' perspective, censorship would be a better option, as the spread of such "sensitive" information that could be misused by malevolent people is a danger in itself<sup>988</sup>.

As Selgelid states, «*scientific openness and the progress of medicine matter, but security matters, too. There is no reason to give absolute priority to the former*

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<sup>984</sup> R.J. JACKSON, A.J. RAMSAY, C.D. CHRISTENSEN, ET AL., *Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox*, in *Journal of Virology*, 75, 3, 2001, p. 1205-1210.

<sup>985</sup> D. MACKENZIE, *U.S. Develops Lethal New Viruses*, in *New Scientist Online News*, 29<sup>th</sup> October 2003, at <http://www.newscientist.com/hottopics/bioterrorism/bioterrorism.jsp?id=ns99994318> (last visited 28<sup>th</sup> January 2013).

<sup>986</sup> In 2001 at the annual conference of the *European Scientific Working Group on Influenza*, one scientist from the Erasmus Medical Center of Rotterdam, Ron Fouchier, announced to have been capable of modifying the genetic code of virus H5N1, and thus obtaining a very dangerous virus. Analogous research was being done in the University of Wisconsin. The two studies about H5N1 should have had to be published in *Science* and *Nature*, but the U.S. National Science Advisory Board for Biosecurity (N.S.A.B.B.) intervened for blocking the publication. The National Institutes of Health stated that they needed to review the studies and asked the authors to select some of their results and methods (see at <http://www.nih.gov/news/health/dec2011/od-20.htm>, last visited 28<sup>th</sup> January 2013). Then, the authors opted for a suspension of the publication for 60 days and for an international forum to discuss about the issue. In the end, the N.S.A.B.B. approved the publication, provided that some guidelines were followed (see D. BUTLER, H. LEDFORD, *U.S. biosecurity board revises stance on mutant-flu studies. Decision comes one day after release of new guidelines for dual-use research*, in *Nature*, 30<sup>th</sup> March 2012). In may 2012, Yoshihiro Kawaoka published its study.

<sup>987</sup> See T. TREVAN, *Do not censor science in the name of biosecurity*, in *Nature*, 486, 295, 21<sup>st</sup> June 2012.

<sup>988</sup> About the history of censorship, see B. MARTIN, *Science: contemporary censorship*, in D. JONES (ED.), *Censorship: A World Encyclopedia*, vol. 4, London, 2001, p. 2167-2170.



over the latter; rather, a balance must be struck between the two»<sup>989</sup>, and such balance must be done, according to him, through an evaluation of potential (but tangible and not merely imagined) harms and (tangible) potential benefits. If the harms outweigh benefits, it would be better to opt for censorship. Otherwise, the open access could be admitted. Of course, such a position could be criticized in the sense that, in a context of an uncertainty about benefits and harms as the one of new technologies, it is difficult to imagine what the benevolent and malevolent effects of it could be, and so the cases for censorship and publication are vague and fuzzy to determine and it would leave the place to arbitrariness. Nevertheless, it seems to me that this solution is the most rational one and the most proper for respecting the proportionality and reasonableness principles. So, the restriction of freedom of research for security reasons should be shaped only after a balance between benefits and harms, in presence of real threats and when other alternatives do not occur for protecting security. Such position of “reasonable balance” between benefits and harms looks like a utilitarian one, from the ethical point of view, following a cost-benefits scheme, and it certainly is. However, it can cohabit with other views, as Miller and Selgelid explain. The balance to pursue can be framed in utilitarian terms, in deontological ones (balancing the right to free inquiry against rights to security and health), and according to virtue ethics as well<sup>990</sup>.

Such balance seems to be applied in the case of the research about the mutation of virus H5N1. Indeed, after the big debate about censorship or publication of the results of the study, the publication was admitted. Such an evaluation between benefits and risks led to prefer the spread of knowledge, in order to allow researchers to have access of data for realising methods for fighting against H5N1. However, a narrow censorship of some methods that were adopted for reaching the results was applied<sup>991</sup>.

Beyond the aspect of censorship or publication of research results, there are other ways to balance the freedom of research with the right to security, without hindering progress and studies and at the same time protecting public health. This

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<sup>989</sup> M.J. SELGELID, *A Tale of Two Studies. Ethics, Bioterrorism, and the Censorship of Science*, in *Hastings Center Report*, 37, 3, 2007, p. 40.

<sup>990</sup> M.J. SELGELID, S. MILLER, *Ethical and Philosophical Consideration of the Dual-use Dilemma in the Biological Sciences*, in *Sci Eng Ethics*, 13, 2007, p. 523–580.

<sup>991</sup> See EDITORIAL, *Publishing Risky Research*, in *Nature*, 485, 5, 3<sup>rd</sup> May 2012.

can be achieved through the establishment of controls to research, through a periodic assessment of how research is going on and of biosecurity measures, the screening of orders of biological materials by scientists or other people working in the area (such as DIY members), the control of access, transport, the export of “sensitive” materials (such as some virus strains), the registration and the licensing of facilities that work with pathogens, and the screening of laboratory personnel<sup>992</sup>.

#### *4. Analysis of the Regulation against Bioterrorism On the Basis of the Constitutional Frame and in its Applicability to Synthetic Biology.*

From the regulatory “landscape” individuated above at the international, European and national level, it follows that the constitutional frame that should be taken into account is, more or less, respected, even if some gaps remain.

All the mentioned regulations try to limit the spread by State and non State actors of organisms, genetic elements and toxins that have already been defined as hazardous, but there are no references or very little attention to the possibility of creating new genetic agents and biological weapons through synthetic biology. The definitions of biological agents, toxins and genetic elements are quite the same in the international, European and national legislature. As a result, a sort of harmonization and common standard has been reached.

However, the possibility of extending those regulations to synthetic biology is not so automatic. For instance, the B.W.C. refers to agents that are obtained by chemical synthesis, and in doing so, it seems to “cover” the developments of genetic modification and the creation of artificial life forms as well<sup>993</sup>, as the “*Additional Understanding of art. 1*” explains. The B.W.C., indeed, «*unequivocally covers all microbial or other biological agents or toxins, naturally or artificially created or altered, as well as their components, whatever their origin or method of production*». However, such a chemical synthesis must lead to the production of already controlled

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<sup>992</sup> See J.B. TUCKER, *Biosecurity: Limiting Terrorist Access to Deadly Pathogens*, United States Institute of Peace, Peaceworks n. 52, Washington, D.C., November 2003, p. 28 ff.

<sup>993</sup> A. KELLE, *Synthetic biology and biosecurity awareness in Europe*, Vienna, 2007, p. 5, at [http://www.synthetibiologysafe.eu/uploads///pdf/Synthetibiologysafe-Biosecurity\\_awareness\\_in\\_Europe\\_Kelle.pdf](http://www.synthetibiologysafe.eu/uploads///pdf/Synthetibiologysafe-Biosecurity_awareness_in_Europe_Kelle.pdf) (last visited 28<sup>th</sup> January 2013).

toxins and agents or, at least, to agents having a structure that is identical to, or similar to the one of known agents. So, only one type of synthetic biology seems to be included (the one of re-designing biological structures). It should be noted that it is not the one working with DNA sequences that code for novel organisms, toxins and pathogens. The same provisions are given by the Australia Group, whose rules cover genetically-modified organisms that contain nucleic acid sequences coding for the toxins in the list (not coding for new ones).

Other problematic “extensions” to synthetic biology could be individuated again in the B.W.C. provisions, where the Convention refers only to malevolent use of bioweapons by States, not mentioning non state actors, such as the “lone operators” or “biohackers” or bioterrorists not belonging to States. Such imprecision is problematic with regards to synthetic biology, which is becoming a field where private enterprises have a meaningful role and the States usually do not have enough measures for effective oversight of the progress of the area<sup>994</sup>.

Moreover, synthetic biology challenges the Convention, in the part in which B.W.C. focuses only to control of the materials, without quoting the control to the access to information and knowledge.

Then, the U.N. Resolution 1540/2004 does not contain any reference to materials obtained through DNA technologies and manipulation (genetic engineering), and so synthetic biology could not be, at present, regulated by it.

In the Council of Europe, the openness to changes determined by new technologies and by the development of biology and genetics is mentioned within biosecurity regulations, but it is a vague reference.

With regards to E.U. regulation, it can be observed that toxins are not covered by the routine epidemiological surveillance and the early warning and response system provided by the Decision 2119/98 (that deals only with communicable diseases). Moreover, some new agents could be introduced but they would not be covered by legislation. The model of preparedness and response is in line with the constitutional frame and with the suggested balance of rights. However, this model should be implemented with (a) a system of licensing for the possession of instruments used in biological research and a registry of people working within the

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<sup>994</sup> See, at this regard, Germany’s observation with regards to art. 4 at the 6<sup>th</sup> Conference (BWC/Conf.VI/WP.2, 2006).

biodefence usage of synthetic biology, (b) the definition of criteria for the publication of data on highly pathogenic viruses or toxic agents at Member State and E.U. level, and (c) the creation of a centralised database at least at E.U. level, or preferably at international level, where all DNA synthesisers would be registered by competent Authorities<sup>995</sup>. Moreover, the Database Directive<sup>996</sup> should be applied for regulating databases where sequences of DNA for synthesis are screened.

Looking at the U.S.A. model, it could be observed that the Export Administration Regulation and Select Agent Regulation contemplate the awareness that DNA could be modified for creating toxins or other hazardous biological agents or the hypothesis that GMOs contain genetic sequences carrying on pathogenic features. However, such regulations aim to control DNA sequences that are modified to be malevolent, provided they are similar to the already existing and controlled organisms and toxins. As highlighted in the previous sections, this entails that a lot of fields within synthetic biology are not covered by most of U.S. legislation. The only exception is the Patriot Act, which carries with it criminal and civil penalties for those who possess biological agents that cannot be justified for prophylactic, protective, or peaceful purpose, regardless of whether a biological sample is synthetic, occurs naturally, is infectious, or is a select agent.

It is clear that in the U.S. the attention to bioterrorism and biosecurity seems to be higher than in Europe and it certainly derives from the Anthrax attacks that made the U.S. very afraid of the risk. Yet, a certain negligence in respecting the balance between security and health seems to be present in M.S.E.H.P.A.. It has been defined as a “draconian law”, as criminal sanctions are provided for people who refuse to stay in quarantine. This is on the basis of a written directive by a public health official where a person can be quarantined before a hearing must be held. However, there is a certain vagueness about standards for quarantine, thus allowing for the arbitrary use of force and the permitting of public health authorities to quarantine anyone who refuses to be examined or treated, for whatever reason<sup>997</sup>. In these provisions, a proper balance between public health needs and individual right

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<sup>995</sup> See E.G.E., Opinion n. 25, cit., Recommendations n. 9, 10, 11, 12, 13, 14, 15.

<sup>996</sup> Directive 96/9/EC of 11<sup>th</sup> March 1996, on the legal protection of databases in *O.J. L 77/1996*.

<sup>997</sup> For this criticism, see G.J. ANNAS, *Bioterrorism, Public Health, And Civil Liberties*, in *New England Journal of Medicine*, 346, 17, 25<sup>th</sup> April 2002, p. 1337-1342.

to health (and refusal) would be absent. It is appropriate to note here that, as the Justice Robert Jackson (in the U.S. Supreme Court of Justice) said, that the fight against terrorism cannot be separated from human rights, and «*Constitution is not a suicide pact*»<sup>998</sup>.

In the U.K. a reference to the international lists of pathogens and biological agents is chosen, but there is an “open door” to the admissibility of synthetic agents as well. This is visible in the part of legislation where the Secretary of State is vested with the possibility to extend the list to include further pathogens or toxins if suspected of being used for bioterrorism.

In Italy, no references to synthetic biology are made, except in the “*Code of Conduct*” promulgated by the National Committee for Biosafety, Biotechnology and Life Sciences. In this Code, there is the recommendation to monitor the production of substances obtained by a synthetic organisms if they are not equivalent to the known ones, and to forbid research on synthetic organisms when they can be covered by prohibitions that are stated in B.W.C.. Moreover, the drafting of guidelines by journals about publication of results of research that could be “dual use” should be boosted.

In general, the measures of prevention, surveillance and response adopted both in the U.K. and in Italy appear to be compatible and in line with the constitutional balance, indicated above.

##### 5. *Different Proposals for the Governance of Biosecurity Risks of Synthetic Biology.*

After considering the regulatory framework that has been enacted so far for the management of bioterrorism, its compatibility with the constitutional balance of rights and its applicability to the new challenge represented by synthetic biology, it is necessary now to consider whether specific frameworks of governance of biosecurity risk for synthetic biology have been proposed, and what they are. Up till this point, I have tried to check the application of the existing legislative framework about bioterrorism to synthetic biology, keeping in mind that it was not born for addressing

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<sup>998</sup> See case *Terminiello v. Chicago*, 337 US 1 (1949) Jackson dissenting.

the risk generated by synthetic biology. In this section, the focus will be put on those proposals which are drafted precisely for synthetic biology.

### 5.1. *A Joint Statement by International Journal Publishers.*

One of the first initiatives about biosecurity risks of synthetic biology is represented by the “*Statement on Scientific Publication and Security*”, enacted in 2003 by international journal publishers (i.e., the American Society for Microbiology and the editors of *Science*, *Nature* and *Proceedings of the National Academy of Sciences of the U.S.A.*) warning that «*there are occasions that an editor may conclude that the potential harm of publication outweighs the potential societal benefits*»<sup>999</sup>, and in that case, the publication should be modified or not be published. The statement is a clear recognition of the fact that «*journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse*»<sup>1000</sup>. So, the dual-use feature of life science research urges scientists to be careful of abuses and misuses, and it calls for the journal editors to exercise responsibility, when confronted with research papers that could be “sensitive” from the biosecurity standpoint. However, it should be noted here that the methods in which to recognise such “sensitive research” remain to be determined.

### 5.2. *The U.S. National Research Council and National Science Advisory Board for Biosecurity, and their Recommendations.*

In 2003, the National Research Council which is not a government body, but can give recommendations to the Government, formed a Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology. The committee enacted a report entitled “*Biotechnology Research in an Age of*

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<sup>999</sup> R.M. ATLAS ET AL., *Statement on scientific publication and security*, in *Science*, 299, 5610, 2003, p. 1149.

<sup>1000</sup> Ibid.

*Terrorism*”, commonly called the “*Fink Report*” after the committee chairman, Dr. Gerald Fink<sup>1001</sup>.

The report outlines the steps that the U.S. government should take to prevent the misappropriation of legitimate biotechnologies by terrorists. However, it should be noted that it does not mention synthetic biology *per se*, but the reference to the development of biotechnology and the possibility of using it in a malevolent way allow for the interpretation that the recommendations can be referred to synthetic biology as well. In the report there are relevant recommendations for educating the scientific community about risks of “dual use”, the need of employing local institutional biosafety committees and of creating a new entity, namely the National Science Advisory Board for Biosecurity (N.S.A.B.B.). The report further recommends that the scientific community continues to adopt a self-governance model for scientific publications and to look for a better means of communication between law enforcement and the scientific community. It also suggests the necessity for a set of codes of conduct for scientists. It underlines seven experiments of concern: (1) the demonstration how to render a vaccine ineffective, (2) the confer of resistance to antibiotics or antiviral agent, (3) the enhancement of the virulence of a pathogen, (4) the increase of transmissibility of a pathogen, (5) the alteration of a pathogen’s host range, (6) the enablement of evasion of diagnostic tools, and (7) the weaponization of a biological agent. The Committee also intervenes in the discussion about whether or not to publish some of the experiments that could entail potential misuse, and it urges for the prevention of «*the destructive application of biotechnology research while still enabling legitimate research to be conducted*».

After the Fink Committee, the U.S. National Academy of Sciences set up the Committee on Advances in Technology and the Prevention of their Application to Next Generation Bioterrorism and Biological Warfare Threats, the so-called “Lemon-Relman Committee”, named after its two co-chairmen<sup>1002</sup>. This Committee broadened the work of the “Fink Committee” in several directions, in particular

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<sup>1001</sup> NATIONAL RESEARCH COUNCIL, *Biotechnology Research in an Age of Terrorism*, Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, Washington, D.C., 2004.

<sup>1002</sup> U.S. NATIONAL RESEARCH COUNCIL, *Globalization, Biosecurity, and the Future of the Life Sciences*, Committee on Advances in Technology and the Prevention of Their Application to Next Generation Biowarfare Threats, Washington, D.C., 2006.

putting the focus globally, and specifically referring to synthetic biology as a new source of threat for biosecurity.

Then, the N.S.A.B.B. was established within the N.I.H. in 2004 in response to the “*Fink Report*”. It is composed of scientists and national security experts, governmental and non, with the role of advising institutional biosafety committees and recommending specific strategies for the oversight of potential dual-use biological research, while taking into consideration both the national security concerns and the needs of the research community. More specifically, the N.S.A.B.B. is meant to advise on (1) the strategies for local and federal biosecurity oversight towards life sciences research, (2) the development of guidelines for biosecurity oversight, (3) strategies to work with journal editors and other stakeholders to ensure the development of guidelines for the publication, public presentation, and public communication of potentially sensitive life sciences research, and (4) the development of guidelines for mandatory programs for education and training in biosecurity issues. The N.S.A.B.B. usually indicates the scientists as the only judges for identifying the “sensitive research” of colleagues and for addressing conduct issues.

Since 2006, one specific group is formed within N.S.A.B.B. that focuses specifically on synthetic biology, and it has enacted a report on biosecurity implications of *de novo* synthesis of select agents (2006), recommending: «(1) a specific definition of which sequences are covered by the Select Agents Registry, (2) a formal and consistent process for comparing synthesis orders to the registry by using software, and (3) the maintenance of records of orders for five years»<sup>1003</sup>.

In 2009 the National Security Council has published the “*National Strategy for Countering Biological Threats*”<sup>1004</sup>, taking into account the evolution of synthetic biology and calling for government action in addressing new threats and responsible conduct, but without referring to specific federal actions.

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<sup>1003</sup> N.S.A.B.B., *Addressing Biosecurity Concerns Related to the Synthesis of Select Agents*, Washington, D.C., 2006, at <http://oba.od.nih.gov/biosecurity/pdf/FinalNSABBBReportonSyntheticGenomics.pdf> (last visited 28<sup>th</sup> January 2013). See p. 10-13.

<sup>1004</sup> N.S.A.B.B., *National Strategy for Countering Biological Threats*, Washington, D.C., 2009, at [http://www.whitehouse.gov/sites/default/files/National\\_Strategy\\_for\\_Countering\\_BioThreats.pdf](http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf) (last visited 28<sup>th</sup> January 2013).



### 5.3. *Inter Academy Panel Statement on Biosecurity.*

The Inter Academy Panel (I.A.P.) on International Issues, a worldwide network of scientific academies, drew up the “*I.A.P. Statement on Biosecurity*” at the end of 2005<sup>1005</sup>. This statement provides the guidelines for the compilation of codes of conduct. Four principles are crucial: (1) awareness (i.e., making researchers aware of biosecurity risks in life sciences and new technologies), (2) Safety and Security (the necessity of indicating safety and security requirements for research activities), (3) Education and Information (to scientists), and (4) Accountability and Oversight (that is, researchers should signal abuses and supervise activities).

From I.A.P. Statement, the International Union of Microbiological Societies (I.U.M.S.) and the International Union of Biochemistry and Molecular Biology (I.U.B.M.B.), respectively in 2005 and 2006, adopted their codes of conduct accordingly<sup>1006</sup>.

### 5.4. *The Goldman School of Public Policy’s Proposal and the Declaration of Civil Organizations at the Second International Meeting on Synthetic Biology (SB 2.0).*

During the Second Conference about synthetic biology (2.0), taken at Berkeley in 2006, a White Paper written by Stephen Maurer et al. from the Goldman School of Public Policy (California) began to circulate<sup>1007</sup>. It insisted that (1) commercial gene synthesis companies adopted the best-practice screening methods, (2) a list of software tools was drafted, (3) “experiments of concern” could obtain independent expert advice before proceeding, (4) members had an ethical obligation to report dangerous behaviours, (5) a clearinghouse for helping community to

<sup>1005</sup> INTER ACADEMY PANEL ON INTERNATIONAL ISSUES, *IAP statement on Biosecurity*, 7<sup>th</sup> November 2005, Trieste, at [http://www.nationalacademies.org/morenews/includes/IAP\\_Biosecurity.pdf](http://www.nationalacademies.org/morenews/includes/IAP_Biosecurity.pdf) (last visited 28<sup>th</sup> January 2013).

<sup>1006</sup> I.U.M.S. *Code of Ethics against Misuse of Scientific Knowledge, Research and Resources*, Presented at the I.U.M.S. General Assembly on 28<sup>th</sup> April 2006. I.U.B.M.B., *Code of ethics of the International Union of Biochemistry and molecular biology*, in *Biochemistry and Molecular Biology Education*, 34, 3, May 2006, p. 167.

<sup>1007</sup> S.M. MAURER, K.V. LUCAS, S. TERRELL, *From Understanding to Action: Community-Based Options for Improving Safety and Security in Synthetic Biology*, Goldman School of Public Policy, University of California at Berkeley, April 2006.

identify and respond to the biosafety/biosecurity implications was created, and (6) investments in biosafety and biosecurity measures should be taken. The document placed a lot of emphasis on the governance options for synthetic biology, that could be implemented through community self-governance without outside intervention.

Against this position, some civil organizations (E.T.C., for example) drafted a Declaration<sup>1008</sup>, asking for a stricter governance, that did not allow the scientific community to govern by itself. In particular, the Declaration focuses on DNA synthesis that could give rise to safety or security concerns, and suggests the improvement of existing software tools for screening DNA sequences.

### 5.5. “*Synthetic Genomics: Options for Governance*”.

The report “*Synthetic Genomics: Options for Governance*” by Garfinkel et al. (2007)<sup>1009</sup> deals with biosecurity risks in a specific area of synthetic biology, i.e., the one combining methods for the chemical synthesis of DNA with computational techniques for its design.

The report has three targets: (a) gene synthesis firms, oligonucleotide manufacturers and DNA synthesizers, (b) owners of a laboratory that synthesise DNA, and (c) users or consumers of synthetic DNA and the institutions that support or oversee their work. The policy options that must be enacted in order to prevent incidents of bioterrorism consist of, for the first category of addressees, the screening and checking orders of synthetic DNA, then their certificating through a biosecurity responsible officer, and finally the proper storage of the records. Then, the owners of the DNA synthesizers must register their machines and be licensed. Finally, the legitimate users should incorporate education about the risks and the best practices as part of university curricula, follow biosafety manual and best practices in labs, increase responsibilities and oversight of Institutional Biosafety Committees. The authors of this report implicitly affirm the need for further regulation of the field.

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<sup>1008</sup> See footnote 438.

<sup>1009</sup> M.S. GARFINKEL, D. ENDY, G.L. EPSTEIN, R.M. FRIEDMAN, *op. cit.*

5.6. *The Initiative of the International Consortium for Polynucleotide Synthesis (I.C.P.S.).*

The International Consortium for Polynucleotide Synthesis (I.C.P.S.) has proposed a DNA synthesis order screening process (2007), suggesting that «individuals who place orders for DNA synthesis would be required to identify themselves, their home organisation and all relevant biosafety information. Next, individual companies would use validated software tools to check synthesis orders against a set of select agents or sequences to help ensure regulatory compliance and flag synthesis orders for further review. Finally, DNA synthesis and synthetic biology companies would work together through the I.C.P.S., and interface with appropriate government agencies (worldwide), to rapidly and continually improve the underlying technologies used to screen orders and identify potentially dangerous sequences, as well as develop a clearly defined process to report behaviour that falls outside of agreed-upon guidelines»<sup>1010</sup>.

5.7. *The Proposals of the International Association of Synthetic Biology (I.A.S.B.) and the International Gene Synthesis Consortium (I.G.S.C.).*

The I.A.S.B., the first international organization to actively support a safe and sustainable synthetic biology, founded in 2008 by 6 German small gene synthesis providers but open to all companies, pushes for the development of guidelines, codes of conduct and best screening practices for scientific community. In its report “*Technical Solutions for biosecurity in synthetic biology*” (2008) about the First Meeting of the I.A.S.B., the importance of reaching these aims has been underlined:

(1) Harmonization of screening strategies for DNA synthesis orders, realising a forum to discuss shortcomings and to share technical resources;

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<sup>1010</sup> H. BÜGL, J.P. DANNER, R.J. MOLINARI, J.T. MULLIGAN, H.-O. PARK, B. REICHERT, D.A. ROTH, R. WAGNER, B. BUDOWLE, R. SCRIPP, J. A.L. SMITH, S.J. STEELE, G. CHURCH, D. ENDY, *DNA Synthesis and Biological Security*, in *Nature Biotechnology*, 25, 6, 2007, p. 627.

(2) Creation of a central virulence factor database, i.e., a web-based, publicly accessible database containing the annotated genomes of selected viruses, bacteria, pathogens;

(3) Publication of an article on the status quo of synthetic biology;

(4) Establishment of a technical biosecurity working group with members from the I.A.S.B. and the I.C.P.S., in order to discuss improvements and next steps for biosecurity measures, and

(5) Commitment to security screening: each member, that already screens incoming gene orders for potential biosecurity risks and customers, should advertise these practices<sup>1011</sup>.

At the 2009 Second Meeting, a “*Code of Conduct and Best Practices*” has been drafted<sup>1012</sup>, which stresses the importance of (a) public discussion, (b) distribution, (c) a review of the Code, (d) the necessity of screening all gene synthesis orders and the customers for ensuring the legitimacy of the order, (e) keeping the records (the positive and suspected ones are stored for 8 years), (f) avoiding the delivery to private addresses, (g) cooperating with authorities and the community, and (h) informing about orders indicating illegal procurement activities. When a potential pathogen is identified by a software, the order is reviewed by an expert and it can be accepted, or rejected. Potential customers are screened against available lists provided by state authorities. This Code is considered as binding to its I.A.S.B. signatories, but is also a guideline for non I.A.S.B. companies.

Similar ideas are shared by the International Gene Synthesis Consortium (I.G.S.C.), that is not open to all companies, but restricts membership to companies with more significant market shares. After the drafting of the “*Code of Conduct*” by the I.A.S.B., some companies proposed a less costly approach. In particular, DNA 2.0 and Geneart, both members of the I.G.S.C., proposed lower requirements for sequence screening, and placing the emphasis on fast and cheap computerized checks against a predefined list of threats. Thus, I.G.S.C. has enacted “*Harmonized*

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<sup>1011</sup> INTERNATIONAL ASSOCIATION SYNTHETIC BIOLOGY, Report on the Workshop “Technical Solutions for Biosecurity in Synthetic Biology”, 2008, <http://www.ia-sb.eu> (last visited 28<sup>th</sup> January 2013), p. 16.

<sup>1012</sup> INTERNATIONAL ASSOCIATION SYNTHETIC BIOLOGY, *Code of conduct for best practices in gene synthesis*, 2009, at <http://tinyurl.com/asbcode/> (last visited 28<sup>th</sup> January 2013).

*Screening Protocol*”<sup>1013</sup>, that opts for automated screening as a filter to identify pathogen and toxin DNA sequences.

Both the I.A.S.B. and the I.G.S.C. codes involve an automated step, in which the genes in a customer’s order are compared against those from organisms on lists such as the U.S. Centre for Disease Control and Prevention’s “select agents” list. Although the I.A.S.B. standards specify that a human expert will follow up on possible “hits” identified in the automated screening step, the DNA 2.0/Genart code ends with the automated screening step. Only when there is any suspicion of potential threat in the ordered sequence or in the customer’s identity, should the I.G.S.C. companies report the request to authorities. This system is simpler and less costly because it creates a list of genes and a threshold, under which orders are considered as dangerous and thus refused. The system, however, «*worries some observers, because it is difficult to translate the list of select-agent organisms into lists of dangerous genes*»<sup>1014</sup> and because the element of human screening is completely absent.

#### 5.8. *The U.S. Department of Health and Human Services and the Voluntary Screening Guidelines for Providers of Synthetic DNA.*

In 2010, the U.S. D.H.H.S. released the “*Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*”<sup>1015</sup>. It refers to synthetic products, so that the order of them could be in line with S.A.R. and E.A.R.. The compliance with the Guidance is not compulsory but voluntary. The Guidance suggests that all double-stranded DNA orders are screened (“sequence screening”) against GenBank, the National Institutes of Health (N.I.H.) genetic sequence database, which is an annotated collection of all publicly available DNA sequences. When receiving an

<sup>1013</sup> See at <http://www.genesynthesisconsortium.org/wp-content/uploads/2012/02/IGSC-Harmonized-Screening-Protocol1.pdf> (last visited 28th January 2013).

<sup>1014</sup> E. CHECK HAYDEN, *Keeping genres out of terrorists’ hands*, in *Nature*, 27<sup>th</sup> July 2009.

<sup>1015</sup> See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*, 13<sup>th</sup> October 2010, at <http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndnaguidance.pdf> (last visited 28<sup>th</sup> January 2013). For a commentary, see G. KWIK GRONVALL, *HHS Guidance on Synthetic DNA Is the Right Step*, in *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 8, 4, 2010, p. 373-376.

order for synthetic double-stranded DNA, providers perform also a “customer screening” (checking the identity and affiliation of the customer). If the customer is a suspected one (as indicated in lists of people forbidden of access) or the agent is a select one, a “follow-up screening” must be pursued, by controlling the certificates and asking for the purposes of the usage of the agent. If the “follow-up screening” does not resolve the concerns about the order, the U.S. Government or the F.B.I. or the C.D.C. should be contacted for further assistance.

These Guidelines are voluntary, but they are meaningful, because they represent the first set of specific rules issued by a government with regards to synthetic biology, and they take into account the role of industries and scientific community as well. Thus, this guidance is a mix of government and self-regulation model of governance.

*6. Suggestion of a New Model: a “Prudent Vigilance” Approach for Managing Biosecurity Risks of Synthetic Biology.*

As it has been established thus far, different models of governance have been suggested with reference to the risks of biosecurity in the field of synthetic biology. Bringing to mind the model of “*prudent vigilance*” presented in the second chapter of this work, the aim of this section is to show how this model could concretely operate and represent a new approach for managing biosecurity risks<sup>1016</sup>.

In my opinion, a proper model for governing this type of risks of synthetic biology should be:

(1) from the point of view of its features: a model that consists of an ongoing and periodically revised assessment of biosecurity risks. It should be conducted with the involvement of all the stakeholders (governments, industries, scientific community, researchers, consumers, and so on) in a flexible way, so as to take into account all the scientific, economic, social, political, and ethical aspects involved

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<sup>1016</sup> About the evolution of the governance of biosecurity risks of synthetic biology, see the analysis developed by S.M. MAURER, *End of the Beginning or Beginning of the End? Synthetic Biology's Stalled Security Agenda and the Prospects for Restarting It*, in *Valparaiso University Law Review*, 45, 4, 2011, p. 73-132.

within biosecurity needs. The purpose must be to assume proportioned measures of governance, i.e., measures based on the principles of proportionality and reasonableness among rights, and thus finding a proper balance between rights and interests to protect, without sacrificing or suppressing any of them.

Kelle, in this instance, suggests an approach that «(a) includes all stakeholders in the development of synthetic biology as a discipline and its potential future applications, and (b) is flexible enough to accommodate a range of scenarios of how the field might develop»<sup>1017</sup>;

(2) from the point of view of actors that have to be engaged and sources of law to adopt: this model opts for a mixed model of “hard law” and “soft law”, that integrate reciprocally. The institutions are not the sole actors, but the scientific community, the stakeholders and general public are involved as well in an “engagement” approach;

(3) from the point of view of the enforcement, oversight and control of the policies that have been adopted: this model calls upon for the involvement of judges, government bodies, independent professional bodies, and multi-stakeholders’ bodies. These subjects should cooperate and integrate each other. The tools that could be used are case-law, administrative law, and an autonomous set of measures that are decided on the basis of “soft law”.

Applying these general characteristics of the “*prudent vigilance*” model to the specific case of biosecurity risks, it results that the governance should be reached through an involvement of all the stakeholders. This is established through the “top down” and “bottom up” sources of law, and a mixture of instruments for the enforcement and control. This means that, on the one hand, single laboratories and the whole scientific community should be called to draft the guidelines and the codes of conduct<sup>1018</sup> (“soft law”), that are needed for increasing the awareness of risks posed by new technologies and for assigning to professionalization a tool for

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<sup>1017</sup> See A. KELLE, *Security Issues Related to Synthetic Biology. Between Threat Perceptions and Governance Options*, in M. SCHMIDT (ED.), *The Technoscience*, cit., p. 114.

<sup>1018</sup> It can be noted that a lot of codes of conduct for scientific community have been proposed at many levels (for instance by American Society for Microbiology, Australian Society for Microbiology, American and British Medical Association, and others) after the 5<sup>th</sup> Review Conference B.W.C.: for further details, see F. LENTZOS, *Managing Biorisks: Considering Codes Of Conduct*, in *Nonproliferation Review*, 13, 2, July 2006, p. 211-226).

governance<sup>1019</sup>. In this way, synthetic biologists are conceived as scientists having ethical obligations and deontological rules to follow. Indeed, the involvement of scientists «offers them an identity as ‘guardians of science’ in the fight against biological weapons and bioterrorism, rather than the passive recipients of bureaucratic regulations»<sup>1020</sup>. The drafting of deontological codes and codes of conduct can also increase the trust of the general public on the scientific community<sup>1021</sup>, because people could hold the biologists accountable<sup>1022</sup>.

On the other hand, the intervention of the States and governments through “hard law” cannot be neglected. However, it must be meant to be complementary with the one of the scientific community, and it should consist in delineating the general rules to scientists (such as the introduction of licenses for dealing with products or the duty to keep the State informed of developed research). Governments could also have a role in the phase of control of the sources of risk coming from the outside and from the State itself (in particular, by means of a decision-making authority embodying both science and security values and composed of specialists in the field).

Moreover, the engagement approach based on “*prudent vigilance*” entails that scientists are made aware of their responsibilities through programs for education and training, that allow the creation of a “culture of responsibility”. Scientific publishers and journals are also involved in the process and are invited in drafting their rules, on the basis of general frameworks coming from governments and legislators.

In this way, different levels of governance could be noted for addressing the biosecurity risks of synthetic biology:

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<sup>1019</sup> L. WEIR, M. SELGELID, *Professionalization as a governance strategy for synthetic biology*, in *Systems Synthetic Biology*, 3, 2009, p. 91–97.

<sup>1020</sup> C. MCLEISH, P. NIGHTINGALE, *work cit.*, p. 1648.

<sup>1021</sup> M.J. SELGELID, *Dual-Use Research Codes of Conduct: Lessons from the Life Sciences*, in *Nanoethics*, 3, 2009, p. 180.

<sup>1022</sup> It could be observed at this regard, that since from the 1990s Joseph Rotblat formulated the proposal of a “Hippocratic Oath for Scientists”, i.e., a universal code of conduct for scientists. The idea has been criticised because such code would be too general and vague to apply to any kind of science, and so it would be, in the end, useless (see J. ROTBLAT, *Remember your humanity*, in I. ABRAMS (ED.), *Nobel Lectures, Peace 1991–1995*, Singapore, 1999). See also, J. REVILL, M.R. DANDO, *A Hippocratic Oath for life scientists*, in *European Molecular Biology Organization Reports*, 7, 2006, S55-S60.



(a) the level of individual scientists (that are the target of education programmes and must respect the whole set of biosecurity rules);

(b) the level of single laboratories (that are called to draft their own security guidelines, in line with the set of rules and standards adopted in the international and national frame);

(c) the level of educational and research institutions (that must supply scientists with educational training and control the compliance with the security rules);

(d) the level of scientific communities and/or organisations (that are called to settle their codes of conduct, respecting what provided in higher sources of law);

(e) the level of science publishers (invited to establish their deontological rules (about publication or censorship of scientific researches that arise “dual use” concerns);

(f) the level of national governments (that use laws, binding statutes, decrees for defining the regulation in biosecurity field); and

(g) the level of international (governance) bodies, such as United Nations, B.W.C. Review Conferences, W.H.O., and other bodies dealing with biosecurity and called to set a harmonized and shared set of standards.

So, the self-governance approach chosen by the “*Fink Report*”, by the “*Lemon-Relman*” report, by Garfinkel’s and Goldman School’s reports should be integrated by the “top down” intervention. Similarly, the approach that has been assumed by civil organizations at the Second International Conference (SB 2.0) consisting of supporting the external regulation should not deny the importance of the “bottom up” contribution. The options given by the I.A.S.B., the I.C.P.S. and the I.G.S.C. appear more balanced as seem in the focusing of their activities on the technical solutions to the problem of the potential misuse of DNA sequences, and the suggestion of codes of conduct and best practices, without excluding the role of government and external authorities for oversight and enforcement of these standards. Yet, as Kelle affirms, «*although the proposals for technical solutions to DNA synthesis are certainly to be welcomed as useful building blocks for an overarching biosecurity governance structure, they do not represent an integrated*

*approach that would, for a start, include a coherent set of measures to raise awareness across the synthetic-biology community»<sup>1023</sup>.*

A mixed approach is the one chosen by the D.H.H.S. with the “*Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*”, and an openness in the same direction is given by National Security Council in its last report (2009).

In a nutshell, a proper model for dealing with biosecurity risks of synthetic biology is the one characterized by an ongoing assessment of the risks and the involvement of all the actors and all the sources of law in the process, as well as the presentation of measures that range from ensuring the awareness of risks upon single scientists, to formulating laboratory guidelines, and from codes of conduct to national laws, and European and international provisions.

For the moment, the results of such approach are visible only with regards to the technical issue of controlling the DNA sequence trade<sup>1024</sup>. The screening of customer orders for potentially dangerous DNA sequences, the limitation of sale of DNA sequences, the storage of records of orders are the most adopted measures. Indeed, at the international level the Australia Group has elaborated a system of controls on the export of select biological agents belonging to the list. The U.S., the E.U. and national regulations offer rules about the export controls. The I.A.S.B. has enacted a code of conduct about screening of orders and the U.S. D.H.H.S. has drafted a set of guidance in the same regard. The level of single laboratories and researchers is not controllable, but it is wishful that similar rules could be enacted in line with such a multi-level framework.

The applicability of this approach only to the control of DNA sequence trade shows how embryonic the multilevel governance model is. However, this example demonstrates that such approach can work. Therefore, what is necessary now is to implement it. This allows for the facing of the biosecurity risks of synthetic biology in a comprehensive way, both at the global and at the local level.

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<sup>1023</sup> A. KELLE, *Synthetic biology and Biosecurity*, in *European Molecular Biology Organization Report*, 10, 2009, p. S 26.

<sup>1024</sup> For deepening the issue, see G. SAMUEL, M.J. SELGELID, I. KERRIDGE, *Back to the future: Controlling synthetic life science trade in DNA sequences*, in *Bulletin of the Atomic Scientists*, 66, 5, 2010, p. 9–20.

Furthermore, moving to the phases of enforcement and control of the policies that have been adopted through “hard law” and “soft law”, through “top down” and “bottom up” sources and through the involvement of the public as well, it should be noted that the mixed model based on coordination and integration of tools should be applied in the case of biosecurity risks. It would entail that judges, government bodies, professional bodies which represent scientific community should intervene for the check of the respect of the rules that have been adopted. Moreover, such role of oversight should also be vested upon a multi-stakeholders’ bodies that assemble people from all the different areas of the society, and thus representing the interests of everyone.

*Conclusion.*

Synthetic biology could be misused and could lead to bioterrorist scenarios, if handled by malevolent people, “lone operators” and biohackers. Thus, a set of regulations at the international, European, national level has been developed in the course of the years, not precisely with reference to synthetic biology, but in the fight against bioterrorism. However, provided that some modifications and updates are done to this set of regulations, while keeping in mind the constitutional frame that requires to find a balance between public health or security needs and the freedom of research, such system of rules could be applied to synthetic biology as well. The importance of governing biosecurity at a global level, as it is a global issue, is evident. For this reason, there is a need to accommodate to synthetic biology and to the constitutional frame that set of “hard law”, which has been presented in the first part of this chapter. However, a mere “hard law” system (“command and control” model<sup>1025</sup>) is not sufficient for tackling with biosecurity needs. Indeed, the fact of assigning to the governments the role to fix rules onto a scientific community from the outside could be too costly to implement and too limiting to the development of scientific progress. For instance, if decisions about what research is to be done and what papers are published are left in the hands of bureaucrats and governments, they

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<sup>1025</sup> See R. BALDWIN, C. SCOTT, C. HOOD, *A Reader on Regulation*, Oxford, 1998.

will probably make security prevail over science values<sup>1026</sup>. Furthermore, a “command and control” system is *«less effective where the target and scope of regulation are not easily defined. [...] [It is] also difficult to implement or enforce when the institutional behaviour to be influenced is complex, diffuse, and rapidly changing—all traits that characterize the diverse bioscience community»*<sup>1027</sup>.

On the other side, if a “pure” self governance model is preferred, the opposite situation is likely to be generated, i.e., the situation of favour for an absolutely free research, without any limit.

So, *«the balance between preventing and mitigating the “Persephone effect” - the likelihood of beneficently intended research being applied towards evil ends - and maintaining the imaginative freedom that fuels scientific inquiry»*<sup>1028</sup> can be rationally and adequately reached only through a new model of governance, in which governmental governance is applied in concert with other ways of governance. Taking in mind that *«governance systems that rely on voluntary standards or institutional practices cannot, alone, guarantee the prevention of bioterrorism or protect against malignant uses of biology. But international treaties or national top-down regulation cannot, on their own, deliver such promises either»*<sup>1029</sup>, the solution is a convergence of multilevel sources and actors. The regulatory multiplicity<sup>1030</sup> and the co-presence of external regulation and codes of conduct, guidelines, deontological rules<sup>1031</sup> enacted by scientific community itself could determine a more complete regulatory and governance system, that appears as more suitable for balancing freedom of research and security needs. Such framework should assess and monitor in a constant way the developments of science and its risks.

The implementation of “hard law” and “soft law” rules for countering bioterrorism would have to deal with (1) the level of scientific practice (security and

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<sup>1026</sup> See B. RAPPERT, *Codes of conduct and biological weapons: an in-process assessment*, in *Biosecurity and Bioterrorism*, 5, 2007, p. 145–154.

<sup>1027</sup> G. KWIK, J. FITZGERALD, T.V. INGLESBY, T. O'TOOLE, *work cit.*, p. 30.

<sup>1028</sup> G. KWIK, J. FITZGERALD, T.V. INGLESBY, T. O'TOOLE, *work cit.*, p. 31-32.

<sup>1029</sup> *Ibid.*

<sup>1030</sup> See F. LENTZOS, *Countering misuse of life sciences through regulatory multiplicity*, in *Science and Public Policy*, 35, 1, February 2008, p. 55–64.

<sup>1031</sup> About the moral duties to be embedded within deontological codes for life scientists (such as the obligations to prevent bioterrorism; to engage in response activities; to consider negative implications of research; not to publish or share sensitive information; to oversee and limit access to dangerous material; and to report activities of concern), see F. KUHLAU, S. ERIKSSON, K. EVERS, A.T. HÖGLUND, *Taking Due Care: Moral Obligations In Dual Use Research*, in *Bioethics*, 22, 9, 2008, p. 477–487.

safety rules for laboratories), (2) the level of information dissemination (giving external rules for publication and supporting the enactment of codes of conduct by journals and scientific editors), (3) the level of technology application (rules about the monitoring of all DNA synthesis orders from all suppliers in a coordinated way, the supplying people with a system of epidemiological surveillance and response in case of bioterrorist attack, the possession, trade and transfer of biological material), (4) the necessity of creating a culture of responsibility and cooperation between the scientific community and authorities<sup>1032</sup>, (5) the need to make scientists aware of their responsibilities and the risks of their work, and finally (6) the boosting of the research on synthetic biology, and using it as a means for fighting against bioterrorist threats coming from itself (for instance, adopting synthetic biology for designing new ways of resistance to bioterrorism, such as new vaccines, drugs and anti-viral therapies against pathogens and biological agents)<sup>1033</sup>.

In addition, a mixed model for the oversight and control of those policies should be adopted. The cooperation and integration between different subjects seems the best way for enforcing those codes of conduct and for ensuring the application of international and national laws. In particular, bodies aimed at the oversight of the security rules and composed of both government, security, scientific community members, and other stakeholders should be implemented and boosted.

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<sup>1032</sup> See B. ALBERTS, R.M. MAY, *Scientist Support for Biological Weapons Controls*, in *Science*, 298, 1135, 2002. See also R.M. ATLAS, *Toward global harmonization for control of dual-use biothreat agents*, in *Science and Public Policy*, 35, 1, February 2008, p. 21–27.

<sup>1033</sup> About this proposal, see G. MUKUNDA, K.A. OYE, S.C. MOHR, *What Rough Beast? Synthetic Biology, Uncertainty, And The Future Of Biosecurity*, in *Politics and Life Sciences*, 28, 2, August 2009, p. 2-26.



## CONCLUSION

*“Future is not a place where we are going to,  
but one we are creating”*

*(J. Schaar)*

Synthetic biology promises to radically revolutionise the next few years. After Venter’s “Synthia”, numerous new discoveries and targets have been achieved<sup>1034</sup>, and many more will surely be improved in the course of the time. Scientists are willing to explore all the possible dimensions of research, and they are not limiting themselves to working within the existing fields. In Drew Endy’s words, *«Instead of just imagining the world as it exists, and as we inherit it from nature, I think it’s becoming increasingly important that we understand how to imagine worlds that might be, how we would choose how to design and construct them»*.

The U.K. Royal Academy of Engineering, for instance, has worked out a pattern timing for the main applications of synthetic biology<sup>1035</sup>:

(a) within five, ten, and twenty-five years, the available applications will include routine and economically viable synthesis of large synthetic DNA molecules. They will incorporate synthetic biology techniques into biotechnology processes for the improvement of therapeutic properties of existing drugs and reduce or eliminate the side effects for the individual. There will be the production of new drugs based on the known therapeutic properties of certain plants or the coupling of synthetic biology to tissue engineering. There will be the production of more efficient biofuels, the reduction of CO<sub>2</sub> levels through the development of artificial leaf technology, and the production of

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<sup>1034</sup> For example, recently the synthesis of the first eukaryotic species (see E. MORENO, *Design and construction of “synthetic species”*, in *PLoS One*, 7, 7, 2012, p. e39054 ff.). in fact, Dr. Moreno, from Bern University, was able to produce a new species of fly, starting from the manipulation of a group of known genes. He generated a fly having different phenotype that is capable of reproducing with those belonging to its same species and not with those coming from the original species. In this way, it was demonstrated for the first time that a passage from transgenic to synthetic species is possible.

<sup>1035</sup> U.K. ROYAL ACADEMY OF ENGINEERING, *op. cit.*, p. 7-8.

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new types of environmentally friendly pesticides. It is certain that there will be the construction of standard biological parts being incorporated into many kinds of devices, and the production of biologically based memory and biologically based microprocessors that perform control functions similar to those in living systems;

(b) Within twenty-five years, possible applications of synthetic biology will include biosensors permanently residing in the body, adaptive antibiotics, enzymes which can break down a much wider range of biomass into useful forms, and biologically engineered substitutes for products that are currently derived from petroleum.

It is evident that such new emerging technology offers big potentialities in the fields of energy production, environment, industries, and biomedicine. However, at the same time it poses some risks and concerns that span different areas.

In view of such situation, the law cannot remain silent as a mute spectator. Neither has it to intervene because it was being pushed by irrational fears nor has it to follow deliria of hypertrophic regulation. Instead, it is called upon to find its proper role in this field.

Synthetic biology represents both an opportunity and a challenge for the law. Here, there is the opportunity to avoid the mistakes of the past, due to the slow and delayed intervention of the law with regards. For instance, in the case of genetic modified organisms, the law was guided more by emotional instances rather by rational ones. At the same, synthetic biology poses a challenge to the law, as it asks for the law to find adequate solutions for managing its development and results.

Currently, lawyers have accumulated a certain experience in their relationship with the field of science and technology. Thus, it is possible to look at the growth of synthetic biology without an apocalyptic or alarmist eye, and without ideological or dogmatic standpoints. Instead, it seems entirely possible and certainly recommendable to seek for pragmatic and reasonable solutions.

This thesis has tried to indicate the possible role of the law in addressing the risks and concerns posed by synthetic biology with special focus on comparative constitutional law. However, the contribution of other sciences, such as ethics, sociology, and economics has not been neglected. Indeed, as synthetic biology is a converging science that assembles multiple fields of research, the law should adopt a similar multidisciplinary approach for dealing with it.



## CONCLUSION

My analysis started with the search of a definition for synthetic biology, in the light of the fact that definitional issues are essential for building an adequate and exhaustive regulatory framework (Chapter I).

Given the uncertainty related to the applications and consequences of synthetic biology because of its nascent and initial stage, I opted for a broad definition, by which I understand synthetic biology to be a converging science and technology that aims to (a) re-designing existing living forms, and (b) design *de novo* artificial parts or systems in the biological world.

The adoption of a this broad notion of synthetic biology is useful and is in line with the search for a model of governance of risks and concerns which could take into account all the different subfields of research within synthetic biology, and all the different stakeholders. Indeed, after the presentation of the main areas of research, approaches, applications, and risks posed by synthetic biology, I focused my analysis on the framing of a model which could be suitable for the governance of both the physical and non physical risks and concerns (Chapter II).

My proposal consisted of (a) taking the traditional model for addressing risks, i.e. the model composed of the phases of “risk assessment”, “risk management” and “risk communication”, and (b) making it available and workable for synthetic biology.

First of all, I re-categorized the broad group of “risks and concerns” of synthetic biology into two subcategories: (1) physical risks (called “risks in a narrow sense”), such as the risks upon the environment, human and animal health, and life, because they can be physically perceived, and (2) non-physical concerns (called “concerns in a narrow sense”), as the ones affecting ethical, moral, economic, and social values and interests.

With this in mind, I moved on to checking the applicability of the aforementioned traditional model of governance. I showed, in a concrete sense, that when the decision makers, the legislators or policy makers decide to regulate synthetic biology, they should first begin from the assessment of its risks and concerns. They should catalogue all the threats that can arise in the field of synthetic biology not only from the scientific viewpoint (identification of the potential harmful events, evaluation of the level of them, and consideration of the probability of the

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consequences that the harmful events could generate), but also from the social, ethical, legal, economic point of view.

Then, the second step consists of the “risk and concern” management, i.e. the phase of policy and choice of the possible actions for regulating synthetic biology. The principles that generally “guide” this phase and that have been adopted so far are (a) the precautionary principle, (b) the cost-benefit analysis, and (c) the proactionary principle. My proposal is to adopt a “fourth way”, which consists of taking the “best” elements of the aforementioned approaches. This new approach is named “*prudent vigilance*”, and it is an elaboration and development of the idea proposed by the U.S. Presidential Commission for the Study of Bioethical Issues (P.C.S.B.I.) in its Report on synthetic biology in 2010.

My suggestion is to face synthetic biology not by fighting against the introduction of this new technology, but at the same time not allowing synthetic biology proceed uncontrolled and without regulations and/or guidelines.

The “*prudent vigilance*” approach looks like a procedural approach rather than a substantive one. Indeed, it does not say *what* actions to take against risks, but *how* to face them. It pursues the innovation and progress of synthetic biology without prejudicing safety, security, values of people, environment, and society. This entails: (a) a flexible and ongoing assessment of risks, through the involvement and cooperation of all the stakeholders, that can concretise the realization of a very “democratization of science” and help in taking into account all the diverse instances, (b) the adoption of a proportional set of actions, i.e. actions that could be proportional to the potential harms, and capable of balancing between concerns, benefits, interests, values and rights.

As for the “risk and concern communication”, this means that the decision and policy makers should communicate the chosen policies to the public and to the society. Such phase must consist of a continuous interaction between actors and recipients of synthetic biology. Policy makers and scientists cannot be far away from the public. The ongoing dialogue is fundamental. Crucial is the contribution of lawyers (together with ethicists, scientists, sociologist, and so on) in being the “bridge” for (a) connecting the policy makers to society, (b) for generating

legitimacy and accountability of synthetic biology, and (c) for building a “good” public perception and a trust that is not altered or emotionally biased.

Thus the law should be to operate within “*prudent vigilance*” approach, i.e. the law has neither to stop the research, nor to avoid it, but it has to adopt the rules that follow the ongoing growth of synthetic biology. This means that the law should be capable of enabling innovation and at the same time taking care of risks, and balancing the different rights and interests at stake according to the principle of proportionality.

From the point of view of the sources of law that could be better adopted in dealing with synthetic biology, my suggestion is to opt for a mixed or hybrid model, in which “hard law” and “soft law” integrate reciprocally. The actors at stake should not only be the institutions (legislator, government and so on), but they should have to include the scientific community, the other stakeholders and the general public, and thus realizing an “engagement” approach. Therefore, the statutory source should be a complement of the deontological one. In this way, the assessment and management of risks would be the result of a convergence between sources coming from “top down” and “bottom up” levels.

Since the field of synthetic biology is an international enterprise that has global effects, the sources of law from the international level are particularly recommended, in order to shape the international standards for dealing with risks. Then, at the regional, transnational<sup>1036</sup> and national level, the implementation of those rules is required. This should be done through “hard law” regulations, particularly if they are the result of the engagement of the expertise component and of the many representatives of the different interests, and through “soft law” rules,

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<sup>1036</sup> It is relevant to hint here, very briefly, at the notion of “transnational law”, which is different from the traditional international law and the governmental/State law. Indeed, with this label we refer to a set of non-hierarchical rules enacted by global institutions and organisms (such as Codex Alimentarius Commission, World Trade Organization, World Bank, etc.), that go beyond the national dimension and link together transnational subjects in civil society as well, forging their legitimacy through ensuring openness, dialogue and the participation of private parties. The main feature of this set of rules is that they do not provide a system of sanctions, they usually consist of standards and guidelines, aimed at influencing the behaviour of national bureaucracies and private parties rather than imposing strict duties. In some key areas the concept of “transnational law” has been fruitful, such as with regards to *lex mercatoria*, corporate governance, public international law, human rights litigation (about the transnational law, see for example S. CASSESE, B. CAROTTI, L. CASINI, E. CAVALIERI, E. MACDONALD (EDS.), *Global Administrative Law: The Case-book*, New York-Roma, 2012, and P. ZUMBANSEN, *Transnational Law*, in J. SMITS (ED.), *Encyclopedia of Comparative Law*, Northampton, 2006, p. 738-754).

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that are enacted by the scientific community in terms of codes of conduct, guidelines, ethic codes, etc.

Once the rules are enacted, the phase of enforcement, oversight and control follows. In this case, my proposal considers the possible instruments for exercising such function. The emphasis is placed upon the coordination and integration between different subjects and tools. I suggested the implementation of the role of (a) the judges through case laws, (b) government bodies (that operate with administrative measures), (c) professional independent bodies, composed of representatives of the scientific community and aimed at controlling the members with autonomous measures based on their deontological codes, and (d) the institution of bodies which assemble different components of society (such as scientists, members of industrial and companies, ethicists, sociologists, religious people, lawyers, government agents, and so on), in order to represent the interests of everyone and to reproduce that “democratization” which has been suggested in the phased of decision making process as well.

The role of constitutional law in the field of synthetic biology is demonstrated with reference to “hard law” and “soft law” sources that are called upon for managing the risks and concerns of synthetic biology. Furthermore, the field of fundamental rights is particularly important for addressing the issues related to synthetic biology. Indeed, the favourite space in which biolegal principles enter a constitutional norm is the space of fundamental rights. The notions of life, health, integrity, justice, equality and so forth, that are key principles of bioethics and biolaw, are at the same time protected by constitutional fundamental rights. So, the Constitutions are an immediate point of reference for any biolegal theme. Synthetic biology constitutes no exception in this regard. For this reason, in the course of this thesis (Chapter III), a particular position has been taken by fundamental rights, in order to (a) verify whether and how the fundamental human rights could shape in the face of synthetic biology, and (b) to offer a constitutional frame, on the basis of which to enact any policy, regulation and measure of governance for the risks and concerns of synthetic biology.

I concentrated my attention, in a comparative perspective, on different human rights instruments at the international, European and national level. I chose to deepen

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the role of five rights that are the most significant in the field of synthetic biology, i.e. (a) the right to life, (b) human dignity, (c) the right to health, (d) the freedom of scientific research, and (e) the right to environment.

With regards for the right to life, the analysis of the legal bills of rights and of the case law shows that the right to life is recognised upon the human being, and the life that the right makes reference to is the human one. The right to life entails both a negative and a positive obligation for the State. In the first sense, it means that the State must avoid any behaviour that could alter or damage the life of its members. In the second one, the State has, at the same time, the duty to intervene for removing any situation that potentially affects life and puts life into risk. This means that, considering the right to life in the field of synthetic biology, it entails that each human being has (1) the right to have access to all the potential applications that synthetic biology could have in ameliorating human life and health (here there is a connection between the right to life and the right to individual health), and (2) the right to be protected from any case of damages that synthetic biology could provoke onto their lives (in the hypothesis of biosafety and biosecurity risks, where the relationship between the right to life and the right to public health is at stake). Therefore, the regulations in the field of synthetic biology should have to take into account the right to life as a fundamental individual right and, at the same time, as a collective interest to be safeguarded, in connection with the right to physical integrity and health and public health issues.

Moreover, on the basis of the principle of equality, such a right to life should be recognised upon all the components of humankind. In addition, the hypothesis that in future synthetic humans could be created requires a re-evaluation of the right to life as a species-norm. Different solutions could be proposed in this regard: (1) the existing bans about cloning and altering the common heritage of human genome could be extended to the creation of synthetic humans, or (2) the analogy between humans as we currently know them and synthetic ones could be done (thus extending the right to life to synthetic beings as well, regardless of their origin), or (3) a hybrid legal protection for the synthetic humans could be thought.

With respect to dignity, the research led to see that this notion is very much cited in legal texts. In literature it is referred to a status that is inherent to human

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beings. It is meant to be (a) the source of all the other human rights, or (b) an expression of freedom or equality, or (c) a subjective individual right itself, or (d) a limit to other rights, or (e) a parameter in balancing operations, or (f) a principle. However, it is still unclear what it is exactly is.

Dignity is usually vested upon human beings, in particular (a) upon the whole human species, (b) upon groups within human species, and (c) upon human individuals. Particularly, in the case of risks of biosafety and biosecurity posed by synthetic biology dignity that vested upon human species emerges. Here, dignity embodies the idea that the existence and integrity of humanity as such has an intrinsic worth and therefore deserves to be protected. So, it empowers the integrity of humankind, and is linked to the right to life and integrity. This facet of human dignity entails that all the measures to prevent random and deliberate proliferation of harmful virus and bacteria must be taken by regulators.

Furthermore, the notion of dignity as referred to the whole human species and also in its individual dimension is at stake in the area of intellectual property rights. The “moral clause” that is contemplated within T.R.I.P.S., and the U.S. and European systems forbids the patentability of the inventions that violate human dignity and/or basic constitutional norms and values. There is one case in which the application of the “moral clause” is surely shared at the international level. This is when the patents could violate the idea of the human genome as a common heritage of humankind. Such provision of the intangibility of the human genome is grounded on the protection of species and individual human dignity. So, the application of the “moral clause” could be at stake when dignity is affected by completely altering the genetic essence of humans through synthetic biology or, at least in the E.U. context (as art. 6 Directive 98/44 states), for example, during the creation of totipotent cells through synthetic methods, producing chimeras from germ-cells, cloning a human being, modifying germ-line cells, and so on. In the light on the E.J.C.’s decision of *Brüstle* case, it is also likely to think that inventions within the field of synthetic biology requiring the destruction of human embryos, even though the claims of the patent do not concern the use of human embryos, are unpatentable.

Dignity as vested upon the whole human species value is at stake with respect to international justice concerns as well. In this case, dignity is closely connected to

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the principles of justice, solidarity, and equality, in order to strengthen them. In the light of this notion of dignity, regulation in the field of synthetic biology that aims to deal with international justice concerns should have as a target the equal distribution of resources and equal access to them by everybody all over the world.

I also highlighted the issues where an overcoming of the notion of human dignity is proposed, i.e. the claims of moulding the notion of non-human dignity (“dignity of creature” in Swiss Constitution) and the notion of post human dignity (as in the transhumanists’ position about enhancement). In the first case, where dignity as a species feature is contested, biocentric and animalist positions claim that human dignity extends to non human animals and synthetic organisms as well. Thus, the notion of human dignity would be in the position to be reshaped, so as to accommodate the reference to synthetic organisms. However, I believe that the status of synthetic “creatures” cannot be the one of dignity and I demonstrated that here there is the risk to use dignity as a synonym of “integrity”, and thus emptying the content and function of dignity. For this reason, I proposed to recognise a value to creatures (even synthetic) and to admit the importance of protecting their “well being”. So, in the future, it is likely to elaborate a sort of legal protection to them. However, the status of these “creatures” cannot be the one of “dignity” in the terms that has been elaborated so far.

As for the matter of “enhancement” through synthetic biology, human dignity can be at stake because it can be (a) a way for banning any intervention on human beings (in connection with the idea of human genome as a common heritage of humankind that must be preserved as untouchable, and being beneficial for future generations), or (b) a notion that must be overcome and substituted by a “post human dignity”. Here, human dignity is challenged again and it is difficult to understand how to shape it and how to reach a solid conclusion on its role. In my opinion, the fact of bringing dignity out of the human would mean again to empty the content and significance of dignity, making it a piece of rhetoric. For avoiding such risk and preserve the original significance that dignity has, it should be brought back to its original position. This means that dignity is strictly inherent to human beings and it indicates how human should be treated. This is not to say that the enhancement through synthetic biology should be banned. However, it should proceed in a prudent

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manner and never arrive at the point of annulling human dignity. This implies to try to delineate a threshold between synthetic and human, and in prospect to find qualitative and/or quantitative criteria, in order not to delete the core and original content of dignity.

With respect to the right to health, its two main dimensions are (a) an individual dimension, which focuses on health as a status, i.e. a situation of wellness belonging to the single human being who, on the basis of this right, can find him/herself in a claiming position towards both the State, and the other citizens, and (b) a collective or public dimension, which concentrates on population and intends this right as a right belonging to groups, to general society, and to the whole community.

The role of the right to health in the context of synthetic biology is evident if considering the development of synthetic applications in the biomedical field, such as in the creation of vaccines, of new drugs, vectors and therapeutic products. So, the right to health calls upon for its protection and promotion in the area of synthetic biology. However, the paradox of health is that, with the growth of new technologies and the development of new instruments for improving human health, resources are lacking and these technologies may cost too much for it to be accessible to everyone. This applies for synthetic biology as well. Here, the potential of the right to health should show itself in all its strength as a fundamental human right having a minimum and essential “core” that States should protect and implement, in line with Sen’s opinion, for example, and with the Italian Constitutional Court. Far from considering it as a mere aspiration or as a programmatic social right (coincident with the right to healthcare) or an economically dependent right which can only be achieved progressively according to the State’s will and availability of financial resources, the right to health in the context of synthetic biology entails it to overcome the aforementioned paradox. In its individual dimension it should be protected without discriminations and inequalities, thus granting equal access to each individual to the results of research within the field of synthetic biology. It should also pursue a rational distribution of resources within States and healthcare systems for making it effective. In these cases, the right to health links to the principle of equality.



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If the individual dimension is brought to a global level, it entails that the individual right to health becomes a collective right to health, and it should embrace the right to development. Indeed, the right to health is essential for the implementation of the development. On the other hand, the fact of pursuing the right to development, through synthetic products, helps ameliorating the qualities of health of populations. So, if the right to health is linked with the principles of equality and justice, it pushes for the equal access to vaccines, drugs and other medical devices for poor and rich countries. And here comes the problem, because synthetic biology risks to be too expensive, elitist and accessible only to a few people in the world. That's why the right to health needs to be tied with other principles and rights, and it should be kept in mind in shaping policies that guarantee the broadest access to synthetic products and applications throughout the world.

With regards to the risks of biosafety and biosecurity, the right to health in its public dimensions emerges when indicating the importance of preventative and reactive responses by the States in the face of emergencies and threats. When policy and decision makers decide to intervene in this field through public health policies (such as vaccinations), they should remember that their intervention does not mean to "sacrifice" other liberties and rights such as individual freedom and autonomy in the name of collective security, but to find a proper balance among security, public health and individual rights according to the principle of proportionality, as the U.S. Supreme Court with the decision of *Jacobson v. Massachusetts* indicates. Moreover, the respect of the human person can never be neglected, as Italian Constitution (article 32) states.

As for the focus on the freedom of scientific research, its relevance with regards to synthetic biology is evident. Formulated as a fundamental freedom, it is a clear symbol of democracy, as it touches the roots of a constitutional framework. This freedom shows, on the one hand, an (eventual) institutional aspect, in the sense that some centres and organisms and structures (such as universities) may be needed for the exercise of the right. On the other hand, this freedom entails an individual aspect, in the sense of a right to be recognised upon the single researcher. In this case, this freedom is shaped as (a) part of the content of the freedom of thought and expression, (b) being a fundamental freedom which has an autonomous content, and

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(c) being connected to a duty for the State in improving and promoting science and research. The freedom of research is not an absolute one, but is always limited and balanced by other values, interests and rights. Such freedom entails the researchers' liberty in choosing their interests of investigation. Moreover, it confers the duties upon the States. These duties consist of "negative" and "positive" obligations. On the one hand, the State cannot interfere in the choice of topics of research. On the other hand, the State should sustain research. The right for the members of community of having access to the benefits of research without any discrimination in terms of geographical, cultural, economic provenience directly derives from the freedom of scientific research.

In the context of synthetic biology, which represents a type of scientific research which has theoretical, applied and experimental facets, the freedom of scientific research plays a meaningful role and should be constitutionally protected. More specifically, the nucleus of the freedom of research, i.e. the freedom to chose the topics of investigation and to exercise theoretical speculations is intangible. However, when such theory meets the application phase and the results of research are used for specific purposes (such as the use of synthetic biology for developing bioterrorist applications), the freedom of research should be limited in the name of the protection of the right to health, to life, integrity, and dignity. The limitations cannot suppress the freedom of research, and should be in line with the principle of proportionality. On the contrary, if a scientific research like synthetic biology increases the conditions of health with its applications, it should be encouraged and promoted. In this case, the freedom of research could be read as a right that is vested upon a collective subject (i.e. society). It is the right to the further development of research, and to enjoy the benefits of research.

In the field of IPRs, numerous interests come into conflict: (a) the researchers' right to investigate, publish their results and obtain protection for their discoveries and inventions, (b) the interests of enterprises in commercial exploitation of applications derived from that research, and (c) the interests of society of having access to the benefits of research. In this case, the balance among the researches' rights of economic exploitation and personal property of their inventions and the advancement of the "common good" of society must be pursued. The stimulus to

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innovation should be combined with an equitable distribution of the benefits from synthetic biology to society. In this area, the patentability of synthetic products or the introduction of other models is at stake. The main possible solutions for synthetic products could be: (a) to maintain patents but mould them as “human rights”, or (b) to introduce new patterns, such as the “commons” one. The first idea would “save” patents in the area of synthetic biology, but it would recreate the balance among stakeholders, thus reframing more equal relations. The second proposal would boost the share of knowledge among enterprises and researchers, and it would make discoveries transparent, free and available to everyone without any limitation. There is also possible to introduce the “open source” model, as applied within the field of software, provided that the analogy between software and synthetic biology could be done, and that this model could be accommodated as I suggested in the case of patents.

As for the complex relationship between the freedom of scientific research and human dignity I showed how dignity could play a role in blocking research when it goes from a mere thought to actions which could affect the “core” essence of humankind. The limits to patentability for moral reasons are also a limit to research, and they are grounded on dignity. However, it must be noted that sometimes the line where to limit research on the basis of dignity is not so easy to draw, because what appears to someone as a threat to dignity can be seen by others as a benefit for humanity to be improved.

Finally, looking at the right to environment I demonstrated its relevance in the context of synthetic biology, by saying that it should be meant as a right in itself, i.e. a right to a safe, healthy, sustainable environment, in which environment is read as a specific good to be protected and preserved by human beings. In this perspective, the right to environment is linked to the right to health and development. The environment is seen as a good towards which human beings have specific responsibilities and duties, in line with the principle of solidarity. It must be defended, because the survival of human beings in current and future generations depends on it. Numerous applications of synthetic biology such as biofuels or methods for bioremediation could have an impact on environment. On the other hand, though, synthetic biology could provoke harms to environment and

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biodiversity. Therefore, the right to environment must be adequately considered in facing with biosafety risks, and in particular when choosing the policies under the “prudent vigilance” approach. In addition, this right entails that research in the area of synthetic biology is oriented in a way that respects biodiversity and does not undermine the value of environment for current and future generations.

After having drawn the constitutional frame on the basis of which any policy for addressing the risks of synthetic biology should be taken, my analysis consisted of an attempt to “translate” into practice the model that I have been delineating in the thesis. I chose to concentrate the attention on biosecurity and bioterrorism (Chapter IV). Synthetic biology puts humanity in front of the “dual use dilemma”, where synthetic biology could be used for benevolent and malevolent purposes at the same time. Pathogens could be created through synthetic biology and used for bioterrorist aims by spreading them all around to generate fear, morbidity and mortality. The norms that have been adopted so far for dealing with bioterrorism encompass several fields, such as criminal law, public health (and medical) law, emergency management law, and national security law. My analysis considered the existing framework that has been enacted at the international and European level, and in the systems of the U.S.A., the U.K., and Italy. I evaluated the adequateness of this set of rules in the light of the constitutional frame. I also checked whether the existing framework could be able to respond to the challenges posed by synthetic biology. In particular, I considered the compliance of the rules in the field of biosecurity with the balance between security and other rights according to the principles of proportionality and of reasonableness. Firstly, I demonstrated that the relationship between the right to security and the right to individual health (here consisting of the right to refusal of compulsory treatments and vaccinations that are imposed by States for preventative reasons and in response to bioterrorist epidemics) must shape so as to allow the limitation of the right to individual health for temporary periods, for necessity reasons, and using the least restrictive means for doing it. Indeed, for public health reasons the consent to compulsory treatments can be avoided, provided that the principle of proportionality is respected and the respect of human dignity is never trumped. Secondly, I focused on how to balance the right to security and the freedom of scientific research. Scientific research and publications of potentially

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dangerous biological agents could be used for bioterrorist purposes. Therefore, the need of finding how and where to draw the line among admitted research must be fixed. I showed that there is a need to evaluate potential (but tangible and not merely imagined) harms and tangible potential benefits. If the harms outweigh benefits, it would be better to opt for censorship of publications that are the result of the scientific research. Otherwise, the open access could be admitted.

Then I compared the existing framework against bioterrorism to the balance between the aforementioned constitutional rights (of security, individual and public health, and the freedom of scientific research). My conclusion here was to individuate a good compliance of the existing rules with the constitutional frame, although some gaps remain. Most of the regulations contain no references or very little attention to the possibility of creating new genetic agents and biological weapons through synthetic biology. They allow the possibility of extending the list of biological agents to include toxins or other pathogens that are the result of the modification of DNA, provided that the new pathogens are similar to the existing ones. This means that most of the creations coming out from synthetic biology are not included in that type of lists.

The International Convention on Biological Weapons (B.W.C.) refers only to malevolent use of bioweapons by States, and does not mention non state actors, such as the “lone operators” or “biohackers” or bioterrorists. Moreover, B.C.W. focuses only on the control of materials, without quoting the control on the access to information and knowledge. At the international level again, the Resolution 1540/2004 of the United Nations does not contain any reference to materials obtained through DNA technologies and manipulation (genetic engineering), and so synthetic biology could not be, at present, regulated by it. The E.U. model should be implemented as well in the light of the constitutional frame. In the model of preparedness and response to bioterrorist attacks it would be preferable to (a) add a system of licensing for possession of instruments used in biological research, (b) create a registry of people dealing with biodefence use of synthetic biology, (c) give the definition of criteria for the publication of data on highly pathogenic viruses or toxic agents at Member State and EU level, and (d) create a centralised database at least at EU level, or preferably at international level, where all DNA synthesisers

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would be registered by competent Authorities. The Database Directive (Directive 96/9) should be applied for regulating databases where sequences of DNA for synthesis are screened.

In the U.S.A. the attention to bioterrorism and biosecurity seems higher than in Europe and it certainly derives from the Anthrax attacks that made the U.S.A. very afraid of the risk. Yet, a certain negligence in respecting the balance among security and health seems to be present in some pieces of legislation (such as the “*Model State Emergency Health Powers Act*”, M.S.E.H.P.A.). So, the existing framework is not entirely capable of addressing the biosecurity risk posed by synthetic biology.

In the U.K. there is an “open door” to the admissibility of synthetic agents in the part of legislation according to which the Secretary of State has the possibility to extend the list to include further pathogens or toxins if suspected of being used for bioterrorism.

In Italy, no references to synthetic biology are done, except in the Code of Conduct promulgated by the National Committee for Biosafety, Biotechnology and Life Sciences, where there is the recommendation to monitor the production of substances that are obtained by a synthetic organisms if they are not equivalent to the known ones.

In addition, in the final parts of this thesis, I considered the different proposals that have been elaborated by research institutions, government ones, international independent associations and single scholars with reference to biosecurity risks of synthetic biology and I compared this analysis with my own proposal. I demonstrated how the model of “*prudent vigilance*” could concretely operate and represent a new approach for managing biosecurity risks of synthetic biology.

This entails that, first of all, the assessment of risks should be done by assembling all the different stakeholders, i.e. government members, scientific community, industries, security expertise, public health and sanitary personnel, journals and publishers. Then, the phase of management prescribes that the set of actions for addressing the biosecurity needs should be decided through an engagement approach and a multi-stakeholders’ dialogue. As for the sources of law to adopt, my proposal is to call for “top down” and “bottom up” sources of law. It

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means that, on the one hand, single laboratories and the whole scientific community should be called to draft guidelines and codes of conduct (“soft law”). On the other hand, the intervention of the States and governments through “hard law” cannot be neglected, but it must be meant as complementary with the one of the scientific community, and it can consist of delineating the general rules to scientists (such as the introduction of licenses for dealing with products or the duty to keep the State informed of developed research). Governments could also have a role in the phase of control of the sources of risk coming from outside and from the State itself (in particular, by means of a decision-making authority embodying both science and security values and composed of specialists in the field). Moreover, programs of education and implementation of a “culture of responsibility” should be pursued among the scientific community by research institutions and centres of research. The science journals are also invited to draft their own codes of conduct and guidelines.

In this way, a proper model for dealing with biosecurity risks of synthetic biology could be obtained. It is the one characterized by an ongoing assessment of risks and involving all the actors and all the sources of law in the process, presenting measures that range from ensuring awareness upon single scientists about risks, to laboratory guidelines, from codes of conduct to national laws, European, international and transnational provisions. Also in the phases of enforcement and control of the policies that have been adopted through “hard law” and “soft law”, and through the involvement of the public, it should be noted that the mixed model based on coordination and integration of tools should be applied in the case of biosecurity risks. It would entail that judges, government bodies, professional bodies which represent scientific community should intervene for the check of the respect of the rules that have been adopted. Moreover, such role of oversight should also be vested upon a multi-stakeholders’ bodies that assemble people from all the different areas of the society, and thus representing the interests of everyone. So, from the viewpoint of the sources of law, the decision-making process and the oversight the multilevel and plural dialogue must be implemented.

In summary, my proposal consists of an attempt to enucleate the role of the law in the relationship with synthetic biology, and to individuate a possible solution for dealing with the risks and concerns that synthetic biology poses. There is no

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doubt that synthetic biology generates, and will increasingly generate, great attention because of its potential benefits and applications. Certainly, it has yet to show more innovative achievements. However, its concerns and risks cannot be neglected. The time to act and address them is now. As lawyers and as citizens, we are, maybe for the first time in the relation between science and society, on perfect time. It is up to us to decide what to do and in which direction to move. This is the challenge to which synthetic biology invites all of us to respond.



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