FONDAZIONE ROSSELLI

Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products

Final Report

Fondazione Rosselli, appointed by the Directorate for the Internal Market of the European Commission (Contract No. ETD/2002/85), has carried out this study on the economic impact of the development risk clause as in the Directive 85/374/EEC on the liability for defective products.

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EXECUTIVE SUMMARY

This study analyses the economic impact of the Development Risk Clause (the "DRC") as in the Directive 85/374/EEC (the "Directive) on liability for defective products. The study focuses on the clause's economic impact, which excludes liability for damage caused by a defect that could not be foreseen given the technical and scientific knowledge available at the time the product was developed.

The use of the DRC in Europe is still rather limited, but this evidence does not by any means imply that the impact of the clause is not relevant. In addition to the fact that both consumers and producers associate a great deal of symbolic value to the DRC, this report highlights a number of different aspects which demonstrate how the DRC has played a crucial role in finding the right balance between consumer protection and innovation in Europe, well beyond its limited use in courts.

The DRC was defined in order to establish a satisfactory compromise between the need to stimulate innovation and consumers' legitimate expectations for safer products. The crucial argument of the current debate on the DRC is that removing this clause would stifle innovation. It is very difficult to collect sound empirical evidence on the effect the DRC has on a company's innovative effort. Our theory predicts the DRC's outright removal would encourage more process innovation and see an increased rate of incremental innovation. It would however result in a considerate decrease of product variety, radical innovation and basic research. Our survey and case studies seem to converge on the belief that the most plausible strategy for firms to cope with the increased uncertainty and risk in a stricter liability regime, is a reduction of their innovative output.

Another important part of the study concerns the impact that removing the DRC would have on companies' insurance costs. Although evidence shows that different methods of implementing the Directive in Member States do not result in different insurance rates, our findings indicate that removing the DRC would lead to higher insurance costs in certain industries. However, in industries where development risks are higher and matter the most, such risks would not be insurable, i.e. there simply would be no insurance market for specific

risks. The possible increase in insurance costs following removal of DRC could have an impact on market structure and competition.

In conclusion, the findings presented in this report seem to indicate that the often-used argument of the Development Risk Clause being a significant factor in achieving the Directive's balance between the need to preserve incentives to innovation and consumers' interests is well-founded and is based on the following:

- the DRC protects incentives to innovate by reducing the innovation-related risks, by not diverting resources from R&D to insurance policies and by pushing firms to align to state of the art knowledge
- the DRC is probably one key factor in determining the relative stability of product liability insurance costs in European industry and keeping litigation at a reasonable level
- in a strict liability regime, companies in high-tech / high risk sectors would find it very difficult to obtain a reasonable insurance policy which covers their developmental risks.

The combination of these factors leads us to conclude that the costs of letting the producers innovate their products in a full strict liability environment would be extremely high, especially for companies but also for consumers in the long term.

Due to the nature of development risks, they tend to result in events which have a huge impact yet a very low probability of occurrence. It is, of course, almost impossible to effectively compare the additional costs companies would incur in a strict liability regime against the expected benefits that consumers would enjoy in a more protected environment (i.e. by removing the DRC). Policy-makers should, however, keep in mind that development risks have to be carefully supervised, especially in a society that highly values technological innovation and actively promotes it. More specifically, our study points out that there are specific and crucial instances in which the DRC could fail to provide producers with the right incentives to advance the technological state of the art, to the point that would be socially desirable in product safety matters. We suggest that the dilemma between the DRC's advantages and disadvantages should be tackled, so as to limit the probability

that critical events occur, and reassure consumers in matters concerning the safety of highly innovative products.

One answer might be to search for any possible institutional solutions that would *guarantee consumers the same kind of protection that they would enjoy without the DRC, without eliminating the DRC itself*. The report discusses alternative protection schemes, some of which are already available and others that might be relatively easy to implement at EU level. These schemes are, in principle, able to provide consumers with a desirable level of protection. One crucial message is that the Commission should direct its policy efforts to harmonising protection systems in Member States and implementing innovative prevention and protection schemes at EU level. The main policy methods could be centralised compensation funds, possibly industry-specific and of a mixed private and public nature. Success in such an innovative effort would allow the Commission to adhere to its balanced policy approach in which the DRC is a key element. An alternative policy direction might be a slight tightening of the DRC, i.e. associating liability for development risks to the producer's negligence in assessing such risks and acting to reduce them. This would reinforce incentives for advancing a lacking state of the art, where this may be appropriate, and introduce liability for what is essentially irresponsible behaviour.

Notwithstanding keeping the DRC in operation, there are nevertheless a number of secondary issues that should be addressed without delay. Since the present disparity in applying the clause in different Member States and industries no longer seems to be acceptable, steps should be taken to harmonise its application. Secondly, it is highly recommended for the Commission to endorse an initiative aimed at clarifying the implications of different definitions of the "state of the art knowledge" and provide a set of normative guidelines to be applied uniformly in European courts. Finally, effort should be directed towards the enforcement of greater compatibility between directives dealing with product safety (including General Product Safety legislation) and liability law.

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FOREWORD – METHODOLOGICAL ISSUES

General remarks

Collecting empirical evidence about the economic impact of the application of the Development Risk Clause (the "DRC") is a rather complex methodological and practical task. Various studies carried out over the past few years confirm that the use of the Directive is still rather limited in Europe. Within such a relatively limited number of cases, the use of the specific provisions of the Development Risk Clause (DRC) is a rare event. This is, of course, a major source of difficulty when trying to collect data and facts concerning the economic impact of the DRC.

Empirical problems in assessing the economic impact of DRC

The problems arise from both the lack of inter-country comparisons and historical analysis. On one hand, time-series are rather short and lacking in relevant information. Actual cases available are few and all relatively recent. As Lovells' study on Product Liability[1] has already demonstrated, there are very few cases where consumers and companies have explicitly used the state of the art defence in courts. Our study confirms that if the review bases the DRC's impact exclusively on its use in courts, then it is obviously still very limited. Nevertheless, the evidence that the DRC is still of limited use in courts, should not lead us to conclude that the clause's impact is not relevant. There are at least three examples that emerged from our analysis that allow us to conclude that the DRC is indeed very relevant (and this justifies its importance in stakeholders' perception), although this is not reflected in juridical cases.

Three examples testify that the DRC is a very relevant issue for both producers and consumers.

The first position (expressed mainly by producers) states that the fact that the DRC is not yet widely used in courts singly demonstrates that the Directive has found the right balance between consumer protection and producers' incentive to innovate while fully respecting safety requirements.

The second position, which seems highly plausible, states that many of the disputes arisen over recent years have been settled out of court, that by definition are kept confidential by the parties involved. Collecting evidence about settlements is almost an impossible task.

Finally, a third element that has surfaced through questionnaires and interviews is that the relatively poor evidence about the application of the DRC is the result of

[1] http://europa.eu.int/comm/internal_market/en/goods/liability/lovells-study_en.pdf

incompatibility between national legal systems and the EC Directive on product liability. The Directive was set up in such a way as to enable each country to keep national legislation favourable to consumers, at least in some ways. In fact, since Article 13 of the Directive states that the application of the DRC does not interfere with pre-existing legal provisions in Member States, consumers often have several alternatives when choosing which type of defence to use in courts. In fact, there is evidence that in many disputes related to defective products, consumers have been able to rely on country-specific legal provisions, through which they enjoyed a similar level of protection, if not greater, to that which they would enjoy in a strict liability regime (i.e. without Development Risk Clause).

Cross-country comparisons.

On the other hand, cross-sectional evidence, i.e. comparing different countries which are characterised by different liability regimes, is also a relatively poor source of empirical information. There is too little heterogeneity and variance to allow us to compare markets in different Member States. The two countries (Luxembourg and Finland) where a strict liability regime is in force represent too small a part of the aggregate European market to allow a consistent statistical estimation of differences in prices, insurance rates and innovation activity. It should also be noted that the liability regime is typically defined with reference to the destination market, i.e. the market in which the defective product is sold to consumers. Given the nature of the European internal market, where trade is substantially free among different Member States, it is very difficult to treat single countries as independent markets. Most leading European companies compete in almost all Member States and have significant market shares in many Member States with different liability regimes. This situation tends to homogenize firm-level differences, preventing any kind of empirical estimation of impact on companies' cost functions in different countries.

Methodological approach

Implementation of the DRC

The first step of the study was the analysis of the implementation of the Development Risk Clause (the "DRC") (provided by Article 7 (e) of the Directive 85/374/EEC (the "Directive") in national legislation. Particular attention was given to Article 15 (b)[2] and Article13[3] of the Directive. This was done in order to clarify the EU's legal framework on the DRC and describe the development risk regulation in each Member State. In addition, the research team evaluated the practical cases involving the application of the state of the art defence, its interpretation and the practical cases in which the state of art defence might have been applied (and was not), along with the solution found for each of these cases.

The option offered by Article15 of the Directive together with the possible differences in applying the DRC required analysing the literature and doctrine on the application and interpretation of the DRC in each Member State carried out by national scholars/academics and by the courts.

During this phase of the analysis the Rosselli Foundation's network of experts verified the most important findings in each Member State. This type of analysis gave the research team a clear picture of the different models of implementation existing in the different Member States.

Analyzing the economic impact of the DRC.

As far as the economic impact of DRC is concerned, the methodological problems encountered were mainly related to the scarcity of empirical evidence mentioned above.

The problems in collecting extensive data-based evidence on the economic impact led us to rely on a wide number of methodological tools. Our methodology was based on the following:

- A multi-disciplinary review of scientific literature relevant to product liability, including the fields of law, industrial economics, R&D policy and product design and development.
- Interviews of selected academic experts in the field.

[2] By way of derogation from Article 7 (e), that each Member State could provide in this legislation that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

[3] This Directive shall not affect any rights that an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.

- An electronic questionnaire sent to a total of about 300 people[4], including Companies, Producers Associations, Consumers Associations, Insurers and their associations, National Ministries, Public Institutions, Legal Experts.
- Telephone interviews that enabled us (in addition to filling in the questionnaire) to collect a wide number of specific opinions and different views. Interviews involved 75 stakeholders from various companies, producer associations, consumer associations, Ministries, public institutions and legal experts.
- Two workshops (one held in Milan and the other in Brussels, where consumers and producers associations were given the chance to express their views on selected issues. The workshops were carried out using a Metaplan methodology, which is set up to help stakeholders to converge on selected statements and validate them through an iterative process.

We are confident that the combination of these different sources represented a sound base from which to make our conclusions. The following section contains a detailed explanation of the methodological process that led us to this conclusion.

The methodology-setting process.

The initial step was the analysis of relevant literature on the subject, including academic papers, legal documents and former studies. This allowed us to highlight critical issues and formulate specific theories on the economic impact of the DRC.

We then began the first part of the actual study, which, according to our original plan should have been based on desk-research and public data. Unfortunately, this approach proved to be rather ineffective due to the lack of evidence motivated above. Almost immediately, realised that there was no chance of reaching statistically sound conclusions from the minimal information that was initially collected on the DRC.

The survey.

We therefore tried to collect some further information through sending electronic questionnaires to 291 stakeholders. Different

[4] The number is not precise due to the fact that beside the 291 questionnaires th
the research group to stakeholders, there are additional questionnaires that wer
including producers' associations that voluntarily offered to disperse it to members and associates,
therefore, our estimate about 300-320 questionnaires.

questionnaires were sent to producer and consumer associations. The first version of the questionnaire was relatively long and ambitious. This was due to our perception that given the importance of the issue, both producers and consumers would have had the incentive to provide us with detailed information. Unfortunately, the response rate was not satisfactory. This was partly due to the questionnaires' relative complexity, but also to the fact that it was very difficult to reach the right person in the organisations - someone having the appropriate competencies in a very specific topic who is also allowed to speak on behalf of the organisation. Regarding the few answers that we were able to obtain, the information provided was in most cases incomplete, partial and superficial.
This result convinced us that we had to adopt a different strategy if we wanted to achieve a satisfactory response rate. We therefore decided present stakeholders with a simpler version of the questionnaire and a direct telephone interview. This allowed us to reach the right people in the organisations (often experts in their legal department) get them to fill in the questionnaire and, if possible, to provide more information and to let us know their insight into the problem. This third attempt has proven to be far more effective. Although the number of responses is not high enough to allow us proper statistical estimation and generalisation of results, we were able to contact many more stakeholders and the quality and depth of information provided was actually very satisfactory. In this respect it should be noted that stakeholders (especially private companies) were still fairly reluctant to provide information through the electronic questionnaire (or they did so after a long process) but were very happy to share their views on the problem through the interview, especially after having been reassured about confidentiality. Table 1 (below) reports on the number of questionnaires sent out, divided by typology of stakeholders.

Table 1 summarises the types of stakeholders that were contacted in each Member Country by different methods.

Table 1

	Companies & Producers Associations	Consumers associations	Experts / insurance	Governments	Total
Austria	4	1	4	5	16
Belgium	10	5	1	1	17
Denmark	6	3	1	1	11
Finland	7	3	1	2	14
France	17	3	3	2	25
Germany	29	3	4	1	38
Greece	9	5	3	4	21
Ireland	5	2	1	2	10
Italy	18	8	3	2	33
Luxemburg	2	2	1	1	6
Portugal	6	6	1	1	14
Spain	10	12	1	2	25
Sweden	8	5	1	1	15
The Netherlands	3	2	1	1	7
United Kingdom	23	7	1	4	35
EU	5	0	3	2	10
Total	162	67	30	32	291

The overall response rate by type of stakeholder is indicated in Table 2.

Table 2

	Contacted	Response	No response
Companies / producers associations	162	24	138
Consumers associations	67	17	50
Experts / insurance	30	22	8
Government	32	26	6
Total	291	89	202

The following table reports our response[5] rate by country.

Table 3

	Companies & Producers Associations	Consumers associations	Experts / insurance	Governments	Total
Austria	0	0	4	5	9
Belgium	0	0	1	1	2
Denmark	1	1	1	1	4
Finland	2	1	1	3	7
France	3	0	1	1	5
Germany	7	1	1	1	10
Greece	3	3	3	4	13
Ireland	0	1	1	2	4
Italy	1	4	1	1	7
Luxemburg	0	1	1	1	3
Portugal	0	1	1	1	3
Spain	2	0	1	1	4
Sweden	1	1	1	1	4
The Netherlands	1	2	1	1	5
United Kingdom	2	1	2	1	6
EU	1	0	1	1	3
Total	24	17	22	26	89

[5] By response we account for any kind formal reply to our questions, written or oral.

The workshops.

The workshops, which were organised to get an even further insight into the problem, were also very useful in helping us reach a larger audience for our interviews and questionnaire. The producer associations that attended our meetings (23 people from many member countries and industries) realised the importance of providing information and helped us involve many of their associates as well.
The workshops were organised to achieve a validation of some of the preliminary suggestions resulting from the previous activities. They were based on a presentation of some of the researchers' preliminary findings, followed by open discussion and the use of a specific methodological tool (Metaplan) to best manage the discussion and to converge on an agreement among the participants about some basic statements.

Investigating consumer's protection schemes in Member States.

The information collected in previous activities provided the background for the research carried out with respect to consumer protection issues. The analysis of the means of compensation offered to consumers injured by defective products involved the study of:

- social security regimes/schemes
- special compensation funds
- other system/way/means that could allow injured persons to have compensation
- the relationship between social security scheme / special funds compensation and product liability law compensation.

The starting point was the understanding of the legislation on the functioning of each Member State's national system, in order to have a complete overview of the national regulation on social security systems: means of financing, the damages they cover, the persons who have the right to require social contribution.
The team also investigated the relationship between social security schemes and product liability law. The scope of this part of the study was to understand the following four issues:

- on which basis a person injured by a defective product (in cases that might involve the DRC) might claim compensation from the social security system
- the damage covered by social security systems

- the action of recourse against the producer
- the cases in which consumers could remain without protection/compensation.

The analysis was conducted through both desk-analysis and a survey conducted among involved parties across the EU, by means of a combination of personal interviews (face to face or by phone) and the submission of a descriptive questionnaire to the Ministry of Health and the Ministries of Labour and Social Affairs in each Member State, together with specialised lawyers and consumers associations.

Special compensation funds

We also extended our analysis of the special compensation funds that could intervene in order to compensate damages caused by defective products in cases that (actually or theoretically) involve the DRC and the relationship with product liability law. Specific attention was given to the following aspects:

- the products they apply to
- their means of financing
- the damages they cover
- their relationship to product liability compensation
- the administrative procedure that must be followed in order to obtain compensation.

In conclusion, both scant statistical evidence on the application of the DRC and the difficulty of obtaining survey responses from a statistically representative sample resulted in the study's concentration on quality and depth of contacts with qualified stakeholders, rather than breadth and quantity. We are confident that the number, depth and variety of positions recorded verbally or in writing during the process, has provided an extremely sound and comprehensive body of evidence on which to base the study and its conclusions.

PART I -

FUNCTIONING OF THE DRC

1. The DRC in Directive 85/374/EEC

Debates on the approval of the DRC

Directive 85/374/EEC (the "Directive"), approved on 25 July 1985, on the approximation of the laws, regulations and administrative provisions of Member States concerning liability for defective products, introduced new rulings for the regulation of producer's liability. It aimed at harmonising the different laws existing in Member States "*because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property.*" The great impetus that has been given to consumer protection is typical of advanced industrial economies to the extent that an increased demand for safety is linked to growing incomes. It took a long time for the Directive to be approved due to the number of debates it raised, especially in light of the Thalidomide scandal and the prolonged discussion and negotiation that followed. The first draft of a new directive concerning product liability was put forth in 1975. It met with opposition because of its first article, which extended producer liability to development risks. After much debate involving both producer and consumer associations, the clause was approved. Member States were left to decide for themselves whether or not to put the state of the art defence into practice, thus facilitating the adoption of the Directive and guaranteeing a minimum level of product safety to all consumers in the European Union.

The Directive introduced a common scheme of strict liability which does not require proof of the producer's negligence but instead requires the existence of a defect in the product, the harm and the casual relationship between the damage and the defect. The Directive allows national legislation to introduce limitations and defences that practically dilute the economic impact of strict liability. Among them is the "**state of the art defence**".

Article 7 (e)

The producer shall not be liable as a result of this Directive if he proves:

…. e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered

Article 7 (e) does not refer to product risks but instead to the discoverability of the defect. This suggests that Article 7 (e) is considerably broader than its popular name – the development risks - might imply (Stapleton, 1994, p. 236). According to Article 15 of the Directive, Article 7 (e) is not a mandatory provision since Member States can choose whether or not to consider the producer liable also for development risks.

Article 15

... (b) by way of derogation from Article 7 (e), maintain or, subject to the procedure set out in paragraph 2 of this Article, provide in this legislation that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

Products covered/not covered by the directive 85/374/EEC

The inclusion of primary agricultural products: in Article 15 (1) (a) the Directive offered the option of including primary agricultural products and game in the strict liability regime. According to Article 2 of the Directive 85/374/EEC, 'product' means all movables, with the exception of primary agricultural products and game (even if they are incorporated into another movable or immovable good). A 'primary agricultural product' is a product originating from the soil, stock-farming and fisheries, excluding products which have undergone initial processing. 'Product' also includes electricity. The large economic losses resulting from Bovine Spongiform Encephalopathy (BSE) and the chicken-breeding scandal in Belgium, led the European Union to treat these types of products differently. With the approval of the Directive 99/34/ED, the product liability regime that was introduced by the 1985 directive was extended to also include primary agricultural products[6].

Other forms of liability

The other forms of liability: the liability scheme brought about by the Directive did not substitute the national regulations

[6] Directive 99/34/EC, OJ L 141, 4.06.99.

concerning tort law and contract law, which continue to be used instead of the EEC directive. Despite the fact that national legislation can even be based on a negligence regime (liability with fault), the option offered by the Directive can guarantee a different type of protection for consumers.

The debates on the introduction of the state of the art defence: the debates resulting from the introduction of the DRC in each Member State were animated.

Consumer associations' point of view

Consumer associations' opinions: consumer associations believe that it is necessary to protect consumers from unforeseeable and unknown risks, and that the exclusion of a form of liability for these kinds of risks would constitute a gap in consumer protection (Petitpierre, 1974, p. 165). It was suggested that producers might make up for the cost of compensating damages caused by development risks by increasing the price of their products (thus distributing it among consumers)[7]. Producers might even take out insurance (Iannuccelli, 1999, p. 390). Consumers' representatives did not support the inclusion of the state of art defence because it was said to weaken the principle of strict liability and to introduce an unreasonable burden on consumers who cannot be expected to know what the state of the art of the product concerned is. It was also stated "*the principle of equitable allocation of risks should apply to both undetectable as well as detectable defects. It is not just justified that due to such a relativization of the strict liability principle, the individual consumer has to bear the full risk and the eventually negative consequences of scientific development and limitations.*[8]"

Producers' associations' point of view

Producer associations' opinions: producers associations were (and still are) opposed to the abolition of the state of the art defence. They argue that its exclusion would discourage scientific and technical research as well as the marketing of new high tech products (Simon, 1987, p. 203). Supporters of the state of the art defence pointed out that it is necessary to protect producers from the unpredictable consequences of liability to avoid a situation in which producers lose the incentive to innovate (Cavaliere, 2001, p. 7). Pharmaceutical producers stressed the fact that the original justification for the clause was to provide an overall balance between the interests of consumers, industry and the government in sharing risks and

[7] Barret, *Comité consultatif de consommateur,* Document CCC/156-75-F, 5.
[8] BEUC, Response to the Commission Green Paper on Liability for defective products (COM (99) 396 final), p.8.

the financial consequences for injury caused by products. However, it is still believed that the use of the defence is (and will be) extremely rare and only theoretically relevant in a small number of cases. In fact, the wording of the defence is extremely restrictive and could only serve in very rare circumstances. Taking all things into consideration, the defence is considered to be a critical factor in the protection of European innovation[9].

1.1 Definition of development risk, the "state of the art", and how the defence works

The interpretation of the expression "development risks" has been rather problematic. Development risks may be defined as risks that become apparent only when a new product is used. The classic example often used by scholars is Thalidomide, a medicine that was taken by pregnant women for morning sickness, and in most cases caused abnormalities to the fetus[10].

The interpretation of Article 7 (e) of the Directive

It has been discussed whether Article 7 (e) of the product liability directive introduced a form of liability with fault or has limited the producer's objective liability in cases of development risks. Many authors have upheld the first theory (Trimarchi, 1986, p. 598). It should be noted that the state of knowledge is so broad that producers cannot be expected to know the entire state of the art. Therefore, they cannot be considered negligent if they have looked for available scientific and technical knowledge within reasonable limits. However, if the injured person succeeds in proving that there were some publications or instruments that indicated or allowed for detection of the defect, producers are considered liable (Cerini, 1996, p. 35).

The interpretation of the European Community's Court of Justice. This issue was dealt with by the European Communitiy's Court of Justice (the "ECJ") in the case n. 300/1995[11]. After analysing the development risks defence, the Court introduced an objective test stating that:

The ECJ interpretation

[9] European Federation of Pharmaceutical and Associations, EFPIA, Preliminary Comments on the workshop.
[10] French authors have defined developments risk as the "vice dormant". However it is true that development risks may cause damages that will be show up after many years, but it is not true that all the hidden damages depend on development risks (Cerini , 1996, p. 34).
[11] In www.europa.eu.int .

"(…) the defence can not be satisfied simply because the standards precautions in the interested industrial sector had been complied with.

26 First, as the Advocate General rightly observes in paragraph 20 of his Opinion, since that provision refers to `scientific and technical knowledge at the time when [the producer] put the product into circulation', Article 7(e) is not specifically directed at the practices and safety standards in use in the industrial sector in which the producer is operating, but, unreservedly, at the state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation.

27 Second, the clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been apprised, but the objective state of scientific and technical knowledge of which the producer is presumed to have been informed.

28 However, it is implicit in the wording of Article 7(e) that the relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation.

29 It follows that, in order to have a defence under Article 7(e) of the Directive, the producer of a defective product must prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation was not such as to enable the existence of the defect to be discovered".

The Advocate General's interpretation

The Advocate General refers to the factors affecting the circulation of information, citing the difference between a study carried out in the United States published in an international English-language journal and one that is published only in Chinese and does not exit the boundaries of this region. In a case such as this, it would be unreasonable to hold a European producer liable for a defect that the Asian researcher had found, since it is unreasonable to expect them to know about this work which was published only in Chinese. The 'state of knowledge' must include all data in the information circuit of the scientific community as a whole and must be read in the light of a reasonableness test based on the actual opportunities for the research to circulate. (parag. 23-24):

"23. The aspect which I have just been discussing is closely linked with the question of availability of scientific and technical knowledge, in the sense of the accessibility of the sum of knowledge at a given time

to interested persons. It is undeniable that the circulation of information is affected by objective factors, such as, for example, its place of origin, the language in which it is given and the circulation of journals in which it is published. To be plain, there exist quite major differences in point of the speed in which it gets into circulation and the scale of its dissemination between a study of a researcher in the United States published in an international English-language journal and, to take an example given by the Commission, similar research carried out by an academic in Manchuria published in the local scientific journal in Chinese which does not go outside the boundaries of the region. 24. In such a situation, it would be unrealistic, I would say unreasonable, to take the view that the study published in Chinese has the same chances as the other being known to a European product manufacturer. So, I do not consider that in such a case a producer could be held liable on the ground that at the time at which he put the product into circulation the brilliant Asian researcher had discovered the defect in it. More generally, the 'state of knowledge' must be construed so as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of a reasonableness test the actual opportunities of the information to circulate."

The English Court's interpretation

The "Manchuria exception" in English Courts. The principle expressed by the Advocate General has become known in the English Courts as the "Manchuria exception". The defence applies if, in that particular field, there exist only unpublished documents or research that is not available to the general public or is retained in laboratories or research departments of a particular company. Following this interpretation the state of the art has been construed "*as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of reasonableness test the actual opportunities for the information to circulate.* [12]"

Although producers' subjective knowledge is not relevant, the general available knowledge is of relevance. The possibility of using the defence does not depend on the subjective knowledge of a producer taking reasonable care in light of the standard precautions adopted in the industrial sector in question, but on

[12] A. and others v. the National blood Authority and others, case n. 1998 A458, (2001) Lloyds (Med) 289. Looking at the "Manchuria exception", the judge explained that the right approach is to look at the accessibility of the knowledge. The Manchuria test leads to consider the knowledge not accessible if there are no published documents or research on that particular product, whose defects are only known by a small producer in Manchuria within his/her undertaking and such a knowledge is not accessible.

the objective knowledge available that must be established with reference to the general scientific and technical knowledge.

The burden of proof: the burden of proof is on the producer, who has to prove that - according to the scientific and technical knowledge at the time when the product was put into circulation – the product could not have been considered defective, and that its defects were found out afterwards. The question is whether, in order to use the escape clause, the producer must show that no objectively assessable scientific or technical information existed anywhere in the world, which could have made producers aware of the problem, or whether it is enough for the producer to show that - although the existence of the defect in such a product was or should have been known - there was no objectively accessible information available anywhere in the world, which would have enabled a producer to discover the existence of that known defect in the particular product in question. Scholars have discussed this problem. It has been said that:

Scholars' opinions

- scientific and technical knowledge refers to all the accepted and available knowledge in the respective field, taking into consideration an international perspective and the opinions that have been published or that have been available without unfeasible economic efforts (Fitz et al., 1988; Posch, 1997; Welser, 1988);
- scientific and technical knowledge refers to the standards used to check the product; the producer is liable if can be proven that the product is not safe on the basis of the best level of knowledge (Verardi, 1990);
- the defence will be refused if the technical tools and process for discovery exist. It will be used in cases where discovery is absolutely impossible (Taschner, 1986, pp. 257,261).

The last opinion can be criticized because it imposes too rigid of a liability system and a too stringent burden of proof on the producer. Referring once again to the well-known thalidomide case, testing on pregnant animals began only after the negative effect of this medicine became known, and only after some time it was possible to pinpoint a particular type of animal which would display the teratogenic effect of thalidomide. At the time when the medicine was placed on the market, no one would have thought of testing the drug on that particular animal. Following the above mentioned theory, since the methods for

testing the drug exist and it was possible to discover its consequences, the producer was to be considered liable.

How to establish the general knowledge

In order to establish the general knowledge at the time when the product was put on the market, the judges may demand - as in the Netherlands - an expert's opinion that the producer could not have known the defect from the existing specialist literature or publications. An example from the Dutch case law shows that taking into account the state of the art, after blood suppliers have already carried out two regular and reassuring tests for HIV, they can not be required to do further experimental and laborious tests requiring equipment that is not even available yet. The court stated that the fact that there is a small chance that HIV could be transmitted via a blood transfusion did not constitute general knowledge[13].

Criticism on the directive's wording

The wording of the Directive has been criticised for the fact that it requires an absolute impossibility of detecting the defect. Therefore, the DRC applies only in very exceptional cases (Cousy, 1988, p. 118). Belgian scholars compared the wording of the Directive to the concept of "ignorance invincible du vice" of the product, and commented that the latter definition is broader than that of development risks. The state of the art defence does not require that only diligent producers' knowledge of a particular product be taken into consideration, but instead requires that all of the objective knowledge available be taken into consideration. Consequently, applying the development risks defence proves difficult (Von Kuegelgen, 1997, p. 79). Finally, it was also stressed that the available knowledge does not take into consideration producers' financial and technological capabilities, their specialisation, or the scientific and technological findings available in their specific trading area (Kornilakis, 2000, p. 201).

The appropriate time to assess the available knowledge. The time to take into consideration when assessing the available scientific and technical knowledge is when the product was put into circulation. The definition of "mise en circulation" indicated in the Belgian law is particular. In fact, it states that a product is put into circulation when the producer shows the intention to indicate its use by transferring it to other people or using it for the advantage of third parties[14].

[13] Distric Court of Amsterdam, 3.2.1999, in Nederlandse Jurisprudentie, 1999, 621.
[14] Article 6, law 25 February 1991.

The safeness of the product. Product liability rules apply when damages are caused by a defective product (defined as a product that does not provide the safeness and security that can be legitimately expected by law). Its safety is determined taking into account all the relevant circumstances such as its presentation and the use it can reasonably provide.[15] Therefore, the question to answer is whether the product can comply with the common security standards, and the expectations of safety should be those of the general public.[16] However, the product cannot be considered defective just because a better product has been placed on the market.

When a product can be considered safe

1.2 The implementation of DRC in the Member States' legislation

The Directive 85/374/EEC was implemented in all Member States. Consequently, the regime of product liability applies to all products, including agricultural natural goods and products coming from fisheries and hunting, with a few exceptions in some countries.

Models of implementation of the directive in Member States' national legislation

However, the implementation of the Directive has not gone without criticism, especially with reference to the state of the art defence. Producers pointed out that the exclusion of such a defence could have jeopardised their competitive position, inhibiting innovative research and the development of new products[17]. Those who were contrary to the defence said that its exclusion in the national laws guarantees consumers more complete and exhaustive protection (Von Kuegelgen, 1997, p. 79).

The analysis has been carried out with reference to Member States' national legislation that has implemented the EEC Directive focusing on the product they cover, with particular reference to the following products:

- Agricultural products
- Human/blood derivatives

[15] Riboux v S.A. Schweppes Belgium, 21.11.96, Civ Namur, 5e. ch.
[16] District Court of Amsterdam, 3.2.1999, in Nederlandse Jurisprudentie 8NJ), 1999, 621, Scholten v. Sanquin of Blood Supply.
[17] Halbury's Statutes, volume 39, 193.

- Pharmaceuticals[18]
- Chemicals

Table 4

Member State	Liability for development risk
Austria	No (3)
Belgium	No (3)
Denmark	No (3)
Finland	Yes (1)
France	Yes - Partially (2)
Germany	Yes - Partially (2)
Greece	No (3)
Ireland	No (3)
Italy	No (3)
Luxemburg	Yes (1)
The Netherlands	No (3)
Portugal	No (3)
Spain	Yes - Partially (2)
Sweden	No (3)
UK	No (3)

(1) The state of art defence does not apply to any product.
(2) The state of art defence applies only to particular products and/or in particular circumstances.
(3) The state of art defence applies to all products.

Regarding the application of the state of the art defence in Member States, there are three different models of implementation:

A - The state of art defence does not apply

Member States that do not apply the state of the art defence

In **Finland** and **Luxembourg** producers are liable in cases of development risks. The exclusion of the clause was not readily accepted by producers' associations and producer's trade unions. It was said that the exclusion of the state of the art defence would have curbed scientific and technical research

[18] According to Directive 2001/83/EC, on "the Community code relating to medicinal products for human use" a medical product is:
- any substance or combination of substances presented for treating or preventing diseases in human beings; - any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings. A substance is any matter irrespective of origin which may be: - human, e.g. :human blood and human blood products. Also vaccines are considered to be medicines.

and damaged the imports of foreign products in these countries. In order to export their goods to Luxembourg and Finland, foreign producers have to insure for the damages deriving from development risks. Consequently, their expenses increase, causing a negative effect on the final price of the product. There is no information available on legal proceedings where the development risks clause could have been applied.

B - The state of art defence applies to all products

Member States that apply the state of the art defence to all products

The development risks defence was introduced in most Member States and applies to all products without any exceptions. In the **United Kingdom, Italy, Ireland, Sweden, Greece, Portugal, Austria, the Netherlands, Denmark and Belgium**, doubts arose in regard to the definition of development risks and the precise time when to establish whether or not the state of scientific and technical knowledge did or did not allow for detection of the product's defect.

Differences between the UK Act and the EEC directive

The UK product Liability Act 1997: there are discrepancies between wording of the EC directive and UK Product Liability Act 1997, where Article 4 (1) (e) states that the producer can escape liability showing that "*the state of scientific and technical knowledge at the relevant time was not such a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control*". The provision of the UK Act differs from that of the EC Directive in that the latter refers to the state of the art at the time when the product was put on the market. The UK Act refers to another producer of the same product's knowledge, thus narrowing the point of reference to be taken into consideration when analysing whether the development risks clause applies. Due to its wording, the development risk clause contained in the CPA has been considered a "victory for the producer's lobby" (Caldwell, 1987, p. 614). The interpretation of section 4 (1) CPA, in fact, shows that the pressures exerted by the Confederation of British industry, which stated that the exclusion of the state of art defence "*could jeopardise our competitive position by producing a climate in which innovative research and development of new products is inhibited while our competitors suffer no corresponding restraints*" [19] prevailed, and the state of the art defence was introduced in the CPA using an expression different from that in Article 7 of the EEC Directive. The difference between section 4 of the UK Act

[19] Halbury's Statutes, vol. 39, 193.

and Article 7 of the EC Directive was finally analysed by the ECJ in case n. 300/95, Commission v. UK. The Court concluded that, notwithstanding that there was a difference in wording, it could not be concluded that the UK intended to interpret its statute differently from the Directive, nor was the UK entitled to do so.

C - The state of art defence does not apply for particular products and in particular circumstances

Member States that do not apply the state of the art defence to all products

In some Member States, the state of the art defence does not apply to some specific products. In **Spain,** producers are liable for development risks caused by food, food stuffs, pharmaceuticals and blood derivatives. In **France** and **Germany**, after the scandals resulting from contaminated blood (France) and defective pharmaceuticals (Germany), it was decided that the producer of blood derivatives in France and pharmaceuticals in Germany is always liable, even for the defects which where not known by the science and technology available at the time when the product was placed on the market.

France: the state of the art defence is ruled by Article 1386-11, paragr. 4, of the civil code and it applies to all products with the exception of human derivatives[20]. Article 1386-12, paragr. I, civil code, states that the above mentioned provision does not apply when "le dommage a été causé par un élément du corps humain ou par les produits issus de celui-ci", namely when damage was caused by human derivatives or by other products deriving from them. Moreover, the effect of the exemption for development risks was limited also by Article 1386-12(2) which states that the producer cannot invoke - in a specific circumstance - the grounds of exemption from liability under subparagraphs 4 and 5 of Article 1386-11. This provision says that if producers become aware of a defect within ten years from the time when the product was put on the market, (including a defect due to a development risk) and do not take any of the steps they are obliged to take (i.e., recalling or repairing the product), they cannot escape liability by proving a development risk. France was criticised for having put an additional burden on producers because of this provision. The ECJ ruled that: "*47 In regard to the arguments based on Article 15 of the Directive, it should be noted that whilst that provision enables the Member States to remove the exemption from liability provided for in*

[20] Article 1386-12, paragr. I, Civil Code.

Article 7(e) thereof, it does not authorise them to alter the conditions under which that exemption is applied. Nor does Article 15 authorise them to cancel or amend the rules governing derogations provided for in Article 7(d). That interpretation is not negated by Directive 92/59, which does not concern the producer's liability for products which he puts into circulation. 48 Accordingly, the Commission's third plea is also well founded.[21]"

Germany: Before the implementation of the Directive, **German** national legislation on product liability required producers to prove one of two things in order to be exempted: either that the defective product was the only one that got by all checks, or that the defect depended on a risk the producer could not have foreseen at the time it was manufactured. The German implementation of the European Directive on product liability with the Produkthaftungsgesetz of 15 December 1989 removed the "*odd unit defence"* and maintained the product development risk defence except in a few cases (Larouche,1999, p. 2-3).

Specific rules for **medicinal products** were established under the German Drug Law ("Arzneimittelgesetz") after the Contergan-Thalidomide case. The German Drug Law, taking into account the direct impact that medicines have on the human body, provides for producer's liability in cases of development risks. Section 84 (1) of the German Drug Law states that pharmaceutical companies are liable for development and production risks. A producer that places a hazardous product on the market is liable for previously unforeseen and also for unforeseeable defects. This liability system covers production and development risks that are avoidable at the time when the pharmaceuticals were placed on the market. The scientific knowledge at this specific time is used as an instrument of measurement.

Spain: Under Article 6 (1) (e) of the Ley 22/1994, manufacturers and importers can escape liability by proving that "*the state of existing scientific and technical knowledge at the time when the product was put into circulation did not allow to find out the existence of the defect*." It refers to development risks that are unexpected events called "incertitumbres". Under Article 6 (3), the state of the art defence is excluded for pharmaceuticals, food and food products for human consumption. The aforementioned article states that "*in case of medicines, food or food products directed to human consumption, under the present law,*

[21] ECJ, 25 April 2002, C 52, Commission of the European Communities v. French Republic, in www.europa.eu.int .

the liable subjects cannot call for the exemption provided by letter e) of paragraph 1 of this article." Since the most dangerous risks can arise in the pharmaceutical and food production fields, the Spanish legislator chose a stricter form of liability by establishing that producers of pharmaceuticals, food and food products are liable for development risks.

Table 5

	State of art defence			
Member State	**Agricultural products**	**Human/blood derivatives**	**Pharmaceuticals**	**Chemicals**
Austria	yes	yes	yes	yes
Belgium	yes	yes	yes	yes
Denmark	yes	yes	yes	yes
Finland	no	no	no	no
France	yes with exception (*)	no	yes with exception (*)	yes with exception (*)
Germany	yes	no	no	yes
Greece	yes	yes	yes	yes
Ireland	yes	yes	yes	yes
Italy	yes	yes	yes	yes
Luxembourg	no	no	no	no
Netherlands	yes	yes	yes	yes
Portugal	yes	yes	yes	yes
Spain	yes excluding food a and products for human consumption	no	no	yes
Sweden	yes	yes	yes	yes
UK	yes	yes	yes	yes

(*) The state of art defence does not apply if, within ten years after the product was put on the market, its defects were discovered and the producer did not adopt all the necessary measures to avoid the damage.

2. *The DRC and its economic impact on producers*

The preliminary results of the DRC's economic impact were obtained by questionnaires and interviews carried out by the research group during the first phase of the project. The principal part of the analysis was the DRC's impact on innovation. The significance given to the issue is evident not only by questionnaires gathered, interviews and the workshops, but also by an analysis on the replies to the European Commission's Green paper (http://europa.eu.int/comm/internal_market/en/goods/liability/replies.htm). The different attitudes towards the DRC are classified as in table 6.

As shown in the table, three main facts are quite evident:

- the DRC is not meaningful to a significant number (more than a third) of the socio-economic actors that have replied to the Green Paper, but have not commented on this specific topic
- innovation is a key topic; it is the reply that ranks highest both for and against the DRC
- those favouring the DRC (roughly stated, the view of producers) is significantly more articulated than those who are against it (consumers' view).

The replies to the Green Paper show a tight connection between the DRC and innovation, in which producers' position are multi-faceted.

Altogether, this information suggests that the relationship between innovation and the DRC should be examined, and that - by observing the more varied positions in favour of the DRC - the phenomenon should be investigated in many complex and articulated dimensions.

Table 6

Stance	Argument presented	Percentage
None	No opinion expressed	35.9%
Opinions in favour of maintaining the DRC	Removing the DRC would hinder innovation	35.0%
	Society benefits from innovation and should take development risk	13.6%
	It would be impossible to insure development risk	10.7%
	The burden of proof required by the DRC is demanding enough	9.7%
	Liability should be kept as it is, but co-ordinated with licensing and monitoring schemes	4.9%
	Competitive pressure is enough to promote the state of the art and safer products	3.9%
	Firms cannot advance the state of the art and should not be held liable for it	3.9%
	There is an ambiguous connection between liability and administrative authorisations	1.9%
	Liability is not the right way to tackle wide-ranging risks	1.9%
	Consumers would sue because old products not as safe as new ones	1.0%
	Not all sectors are the same and should be treated differently	1.0%
	Liability should provide incentives for the development of safer products, not make firms act as insurers	1.0%
	Firms could/should be held liable, with the criterion of foreseeability of the risk	1.0%
Opinions against the DRC	It is not fair that consumers bear the full risk of innovation	6.8%
	The DRC introduces ambiguity in the principle of strict liability	3.9%
	If the DRC was removed, insurance costs would increase slightly and be paid by consumers	2.9%
	Since consumers must prove defects, it is fair that producers bear development risk	1.9%
	Manufacturers have best knowledge on risk, so they should hold development risk	1.0%
	Firms should be held liable, but with a cap	1.0%

2.1 Theory

The relationship between innovation and product liability represents an important and complex subject for discussion. In order to understand the fundamental elements of this relationship, it should be noted that placing the emphasis on manufacturing defects rather than design defects shifts the conceptual framework rather substantially. Liability on manufacturing defects tends to affect less innovative firms, whose process technologies do not guarantee state of the art quality and safety, while liability on design defects exerts a more subtle and unclear effect on the rate of product innovation. In the latter, there appears to be a typical U-shaped relationship, which results from contrasting effects. On one hand, less innovative companies incur higher liability costs either in terms of expected value of risk or in terms of insurance costs. Along the same lines, the introduction of strict liability should induce such companies to either increase their level of innovation or to exit the market, thus resulting in an increase in aggregate innovativeness of the industry.[22] On the other hand, it is evident that highly innovative companies face a much higher level of uncertainty when introducing new products than their non-innovative counterparts. Where there is a stricter application of liability, the risk-related cost of uncertainty is higher. Companies would in principle cope with such uncertainty using two alternative strategies: they could either try to reduce the level of uncertainty by focusing their efforts on more predictable and conventional trajectories and decreasing the level of radical innovation, or, they could direct innovation efforts towards quality and safety-related product features. As a consequence, it is certainly very difficult to asses whether the innovative effort displays a positive or negative relationship with respect to a stricter or looser application of liability.

It can certainly be concluded that the kind of innovation performed by the industry is bound to change. In particular, strict liability regimes would induce greater process innovation, an increased rate of incremental innovation but a substantial collapse in product variety, radical innovation and basic research. In order to support this point of view, there are a few empirical studies (Viscusi 1993) illustrating the fact that firms

In principle, a stricter liability regime should favour incremental, rather than radical, innovation, and process, rather than product, innovation.

[22] In this report we adhere to the mainstream meaning of the English term "industry", which refers to the aggregate of the companies operating in an economy or to the set of companies operating in a specific sector. When referring to individual companies, we will use the term "firm".

that introduce new products are characterised by higher liability burdens. The average ratio between product liability insurance premiums and firms' sales is 5 % greater for firms with significant product patents. However, the reverse is true for process patents: firms in industries without process patents have a 15% higher product liability cost rate. The reason may be that safety oriented innovation in the manufacturing process can reduce manufacturing defects and liability costs. More in depth statistical analysis concludes that overall product liability also positively affects product innovation, except at very high levels of liability where on the whole there is a net discouraging effect.

In general, it can be concluded that higher liability is bound to increase innovations that are strictly related to the problem of providing more safety. Moreover, liability exerts a positive effect on process technologies, when these latter are aimed at providing safety. Nevertheless, an increasing level of liability can depress innovation when such innovative efforts are not specifically directed to improve safety. Experts' views seem to converge on the issue that product variety, product novelty and radical innovation react negatively to strict liability regimes. In extreme cases, it is argued that the only feasible strategy for the company, when strict liability is enforced, is to quit any innovation effort, since the expected value of the risk associated to uncertainty becomes unbearable.

2.2 Empirical evidence drawn from questionnaires and interviews

It is difficult to ascertain the impact of the DRC, because there are very few instances of use in court.

The state of the art defence introduced by the Directive was defined in order to strike a satisfactory compromise between the need to stimulate innovation and consumer's legitimate expectations for safe products. One of the main issues expressed in the current debate on the DRC is that removal of this clause would stifle innovation. If one looks beyond the principle empirical evidence about the impact the DRC has on either innovative behaviour or consumer safety, such evidence is quite scarce indeed. As demonstrated in the second part of this study, case law shows but a handful of times the DRC made its way through the judicial process. The following are the main explanations obtained through individual interviews and workshop discussions:

- courts and lawyers do not have enough knowledge and experience with the DRC; lawyers do not trust using this argument in court, also because national laws often provide parallel avenues for litigation by using pre-existing civil legislation (for instance, the concept of "liability for dangerous activities" in Italy);
- the DRC is generally considered to be a defence to be applied to extreme and rare events. There has not been enough time for a significant number of cases to arise since the Directive was implemented into each Member State's national law (the United Kingdom was the first to implement it in 1987 and France the last in 1998);
- many cases that could use the DRC are pre-emptively settled out of court because companies do not wish to taint their reputation by making a public use of the defence and/or they do not want to establish a precedent of losing a liability suit, which would probably lead to a flurry of similar events. The fact that firms prefer to settle before going to court because of these reasons, rather than to simply reduce litigation costs, is confirmed by the fact that settlement always include non-disclosure clauses which bind the two parties to secrecy over the transaction;
- cases that could use the DRC do not end in court because the clause provides a well-defined benchmark for assessing liability. Since companies in general have aligned their products to the state of the art, the possible use of the DRC discourages claimants from suing. Should this position prove to be right, this would confirm the validity of the DRC to entice companies in developing products that are at the state of the art with respect to safety.

This may be explained on practical grounds (little knowledge by practitioners and interference with pre-existing civil legislation), objective reasons (rarity of cases in which the DRC may be applicable and high degree of product safety) or to a widespread use of undisclosed out-of-court settlements.

It is difficult to prove any of these explanations from an empirical point of view, partly because information on some of them would be kept confidential by firms, and partly because it is difficult to find associations with events that have not occurred. The other option - using higher-level proxy indicators that may be easier to measure (e.g., Research and Development expenditure) - would instead suffer from the loose relationship they have with the variables that directly describe the effect of

Correlation between strictness of liability regimes and economic and innovative performance is difficult to ascertain on empirical basis.

the DRC[23]. It is likewise very difficult to analyse the correlation between liability regimes and innovative performance by looking at differentials due to dissimilar national law[24], since local policy and industry specialisation are correlated (policy tends not to be punitive towards local industry, while industry can relocate according to policy) and – most of all - because companies nowadays generally do not operate within the boundaries of a single country (Campbell et al., 1998). This latter statement is also particularly true for European businesses, which operate in a very tightly interconnected single market.

We do not observe differences between European countries where the DRC is not applied, either in general (e.g., Finland and Luxemburg) or in specific industries (e.g. France, Germany and Spain).

Comparing countries with different regimes, it is interesting to observe the macro-level innovative performance of a country like Finland. Finland and much-smaller Luxembourg, are the only countries in the EU that refused to implement the DRC in their national law, but this apparently has not affected their position among the most innovative European countries. Figure 1, taken from the 2002 European Innovation Scoreboard, shows that Finland ranks well above the European average for most of the indicators used. It is, of course, impossible to ascertain whether this is due to the fact that the lack of the DRC does not influence business at all, or that Finland can leverage its substantial exports (approximately 29 % of GDP, of which one third goes to the rest of the EU) to countries where the DRC does exist.

In the same way, insurers do not consider exports to these countries to be more risky. Instead, they do apply higher insurance premia for exports to North America.

The possible irrelevance of the DRC was observed in our contacts with industry and insurance companies, though the limited size of the sample requires this observation to be treated with caution. Insurers and associations of insurance companies confirmed that the questionnaires they use to evaluate product liability require firms to declare their exports made to the NAFTA region (which is considered a high-risk area), but do not check for exports to EU countries where the firm might be held liable for development risk. Similarly, 94 % of producers reported that they do not take any special provisions when exporting to these countries. It cannot be determined whether this is due to the fact that the DRC is irrelevant, or whether

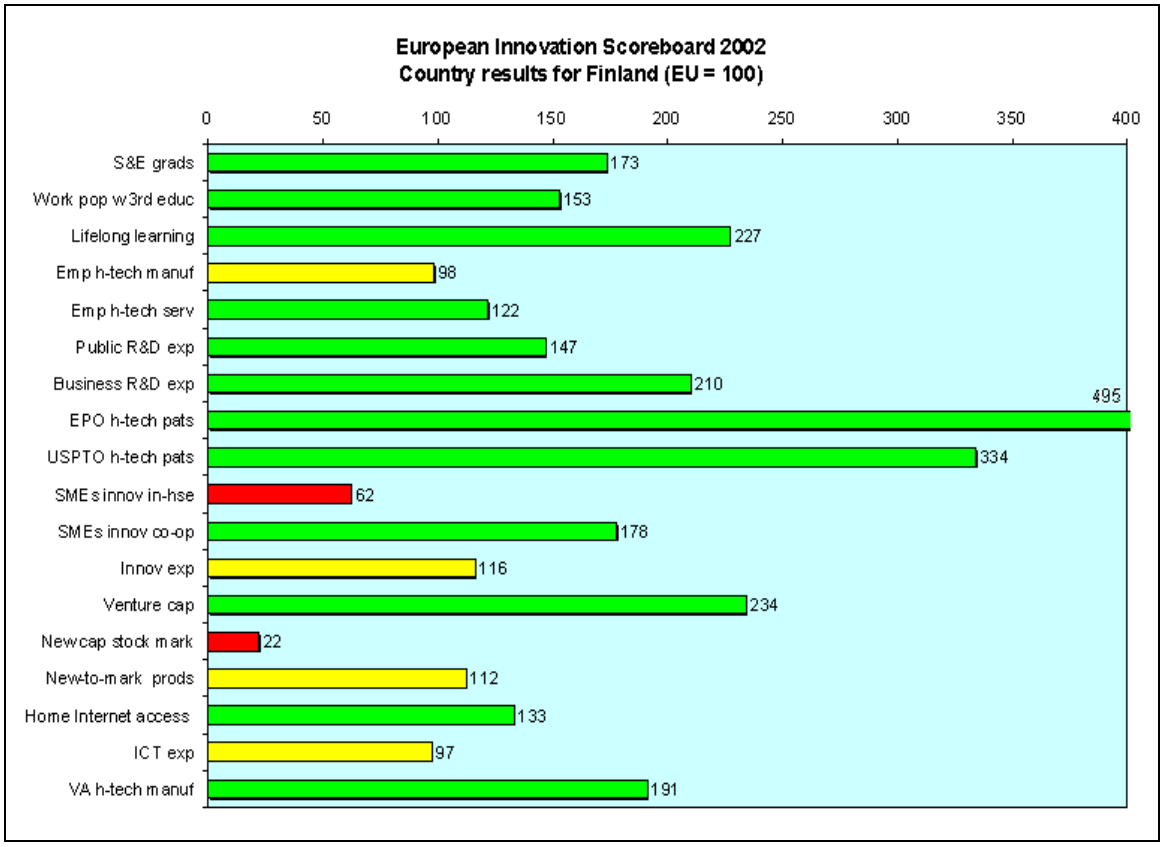
[23] A similar problem has been encountered by scholars from the United States when trying to assess the relationship between liability and innovation (Litan 1991). So, when looking at data from the United States, one find the paradox of an overwhelming amount of anecdotal evidence showing the negative impact of strict liability on innovative performance (see for instance the analysis available for a number of industries in Hunziker and Jones, 1994), but a dearth of sound empirical evidence.

[24] For instance, Campbell et al. (1998) find some correlation between laws imposing a cap on liability and labour productivity growth, but they recognize that the effect is far from being certain.

companies are simply "taking chances" for what amounts to a small part of their business.

Similarly, evidence lacks for other instances where the DRC is not applied (medicinal products in Germany, human derivatives in France and, in Spain, pharmaceuticals, food and food products for human consumption) has led to significant change in business and disruption of innovative performance.

Figure 1



It is undeniable that liability laws in the United States have affected business to some extent, but scholars have generally pointed out that this effect is not due to different doctrine but – rather - to the way the US's judicial process works (Litan 1991, Garber et al., 1998)[25]. It is recognised that the American judicial system tends to adversely affect business in the field of liability not because of the liability burden *per se*, but because of the

The business impact of liability risks in the United States is high indeed, but this may be attributed to the way the judicial system works, rather than to different legislation.

[25] In the specific case of the DRC, it should be remarked that European doctrine seems to US, where the concept of "reasonableness" applied to design defects tends to moderate th and lead it closer to the principle of negligence (Owen 1996).

climate of uncertainty that goes with it. In this context, the most critical factors of the US system appear to be the following:

- the tendency of untrained juries to side with claimants and to deal with expert witnesses in an incompetent way,
- the large differences in the way state and federal courts deal with liability cases,
- evidence discovery rules, which cause businesses to lose inordinate amounts of time to "clean up" internal documentation in the fear it might later be seized and held as evidence, [26]
- the practice for dealing with legal expenses, which creates a system in which filing a liability claim becomes something similar to buying a lottery ticket with low entry cost and a high potential outcome,[27]
- the unpredictability of sums awarded for pain and suffering and for punitive damages, which does not allow companies to reliably weight costs and benefits of their operational decisions with respect to safety.

Comparisons with the U.S. suggest that sound policy should simultaneously be equitable and lead to an environment with low uncertainty. The DRC has the merit of providing firms with a clear reference for evaluating product safety.

One could therefore conclude that if Europe does not want to experience the "liability crisis" that occurred in the United States, any change in legislation should assure that the resulting law is not only equitable, but also creates an environment with low uncertainty, in which all parties can make their decisions in a rational and well-informed way.

In conclusion, it can be said that the DRC has had the merit of providing industry with a clear-cut reference for evaluating product safety. At the same time, there is no evidence that the

[26] A number of authors report that the way liability cases are dealt with in the United States leads – paradoxically enough – to products which are more unsafe. For instance, for fear that an internal memo on a product defect might be used as evidence in the future, companies tend to use unwritten communications, which are less efficient and often cause to leave the faulty design as it is. Moreover, after the III restatement of the Law of Torts, companies are sometimes wary of launching new and safer versions of their products. This happens because juries might interpret the decision to improve the product as an implicit admission that the original product was unsafe and that it could have been substituted by a "reasonable alternative design". This implies a gross misunderstanding that substitution of older designs with alternative and improved ones is at the heart of technological innovation.

[27] In most States claimants and their lawyers agree on contingency fees that depend on the success of the case. On the other side, we have learned from literature (Litan, 1991) and from our U.S. legal correspondent that losing parties are seldom required to pay for the other parties' legal expenses. A court would be expected to ask a losing consumer plaintiff to pay the legal expenses of a successful defendant producer only if claims were found to be absolutely frivolous and pursued with a lack of good faith. The combination of these two practices makes petty litigation quite attractive.

absence of the DRC in specific countries and/or industries has significantly hindered innovation.

The questionnaires sent to producers and consumers had a common question, where respondents were required to express their opinion by selecting the degree to which they agreed or disagreed with ten statements. This enabled their perception of aspects related to the DRC to be evaluated. The findings are summarised in Table 7.

Table 7

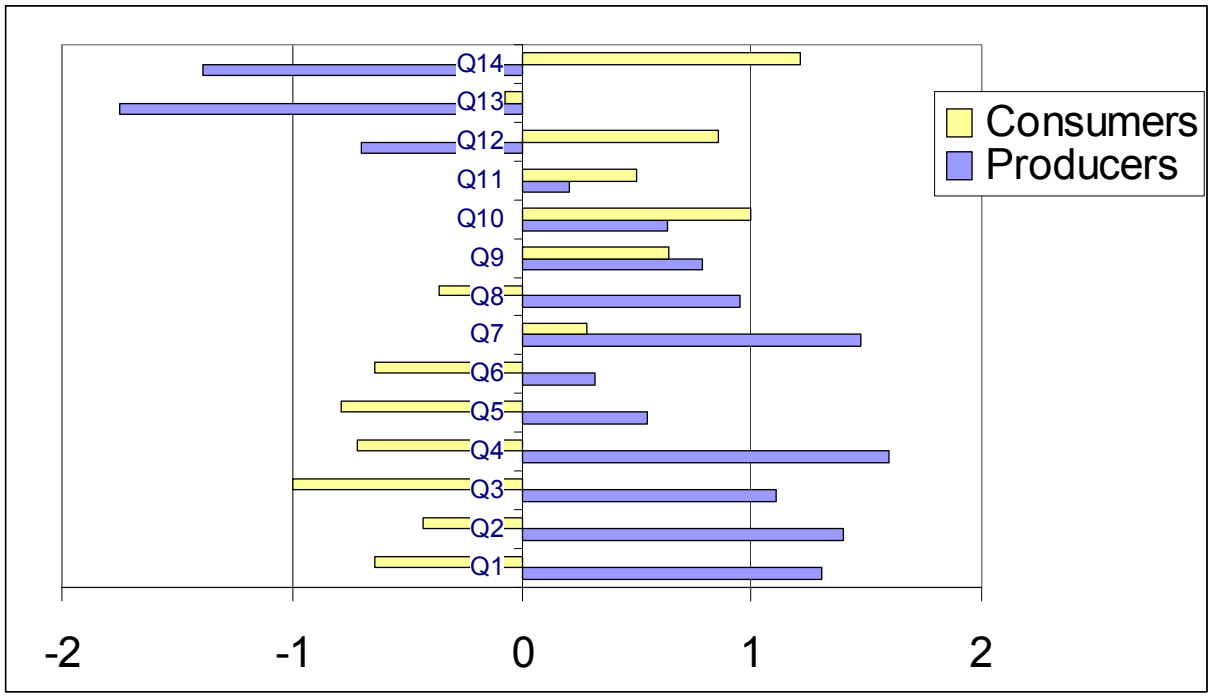
Statement	Average degree of agreement (-2 = strongly disagree, -1 = disagree, 0 = not an issue, 1 = agree, 2=strongly agree)	
	Producers	**Consumers**
Q1. Removing the DRC would prevent companies from innovating	1.30	-0.64
Q2. Society benefits from innovation and should therefore cover development risk	1.39	-0.42
Q3. It would be impossible to insure development risk	1.10	-1.00
Q4. The DRC requires companies to prove their position, and this is demanding enough	1.60	-0.71
Q5. Competitive pressure among firms is enough to promote the state of the art and safety of products	0.55	-0.78
Q6. Firms are not able to advance the state of the art and should therefore not be given this burden	0.31	-0.64
Q7. Removing the DRC could keep a firm liable after administrative authorisation has been granted	1.47	0.28
Q8. Liability has to do with individual firms, and is not the right way to tackle wider risks at societal level	0.94	-0.35
Q9. Development risks are different according to industries, and should be treated differently	0.79	0.64
Q10. Better safety can be obtained by co-ordinating licensing, monitoring and finally liability	0.63	1.00
Q11. Companies share the benefits of innovation with consumers and society, and should therefore share the related risk	0.21	0.50
Q.12 The DRC introduces ambiguity in the principle of strict liability	-0.7	0.85
Q.13 Removing the DRC would not cause excessive increase of insurance costs and would anyway be paid by consumers	-1.75	-0.07
Q.14 Manufacturers have the best knowledge on risk, so they should be held liable	-1.38	1.21

Source: questionnaire to producers and consumers.

The figures in table 7 (above) show the degree that the varying opinions in the two stakeholder categories are "mismatched", (demonstrated graphically below in Figure 2). It is fairly evident that although a number of statements do lead to a rather confrontational debate (namely questions 1 - 6, 8 and 12 - 14), there are a few arguments that may be viewed as a relatively common ground for establishing policy (namely questions 7, 9 10 and 11).

The surveys carried out during the study show that consumers' and producers' opinions on the DRC are not divergent on all issues. There are some shared views that may be used as a common ground for developing policy.

Figure 2



Source: questionnaire to producers and consumers.

2.3 Impact on company's performance

In most studies, the impact of liability on business practice is often limited to a rather high-level evaluation of indicators such as profitability, R&D (Research and Development) expenditure, and so forth. In the context of an item as specific as the DRC it becomes worthwhile to try to take the analysis to a deeper level and to open up the firm's "black box", to highlight three main relevant issues of how research and development is actually run and, finally, to relate this to the DRC.

It is appropriate to investigate the relationship between liability and the "inner works" of the innovation process.

Firstly, there is no such thing as "strict liability" when one examines corporate operations. Firms' operations are essentially based on routines, norms and procedures that may be formal, or informal and tacit. This routine-based perspective is shared by most scholars in the field of innovation economics and strategic management, who also agree that the way with which companies change and adapt to the environment consists in modifying and introducing new procedures and norms (Teece et al., 1997). According to this view, companies will deal with a change in the legal liability regime by adapting their internal product development process to the extent that it is possible or economically viable[28]. Most firms have a formal and highly company-specific product development process that follows a set of quality assurance and product safety guidelines. Any change in liability legislation would be followed by an update of these guidelines and protocols[29], and then the firm would monitor that all people involved in the product development process act in accordance with these guidelines. The surveys submitted by producers demonstrated that the majority of firms have actively translated the current DRC regime into either "making personnel aware of the need to be constantly updated about the current state of the art" (47 % of respondents) or "putting in place a formal procedure for exploring the state of the art" (27 % of respondents).

Companies adapt to liability regimes by designing internal procedures to which employees are required to comply. So, it is easy to have gaps between external liability and the degree of safety that is achieved in actual operations.

The role of corporate routines and procedures may have a significant implication with respect to the effectiveness of liability law. Even if a company is externally subject to strict liability, in reality this regime will be transferred to the employees who make product development decisions in terms of "negligence" with respect to internal standards. Such "negligence" rarely goes beyond disciplinary proceedings or the firing of the employee[30]. The consequence idea is that, should the DRC be eliminated, companies would react by choosing among the following options:

Should the DRC be eliminated, firms would tighten internal procedures to the extent possible, and tackle residual risk by looking for insurance and/or reducing R&D on riskier innovations (which is viewed by some stakeholders as a positive effect).

[28] This can be observed quite commonly in the engineering sciences literature, where the liability legislation is routinely "translated" into proposals for procedural changes to the development process (Wyman 1989, Dowlatshahi 2001, Peters 1998, Ross 1998, Summer 1989, Hecht 2003) or in which defects showing up in liability cases are often traced back to faults in the design process (Hales 1998).

[29] For instance, a firm might enforcing a more thorough "testing of alpha-prototypes" at stage x of the process, or introduce a more stringent "failure mode and effect analysis" at the development stage y, and so on.

[30] Apart from the explanation coming from the routine-based perspective, it would be very difficult to imagine a company transferring strict liability to its employees, exception made for professional organizations acting in a field where the concept of malpractice is more easily codified and where individual responsibilities are easy to ascertain.

- create or adapt R&D procedures so as to reduce the development risk they would now be liable for (which would be a desirable effect for increasing product safety),
- seek some form of insurance or financial coverage, provided that development risk may be properly evaluated and efficiently insured (which would be a second-best option because it would not improve product safety but simply provide consumers with greater protection after the damage has been caused),
- abandon products whose development risk is too high to bear, difficult to insure, or costly to reduce through targeted R&D activity (which, depending on the viewpoint, could be considered to be either a first- or a third-best solution, because of its negative effect on innovation[31]).

In the short term, the choice between these three alternatives would depend on a number of firm-specific factors, such as the ability of the firm to engage in R&D targeted to reducing development risk, which might be of a quite different nature with respect to R&D aimed at improving product performance. The key issue remains the fact that firms can virtuously internalise changes in legislation up to the point where they are able to turn then into internal procedures. Other further options would be either seek some form of insurance or simply forsake the business.

However, insurers would refuse to cover development risks.

According to the survey, the first impression about how companies would react to the abolition of the DRC, 36% of producers stated they would "invest additional resources in safety-related R&D activities in order to reduce Development Risk", 32 % claimed they would "try to get insurance coverage for the additional risk" [32], 24 % would "stop or greatly reduce

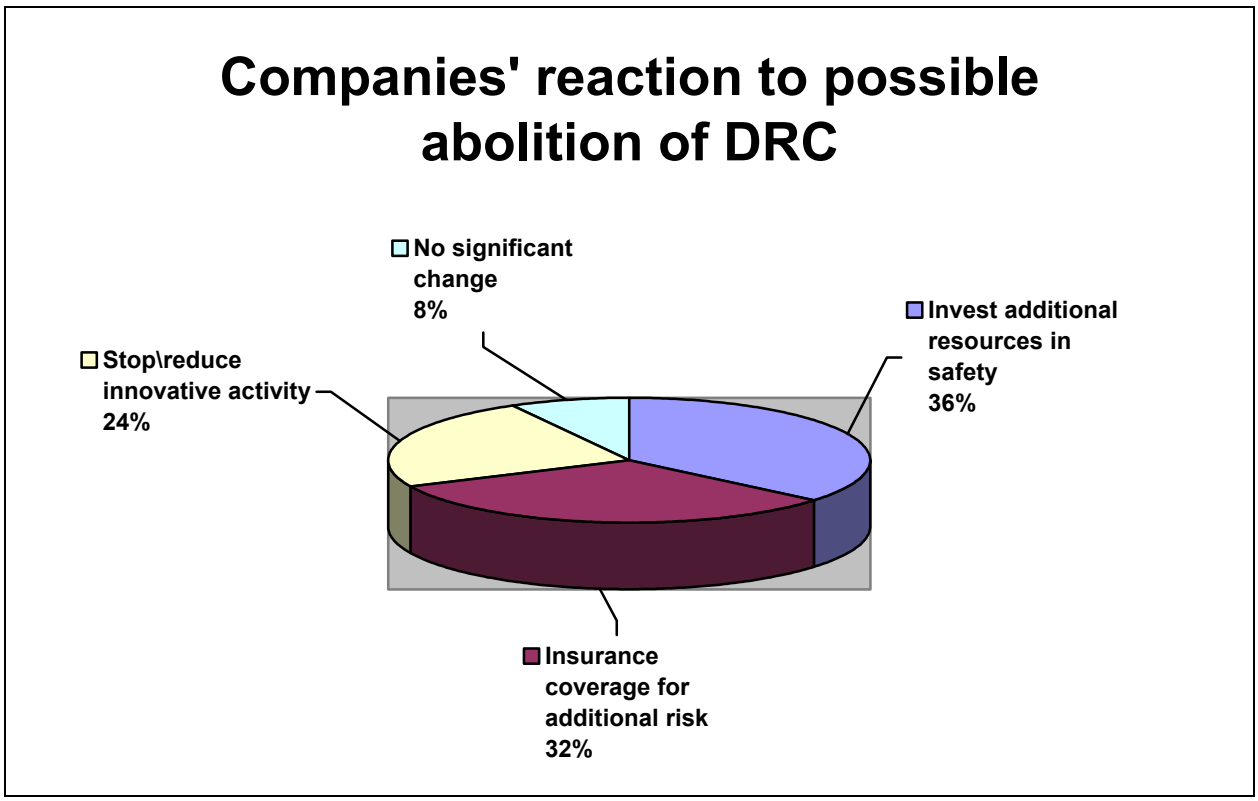
[31] It is noteworthy to mention that viewing the abandonment of riskier fields as a societal loss is based on the hypothesis that any kind of innovation is good *per se* and that the only interference to the innovation process should be to reduce the associated risks. We have encountered alternative and more "interventionist" positions that probably go beyond the scope of liability and tort law. According to these positions, the societal value of technological innovations depends on issues wider than simple technical effectiveness and must include aspects such as safety risks and environmental sustainability. So, should riskier innovations be abandoned because of development risk, this ought to be valued as a positive, rather than a negative, result. More comments on the societal value of innovation may be found in the following footnote 9.

[32] As it will be further discussed further on, insurance companies could refuse to provide coverage for development risk, irrespectively of premia. Such a position is based on two main reasons. First, insurers are not able to correctly

innovative activity", while 8 % state that "there would not be any significant change" (Figure 3).

evaluate development risk because of lack of statistics and information asymmetries. Secondly, even if one could evaluate the firm-specific development risk, this would prevent insurers from performing mutual pooling of risk across a set of producers, which is the very basis on which insurance companies operate.

Figure 3



Source: questionnaire to producers and consumers.

Firms do not react rationally to the unknown. Removing the DRC could – depending on the case – lead to both under-reaction ("take chances") and over-reaction (exit the industry).

Another idea demonstrated by the survey is that firms do not react rationally to what they cannot cope with. Managers' decisions are known to be based on limited rationality. Especially when dealing with events characterised by high uncertainty and catastrophic consequences, it is common to observe over-reaction and decisions made with respect to worst-case scenarios. This appears to be a fundamental cause of the US "liability crises" which has led many US firms to extreme and apparently irrational decisions in product development (Garber et al., 1998). Removing the DRC could, as a consequence, promote virtuous behaviour and create an efficient incentive for developing safer products only for those companies who have the capability to correctly evaluate development risk and to enact activities, such as targeted R&D, to reduce it. Other firms may over-react and abandon the

business, or adopt an opportunistic behaviour in order to reduce potential liability[33].

Excessive liability can distort tradeoffs in business decisions. Should this lead to the withdrawal of life-saving goods, the outcome could be socially undesirable.

Finally, product development is a world dominated by trade-offs. Especially when designing a complex product with many functions and modes of malfunction, there cannot be any "best" design, but only a compromise between performance, life-cycle issues (such as serviceability, environmental impact, ease of recycling, etc.), safety and – of course – cost. Moreover, as noted by Yelkur et al. (2001), firms "*must continuously find a trade-off among consumers generally, who desire an optimal balance between usefulness, cost and safety; future injury victims, who retrospectively desire absolute safety; and shareholders, who desire safety levels that will generate the highest profit*." The tension between technical aspects and between stakeholders' objectives creates a very complex environment for decision-making, in which any source of uncertainty is dreaded by companies and may lead to a socially inefficient outcome, especially for life-saving products[34].

2.4 Linking development risk to the technological life-cycle

Damages due to development risks can be viewed as outliers with low frequency and high value.

To briefly summarise the previous discussion, we have observed that instances of defective products involving development risk are very rare in case law and that the impact on business and insurance due to different legislation (e.g., Finland vs. the rest of Europe) appears to be negligible. This leads to the hypothesis that, despite the fact that development risks are indeed an important issue, they cannot be viewed as part of the product development operations that ordinarily occur within firms. Instead, they must be tackled as statistical outliers with low frequency and, presumably, a very high economic value. As a matter of fact, when talking to industry

[33] For instance, a firm could spin off its riskier operations in a limited liability company and go for bankruptcy in the case of a large liability suit. Enticing this deceptive behaviour, which we have been told is sometimes used by companies exporting to the US, would not increase product safety and would ultimately leave consumers with little or no protection.

[34] For life-saving innovations, such as pharmaceuticals, vaccines or medical devices, companies would evaluate the business case for a product by comparing expected profits (unit profits times a forecast of units sold) against expected liability costs (unit liability costs times the likelihood of the event occurring). From the social point of view this could be harmful, should it lead firms to drop products that save many lives each year, but provide little unit profit, because of the risks associated to liability events that are rare but very costly to them. Correspondents from the United States have told us that – until they have been exempted by a specific statute - hospitals had started refusing blood transfusions from outside the family because they feared suits due to Hepatitis in contaminated blood. Similar considerations can be made for many other cases, such as vaccines, etc.

and consumers about instances of product liability that may involve development risk, the examples that are always taken up range from Thalidomide in the 1960s to the more recent events regarding blood infection due to HIV and Hepatitis, or the BSE[35]. This said, the analysis on development risk cannot be conducted by statistical means, but by trying to profile the roots of excessive development risk with respect to circumstances, severity and behaviour of stakeholders. In order to identify such a profile, the following discussion will be taken a bit "to the extreme", neglecting factors that may have significant impact on firms' behaviour, such as the use of product safety as a feature that may attract consumers, companies' fear of losing a good reputation, basic ethical principles, and so on. It is now possible to examine measures for managing this excessive risk, so that it may be both reduced and appropriately assigned as far as liability is concerned.

It is convenient to "profile" the conditions under which the DRC may lead to excessive development risk

The study has identified four possible methods of classification, which will first be discussed separately and will then be examined together.

2.5 Industry structure and the locus of knowledge creation

The DRC states that "*the producer shall not be liable as a result of this Directive if he proves […] that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered*." The application of this clause must therefore cope with what should be intended by "scientific and technical knowledge". In the case mentioned above (case 300/1995), the ECJ explained that this concept is intended for objective and general terms. Therefore, it includes scientific and technical knowledge "*of which the producer is presumed to have been informed*" and "*is not specifically directed at the practices and safety standards in use in the industrial sector in which the producer is operating*." At the same time, this concept excludes unpublished and private knowledge ("*the relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation*") held by other parties. Since European courts do not usually order the indiscriminate seizure of corporate documents for examination by plaintiffs' expert witnesses, the "state of the

Current legislation is ambiguous concerning privately-held knowledge on product safety and defects

[35] This does not exclude the existence of "minor" cases involving development risk, but we strongly feel that, due to their limited incidence, the debate should focus on the "large and few" and not on the "possible minor" cases.

art" ("SOTA" for purposes of simplification) the DRC refers to does not actually include the private knowledge held by the same defendant. In other terms, if the defendant privately knows about the possible dangers one of their products may have, then they might still use the DRC to be exempted from liability.

The DRC's effect can be attributed to two important variables: industry structure and whether relevant knowledge is produced and held within the industry or exogenously (e.g., research bodies, suppliers, etc.). The four combinations shown in Table 8 provide quite different scenarios with respect to the effectiveness of the DRC.

Table 8

Knowledge creation **Industry structure**	**Endogenous**	**Exogenous**
Monopoly or oligopoly with co-operation	**With DRC** "…keep the SOTA from advancing" **Without DRC** "… advance the SOTA"	**With DRC** "…keep at the SOTA ("clear boundary") and advance it" **Without DRC** "…move towards the SOTA until unprofitable"
Competitive	**With DRC** "…keep at the SOTA ("clear boundary") and advance it" **Without DRC** "…move towards the SOTA until unprofitable"	**With DRC** "…keep at the SOTA ("clear boundary") and advance it" **Without DRC** "…move towards the SOTA until unprofitable"

In the case of a competitive industry, the DRC provides firms with a clear-cut reference for product development and with an incentive to advance the state of the art.

For competitive industry, the state of the art may be defined by the knowledge created by industry players alone (endogenous) or with other parties (exogenous). In either of the two cases, the DRC provides a clear boundary for firms to be exempt from liability. Therefore, firms are given incentive to be at the state of the art by being constantly updated on relevant findings. Questionnaires submitted by companies reported that the DRC had mainly led to an informal policy of "making employees aware of the need to keep abreast of the state of the art" (47 %), while "formal procedures for scanning the state of the art" have been established in 27% of cases. Of course, keeping at the state of the art entails an effort in R&D that, from time to time, helps the firm advance that same state of the art, thus allowing the

progressive development of safer products. This is, for example, the opinion automotive manufacturers expressed in their replies to the Green Paper. In this context, removing the DRC as a "clear boundary" and placing complete liability on firms' shoulders could lead to a more ambiguous and varied behaviour, since each firm would decide to invest in safety-related R&D up to a company-specific point beyond which it would be unprofitable to commit further resources.

In the case of a monopolistic industry, or in the case of close co-operation occurring within an oligopoly, the effectiveness of the DRC is reversed when knowledge is endogenously created. With the DRC in place, firms would have an incentive **not** to advance the state of the art, since this would decrease their chances of escaping liability[36]. The effect of this choice on product safety would indeed be damaging. Conversely, without the DRC firms would be completely liable and the incentive to perform research on product safety would be restored[37]. If in the same competitive setting (monopoly or oligopoly with co-operation), knowledge creation is exogenous to the industry, the objective nature of the state of the art would once again provide a clear boundary. The DRC should be seen as an incentive for safer products while its removal could lead to a more ambiguous outcome.

Conversely, in the case of concentrated industries producing most of the relevant knowledge, the DRC provides an incentive not to advance the state of the art on product safety, and to keep information on known defects secret.

In conclusion, it may be stated that the DRC is a double-edged sword that may, depending on industry structure and on the existence of knowledge sources external to the sector, provide incentives that either favour or prevent the development of safer products.

[36] We are not saying that companies actually act this way all the time, though there have been cases of negligence or fault of this sort. The well-known tobacco industry case in the United States was precisely an instance of firms having private knowledge of the dangers associated to their products and withholding it. While such reckless behaviour must be censured in ethical terms and ought to be legally prohibited, it is fairly easy to explain in economic terms. A firm operating in a market and having committed substantial specific resources that cannot be easily modified and diverted to a different sector will go at great lengths to defend its future income (this, for instance, is the reason explaining price wars initiated to fight new entrants off). In our specific exercise of profiling development risks by taking liability as a sole criterion for decision-making, this indeed would be the rational behaviour undertaken by the firm.

[37] One should also examine with detail the instances in which knowledge appears to be created outside the firm, as in the case of research performed by universities. If such research is industry-funded, it is possible that explicit non-disclosure clauses, or the tacit threat of not renewing the grants, could lead the researchers to the selective publishing of research findings that are not critical with respect to liability of the funding firm. Knowledge, which is critical to product safety, would therefore be withheld and become akin to private knowledge of the firm. Being difficult for a plaintiff to access it, it would therefore escape the definition of "state of the art".

2.6 The pace of innovation

The state of art regarding product safety generally improves in an industry thanks to two main mechanisms. On one hand, industry can dedicate resources to specific R&D activities. These activities can range from basic research into investigating the root causes of potential harm, to greater care exercised during the product development process, e.g. in product testing. Alongside this direct process, the state of art increases because of companies' reaction to product failures on the marketplace. Products in use provide industry with large amounts of information that are key to improving product safety under different conditions of use (mission profiles, weather conditions, etc.) and over time (e.g., fatigue, long-term health effects, etc.). Basically, we now drive safer cars thanks to studies carried out by industry into how people have suffered injury in car crashes over the last century or so.

In industries with a relatively slow pace of technological innovation, the DRC provides a clear reference for product development.

In industries where the pace of innovation is faster, the DRC does not restrain firms from widening the gap between technical performance and safety.

In industries where the pace with which technological innovation increases performance is relatively slow, the development risk will tend to decrease over time. In such cases, growth in the relevant state of art coming from R&D and/or from market experience will in fact be faster than the pace of innovation. Hypothetically, the DRC could become an incentive to be at the "clear boundary" defined by the state of art and that its removal could lead – as previously discussed – to more ambiguous behaviour. In industries where the pace of technological innovation is faster, the slower feedback from the market (especially concerning long-term effects) will make the relevant state of art increase relatively slower than product performance, thus increasing the development risk. In this case, an exempting clause such as the DRC would leave companies free to continue on their technological trajectory despite the widening gap between their technical performance and their current knowledge with respect to safety[38]. Removing the DRC would instead provide an incentive to slow down the pace of innovation and keep it in line with the progress made by the state of art concerning safety matters. This then gives rise to another issue: social benefits of greater precaution compared to

[38] To the extreme, it could be thought that this would be an incentive to speed up innovation and "get away with the profits" before problems appear.

social and competitive disadvantages caused by slower innovation[39].

[39] In the survey of producers, the subset of firms that have declared they would reduce innovative activity in reply to removal of the DRC have declared that such decision would mainly depend on the size of liability (60% of respondents) or the speed of technological development (30% of respondents).

Table 9

Types of industry problem	Industries with rapid pace of innovation	Industries with slower pace of innovation
Enhancing safety often requires firms to provide new and improved product versions and markets (testing them under different conditions and over time – for fatigue, long-term health effects, etc.)	**With DRC** "…promote quick but "open-chain" innovation" **Without DRC** "… slow down the pace of innovation and keep it in line with feedback arising from the market"	**With DRC** "…keep at the SOTA ("clear boundary") and advance it" **Without DRC** "…move towards the SOTA until unprofitable"

2.7 Architectural and incremental innovation

Technological innovation can be categorised in many ways, but one relevant criterion distinguishes between product architecture change and component change. The first type of innovation is fundamental to industry because it leads to determining dominant designs and standards[40]. Dominant design and standards are key elements in a product's life cycle, because when an industry reaches a consensus on their definition, virtually all products in the industry will share the same architecture and the diffusion process will take off. More important yet, firms will make significant specific and non-recoverable investments for developing, manufacturing and servicing products with this architecture. For defects found in specific contexts (i.e., allergic reactions due to the plastic material in the casing of telecommunications equipment), having or not having the DRC might have the "usual" effect of providing a clear boundary for safety vs. encouraging a firm's to behave more ambiguously.

In the case of defects associated to individual components, the DRC provides a clear-cut reference for product development

Should a defect be found in the dominant design (i.e., should EMG radiation released by the same equipment cause harm), having the DRC or not can be seen as a factor determining different behaviour. With the DRC in place, firms would have the incentive to pursue the technically more efficient dominant design without too many concerns for safety, knowing that the still-lacking state of art would provide a shield against liability.

[40] For further explanations on the key role of dominant designs and standards, and on the relationship between the two, one can refer to Utterback (1994).

They would however exercise **some** care knowing that – should harmful consequences arise – the specific investment made would not be recoverable and that it would be very costly to modify the dominant design. Without the DRC, firms would probably deal more carefully with safety because of the liability they could risk. The adoption of a dominant design would therefore be delayed until sufficient knowledge was gained on the subject. Again, this leads to a trade-off between precaution and innovation.

The DRC provides a limited incentive for developing a safe dominant design. Eliminating the DRC would delay the adoption of dominant designs and standards and, therefore, diffusion of innovative products in the market.

Table 10

Type of innovation Problem	Radical	Incremental
Radical (new-to-the-world) innovations entail considerable development risk, while development risk is lower for **incremental** innovations. Analytical models show that high development risk and potential liability leads to extreme behaviour by firms For radical innovations, consumers may both over and underestimate development risk.	**With DRC** "…pursue innovation without too many concerns for safety". Diffusion could be hindered by consumers' fears. **Without DRC** "…either promote or stop innovation, depending on the amount of potential liability and the attitudes of customers (a firm taking DRC can signal confidence to fearful customers)".	**With DRC** "…keep at the SOTA ("clear boundary") and advance it" **Without DRC** "…move towards the SOTA until unprofitable"

2.8 Radical and incremental innovation

Another dimension for profiling development risk lies in the difference between radical (i.e., new-to-the-world) and incremental innovation. It is obvious that incremental innovations have low development risk (i.e., the state of art that concerns safety is sufficiently rich) while radical innovations have higher development risk (i.e., the state of art is still lacking). It might be expected that as in the previous cases, with incremental innovations, the DRC would provide a clear boundary to be reached, while its removal would probably encourage a more indefinite behaviour. Concerning radical innovations, instead, the exemption from development risk allows firms to progress with R&D without too many concerns for safety. Should the DRC be eliminated, theoretical studies endorsed by empirical research show that high potential

In the case of incremental innovation, the DRC provides a clear-cut reference for product development

liability (Viscusi and Moore, 1993) and high development risk[41] lead firms to extreme behaviour, such as abandoning the innovation altogether[42] or, conversely, undertaking substantial research in order to reduce development risk. The case of radical innovation strongly depends on the attitudes of consumers towards radical innovation. In some instances, customers do not value the higher development risk at all, while in others they might over-react to it[43]. In the latter case, a firm accepting liability for development risks may provide a reassuring signal to the market, thus stimulating demand, while exemption from such risks leaves consumers with greater doubt on product safety[44].

Eliminating the DRC would hinder radical innovation. However, should companies accept liability for development risks, this could be viewed by consumers as a reassuring signal on safety of innovative products.

Type of innovation Problem	Radical	Incremental
Radical (new-to-the-world) innovations entail considerable development risk, while development risk is lower for **incremental** innovations. Analytical models show that high development risk and potential liability leads to extreme behaviour by firms. For radical innovations, consumers may both over and underestimate development risk.	**With DRC** "…pursue innovation without too many concerns for safety". Diffusion could be hindered by consumers' fears. **Without DRC** "…either promote or stop innovation, depending on the amount of potential liability and the attitudes of customers (a firm taking DR can signal confidence to fearful customers)".	**With DRC** "…keep at the SOTA ("clear boundary") and advance it" **Without DRC** "…move towards the SOTA until unprofitable"

2.9 The problem of immature technology and changing scenarios

If one considers all the previous dimensions, it is possible to find the occurrence of situations within the technology life cycle, where development risk is high and where the DRC

[41] Author's study on a model adapted from Viscusi and Moore (1993).

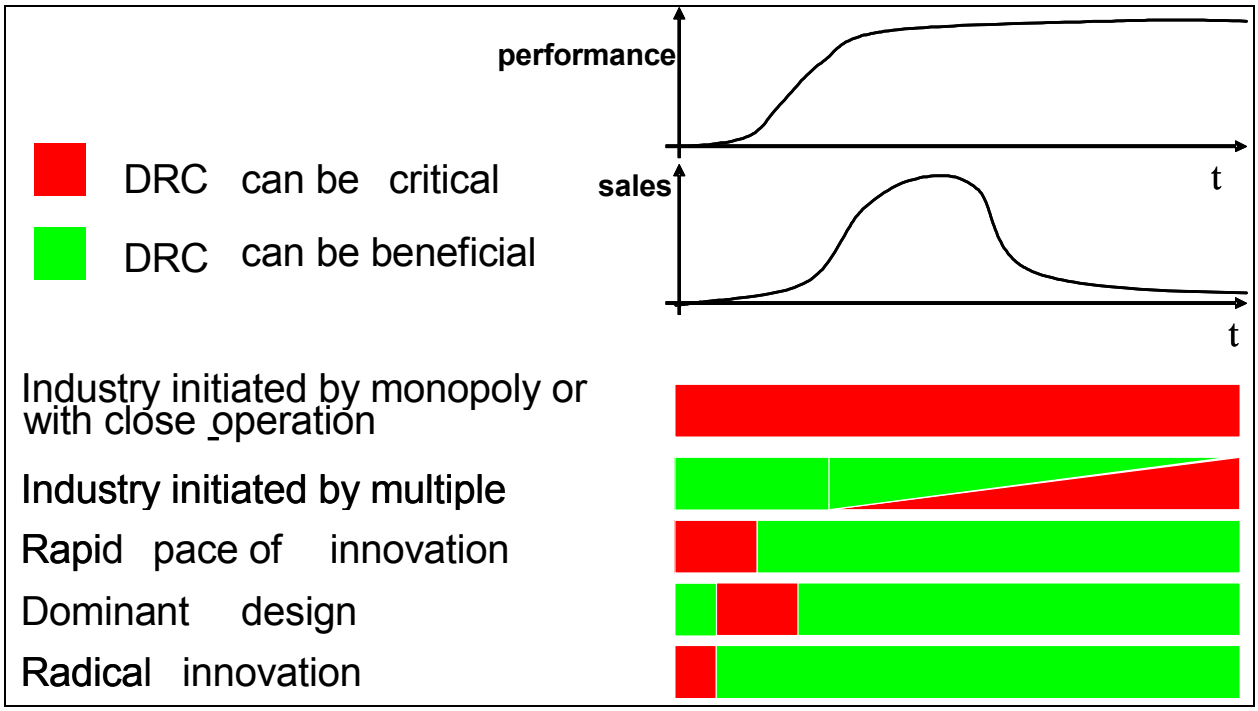
[42] To this purpose, Sunding and Zilberman (1998) note that allocation of strict liability to early-stage hazardous products being developed by a monopolist at the beginning of the life-cycle may result in underproduction from the point of view of social welfare.

[43] To this purpose, one may think of the two opposite cases of cellular telephones being intensively used, despite the many rumours on their hazards to health, and the strong opposition made to GMO food, despite the many years of use throughout the world.

[44] On the connection between liability, innovation and signalling, one can refer to Daughety and Reinganum (1995).

might provide firms with incentives contrary to greater product safety (figure 4).

Figure 4



Aggregating the previous classification makes it quite apparent that high development risk, together with the DRC giving out critical signals to companies, is typically associated with:

- the choices made at the beginning of the technological life cycle. Even though harmful effects may arise much later, the chances of developing a potentially damaging product because of insufficient knowledge are generally higher for immature technology of a radical nature, with little or no experience "from the field", coupled with rapid innovation,
- industries initiated by one or several companies privately owning the relevant knowledge, or industries where commoditization leads to such a situation later in the life cycle.

In summary, the DRC works well in most cases. However, it provides misleading incentives in the case of immature technology and/or with concentrated industries having private ownership of relevant knowledge.

The conclusions on the DRC debate are quite obvious: in any other case, the DRC does probably not have such a significant effect, but it can be seen positively as it reduces uncertainty and provides firms with a sufficiently clear idea of the safety levels

they must achieve in order to avoid liability. By urging firms to keep abreast of the state of art, the knowledge available within the industry tends to increase, progressively leading to safer products. The boundary provided by the DRC can also be seen as a factor that limits excessive litigation (probably by favouring out-of-court settlements), which is known to be an economically inefficient way for compensating victims[45]. If one observes the critical situation being experienced in the United States, keeping excessive litigation under control should be an important issue for policy makers. A major concern should remain, however, for the situations profiled above. In such cases, the DRC may be considered as providing an insufficient means for consumer protection but, above all, a clause that provides distorted incentives concerning product safety.

To complicate matters further, the previous discussion has argued that problems associated with the DRC **originate** during the phases in which technology is in its infancy. However, safety problems due to development risk issues often **manifest** themselves after a substantial amount of time. In our interviews with different industry players and examination of records of past incidents, this can be put down to two main factors: long-term effects and changes in the operating environment.

The first aspect occurs by definition for defects having long-term health effects (e.g., exposure to asbestos, BSE incubation period) and, even more, because statistical evidence showing a link between alleged fault and incident needs substantial time to originate (the product must be widely available on the market) and time to be researched.

Past events show that high development risk and distorting influences of the DRC may also arise in other instances. Defects may have long-term effects, while a changing operating environment may cause previously safe products to become extremely dangerous.

The second aspect is associated with a number of past events and occurs when a mature and seemingly safe innovation becomes unsafe because of exogenous change. For instance, the HIV blood contamination incidents occurred because procedures used to screen blood for transfusions were adequate for "traditional" diseases, but not for "new" problems such as HIV. Similarly, the practice of using meat and bone meal for animal feed had been used for about seventy years without causing any apparent harm to either livestock or people. The BSE pandemic arose for several reasons, including some change

[45] Numerous authors (see for example Cooter, 1991) have commented on this subject, noting that about one third of the sums awarded by US courts in liability cases end up being spent in lawyers' fees and other litigation costs, while a substantial part of these sums are awarded for economically unnecessary damages, such as "pain and suffering".

in the agent causing the disease, or when it was passed down the food chain.

In conclusion, the previous discussion shows how development risks exist during the infancy of new technology (with the DRC providing a potentially distorting incentive to firms) and how complete safety will in any case be very difficult to achieve because such risks tend to emerge over long time spans and/or because of exogenous change.

The complexity of the problem suggests that a simple removal of the DRC would probably cause more problems than it solves. In our colloquia with industry and consumer representatives, it was stated several times that the DRC's current form provides a balance between the expectations and needs of the different stakeholders involved in the liability debate; namely industry, consumers and society. So, even if it could be recognised that the DRC does not perform appropriately in specific and important circumstances, a prudent policy would act so that modifications are localised as much as possible to such specific circumstances, and that accompanying measures are developed, so to maintain a balance in the liability system. The following section comments on this problem and attempts to provide solutions.

2.10 From liability to risk management

Policy must acknowledge that technological innovation provides society with both benefits and with risks. Development risk has to be managed and not simply "swept aside".

The starting point of a discussion on remedies for development risk should be by acknowledging that modern technology provides society with major benefits, albeit riddled with considerable risk. Uncertainty on long-term effects of innovation does exist and must be appropriately managed, if our society is to gain from the socio-economic benefits accruing from innovation. This is particularly true for Europe, if one heeds the Lisbon strategy of making our continent "the world's most competitive and dynamic knowledge-based economy", where there is an obvious link with technological innovation being both the product and the milieu where such an economy can develop itself.

In our discussions with stakeholders on the DRC topic, the debate was generally quite strong and tended to be based on seemingly impossible-to-reconcile matters of principle (e.g., "it is not fair that…") or matters of fact (e.g., "it is not possible to…"). One statement that could be seen as a common ground for all parties was that development risks do exist and must be

appropriately managed (if not, no one would fight so hard to have others keep them).

We experienced this to be a constructive starting point to avoid a confrontational debate where the tendency may be to 'sweep the problem under the carpet', or 'simply throw it into the opponent's yard'. The policy objective therefore becomes something broader than just deciding "who should bear and who should be responsible for development risks" but, given that our society will continuously have to tackle such risks, "how can these risks be appropriately managed" [46]. Deciding on liability and compensation after harm is done, is an important part of this objective, but it must go together with the objective of controlling such risks before they can cause harm.

A generalized removal of the DRC would probably cause more harms than benefits.

In this context, an indiscriminate extension of producers' liability to include development risks would probably cause more harm than benefit, for the following reasons:

Firms would not be able to make fully rational choices, and their responses would not necessarily be socially desirable.

- complete liability over unforeseeable events could lead firms to irrational decisions in R&D and innovation at all levels, from the structuring of the project portfolio down to individual design decisions. In such a setting, attitude towards risk could prove more important than the objective risk associated to products. In other terms, it is possible that risk-averse firms developing relatively safe products would feel deterred from innovation, while risk-prone firms developing more unsafe products could go on with their production and "take the chance". Moreover, strict liability is economically efficient only if those involved can correctly estimate risk, and then equate the marginal advantage due to risk reduction with the marginal cost of greater care. In the case of development risk such knowledge may be imperfect, and this too would lead firms to either over- or under-react with respect to the economically efficient response;

[46] Incidentally, the debate on the DRC has a strikingly close parallel to debates occurring in the field of ethics. Traditional ethics was based on the assumption that the effects of human actions are limited, but the far-reaching effects of modern technology have changed the terms of the debate and led to develop innovative criteria for ethical behaviour. Following Hans Jonas, the famed proponent of the "Ethics of responsibility" (1984), "*No one was held responsible for the unintended later effects of his well-intentioned, well-considered, and well- performed act.* The short arm of human power did not call for a long arm of predictive knowledge. ... All this has decisively changed. Modern technology has introduced actions of such novel scale, objects, and consequences that the framework of former ethics can no longer contain them." (italics added to highlight how this sentence on "old ethics" is similar to the current DRC).

- leaving firms completely liable could become a strong incentive for excessive litigation, since plaintiffs would be guaranteed compensation by demonstrating the existence of a defect and of the causal relationship with the harm suffered. It is possible that this could lead to a worrying situation with petty litigation, such as the one found in the United States,[47]

Leaving firms defenceless would promote litigation, U.S.-stvle.

- complete liability will rarely provide enough financial coverage to compensate victims in the typically large damages caused by development risk[48]. Firms can be liable up to bankruptcy (Cooter 1991), which in the end leaves society with uncompensated victims, a number of unemployed people and the societal loss of an otherwise well-performing firm, whose assets become dispersed. Faced with complete liability, firms could also act opportunistically, spinning off dangerous activities in order to limit their exposure,

Victims would not be fully compensated, because of firms' limited liability and insurers' refusal to provide coverage.

- as has been previously discussed, companies translate a regime of strict liability in a negligence regime within their business processes.

Removing the DRC would therefore lead firms towards tighter internal policies on safety, but with some degree of residual risk uncovered and to act as an improper insurer to this risk. Development risks would not be easy to insure, except those cases where they are so low that having the DRC or not makes no real difference. Insurers have reported us that they are not able to evaluate development risk and that, even if they were, firm-level risk profiling would go against the mutuality nature of insurance activities. Their likely reaction would probably lead to two results: the cost of product liability insurances would increase slightly in some low-risk industries, while coverage would simply not be granted for higher-risk sectors.

Having thus excluded both keeping the DRC as it is now as well as its outright removal, it is possible to imagine a scenario where the DRC is kept, but alongside measures that may help

[47] The immediate reaction of our overseas correspondents to the idea of eliminating the DRC has been to say "who is pushing to have it deleted - American trial attorneys with good connections and wildly profitable cases in Europe perhaps?"

[48] The BSE case has led to 150 casualties and an estimate of 90 billion Euros damages to the livestock industry. It is obvious that cattle feed manufacturers are far from being able to provide sufficient backing to compensate damages to this order of magnitude.

achieve four important objectives, especially[49] in the critical cases outlined in the previous section:

- providing industry with unambiguous incentives and rules so that the safety of the products it sells is not jeopardised by insufficient knowledge, and accepting that this may lead to a slower pace of innovation in a few sectors,
- promoting continuous creation and knowledge transfer about safety in industry,
- providing a system for circumscribing the impact of damage due to development risks,
- providing adequate compensation for victims.

It is possible to envisage a system for "development risk management" able to shield from the shortcomings of the DRC. This system should be harmonized with legislation dealing with "General Product Safety" (2001/95/EC) and with industry-specific directives.

It is at this stage possible to outline a minimal set of complementary means that may help achieve the above stated objectives, in the acknowledgement that other measures are possible and may be added. These means have been drafted coherently with the "areas of agreement" between stakeholders that have been found through the survey sent to producers and consumers (see previous section 2.2 – esp. Figure 2). There is an obvious connection here with other EU directives, and especially the one concerning General Product Safety (GPS), both in the first version currently enforced by Members States (92/59/EEC) and in the more recent version that was due to be enacted in national laws on January 15th, 2004 (2001/95/EC). The "means" listed below are directly derived from the limitations of the DRC that have been previously discussed, without considering the mediating effect caused by such complementary legislation. A comparative study of the joint impact of the DRC and of GPS legislation has not yet been carried out[50], but elements which are present in the latter will duly be highlighted:

[49] The term "especially" implies that these measures could be either be adopted across all industries, or be enacted only in the most critical instances where the DRC could not perform properly. This concept of "dual path" of course leads to the problem of classification, which will be introduced in the following.

[50] Greater coherence between the two directives (and their transpositions in national legislation) should be observed closely. Directive 2001/95/EEC attempts "not to trample" on liability legislation from the side of decreasing consumers' rights. In point (36) of the preamble it states "This Directive should not affect victims' rights within the meaning on Council Directive 85/374/EEC … concerning liability for defective products". Article 16.3 instead states that "Any decision taken by virtue of this Directive and involving restrictions on the placing of a product on the market or requiring its withdrawal or its recall shall be without prejudice to assessment of the liability of the party concerned, in the light of national criminal law applying in the case in question". So, it is clear that compliance with

- schemes for product monitoring and recalls. Under the current liability legislation, companies are required to follow the state of art for new products but have no obligation to monitor the products' compliance which they have already released onto the market. There is such an obligation under GPS legislation, but this is not directly connected to liability. This distortion should be corrected. While it may be argued that it is not correct or economically efficient, to hold firms liable because of knowledge that does not yet exist, it is hard to sustain that firms should not take care of the products they have sold, should new critical knowledge be developed. The overarching objective of this measure would be to avoid having potentially dangerous products on the market, and a secondary issue would be the allocation of both the administrative costs of monitoring and recall processes, and of the technical costs associated to product upgrades or disposals. An equitable principle could be having firms provide the former and customers bear the latter[51].

A clear connection should be made between liability and obligation to monitor and recall defective products.

- mandatory industry-specific compensation funds, with contributions collected from industry and with government intervention in case of catastrophic events. Particularly in the critical areas outlined previously, industry must not be totally shielded from liability arising from the risks that it has taken due to insufficient knowledge. While complete liability and insurance have been shown to be unsatisfactory to achieve this, industry-managed compensation funds would probably provide incentives to align the pace with which it progresses technology and the state of art concerning safety,

Industry-specific compensation funds should be set up for providing coverage for development risks.

- creation and sharing product safety knowledge. The previous discussion highlighted that DRC rotates around the concept of "state of art". In the current interpretation this leaves too many loopholes open for irresponsible firms either hoarding private knowledge on critical

Knowledge relevant to product safety should be kept growing at an appropriate pace and publicly known, which suggests a stronger role for independent research.

the administrative requirements of directive 2001/95/EEC does not shield from liability. What is less clear is the extent to which non-compliance should lead to liability in those cases in which the DRC would exempt from it.

[51] Information technology could substantially lower the costs of monitoring and recall processes, by centralizing the procedure at industry level, eventually with the associated investment being covered by public resources. One could envisage a "monitoring portal" recall information from companies and distributing it to consumers. The example of the RAPEX system used by the GPS directive could be used to this purpose.

aspects of the products they sell, or not investing sufficient resources to increase such knowledge. In order for the DRC to perform correctly, it is necessary that the legally relevant state of the art (i.e. public knowledge) coincides with the actual state of the art (including private knowledge) and is kept growing at an appropriate pace. To this purpose, it is necessary to have sound independent research on product safety[52], together with mechanisms for efficient dissemination to all relevant stakeholders: i.e. firms, researchers, government[53] and the general public. Independent research may be publicly funded, or funded by industry via the previously mentioned compensation funds, and should be accompanied by some legal requirements to disclose information that may be relevant "for the public health". Of course, this "requirement to disclose" is very sensitive and should be carefully studied so that it applies accurately, since it should not reduce incentives to innovate on safety-related aspects. A firm using product safety as a competitive feature ("we make safer cars") would stop doing so if law required it to make such knowledge available to competitors;

– enforcing compatibility between the regime of administrative authorisation (including GPS legislation) and liability. It is possible that, in the future, excessive development risks will lead to a greater use of the instrument of administrative authorisation following the precautionary principle. In such cases, the current rule (according to which firms remain potentially liable even after they have been authorised to place the product on the market) leads to an unclear assignment of responsibilities between producers and public authority that must be solved.[54]

The ambiguous connection between administrative authorization and liability should be solved.

[52] This research on fundamental mechanisms of hazard modes and on processing of epidemiological data would also help avoid instances where so-called "junk-science" makes it way into courtrooms.

[53] As observed in the BSE crisis report, it is also essential that "Government Departments … retain sufficient scientific expertise to enable them to understand and review advice given by advisory committees" (BSE inquiry report, vol. 1, 1278).

[54] In practice, the current situation leads to the following paradox: the government at some time assumes on itself responsibility for evaluating whether a product is safe or not. Then, after some time, it uses such authority to tell the producer that he may place it in the market, according to a set of requirements. However, this decision is not truly responsible because, when authorizing, the government tells the producer that he will remain potentially liable. However still, since the DRC is in place and since damages may of catastrophic nature, the producer does not really assume such responsibility because – if something wrong happens – it will be fairly easy for him to use the state of

The following summary table 11 shows a qualitative way of how the proposed measures (in columns) could help obtain the desired objectives stated above (in rows).

Table 11

	Product monitoring and recall schemes	**Sector compensation funds**	**Mandatory independent research**	**Limitation of liability associated to authorisations**
Unambiguous incentives and rules for developing safer products		*X*	*X*	*X*
Developing and transferring knowledge	*X*		*X*	
Circumscribing the impact of damage	*X*			
Compensating victims		*X*		

As mentioned in the previous footnote, the four measures described above may be applied to all industry or – in order to reduce the burden - only to instances that appear to be more critical concerning development risk. It is possible to propose three different classification schemes:

The ambiguous connection between administrative authorization and liability should be solved.

- by sector. This is the traditional way with which hazardous and less-hazardous industries are profiled by both insurance and government. Not by chance, the DRC's partial removal by a number of Member States was based on sector definitions. This approach has obvious advantages of clarity, but bears the usual problems associated with ex-ante classification. Classifications tend to become obsolete the very moment they are published and this can be detrimental in the case of fast-moving technological innovation. At the same time, one cannot think of revising classifications too often because it would lead industry on an ever

the art defence (referring to the very thorough research that should have been performed by the government) and its limited liability to toss compensation of damages back to the government.

shifting ground (a company could find itself in the "critical" list every other year, making it impossible to be compliant with liability rules). Moreover, the previous discussion has shown that it is not the sector but industry structure and product newness that determine the conditions when the DRC may be critical;

- by administrative measure. An alternative way to identify areas where the DRC should be complemented by the previous measures is to let the administrative authority do so on a case-by-case basis, thus escaping the defects of an industry-based classification. Of course, this leads to greater administrative intervention in business, which is something firms usually dread, probably in the same way US counterparts dread the intervention of judges in their business. However, since it cannot be expected from industry and insurers to recognise and correctly manage critical (i.e. non-measurable) development risk, it is naturally up to the public authority to do so and force adopting the measures when it reputes it necessary[55].
- opt-in, opt-out schemes. This mechanism would require to take a seemingly opposite choice with respect to what has been said until now. Companies would be generally held liable for development risk, but would have the choice to opt in a regime in which they would be exempt from this liability, but with the obligation to adopt the four measures outlined above. This mechanism has the advantage of leaving firms decide for themselves which regime suits them. Low risk industries would probably accept development risk liability and find insurers willing to cover the risk at a reasonable price. Higher risk

[55] To this purpose, it is appropriate to read a few excerpts from the BSE inquiry report, even though one might view it as source that is biased by the situations under which it was written (italics in the text are added).
"… where there is uncertainty all reasonably practicable precautions should be taken. *Precautionary measures should be strictly enforced even if the risk that they address appears to be remote*" (Volume 1, 1283)
"… we consider it desirable that *legislation should clearly empower Ministers to take precautionary measures in a situation where the existence of a hazard is uncertain*. We believe that there are areas where this may not be the case. We have not attempted a detailed analysis of the law in these areas, for this is not part of our task. We draw attention to them so that they may receive further consideration" (Volume 1, 1305, italics added)
"… any powers under UK and European law which enable Ministers to adopt an alternative approach of banning the use of any substances for particular purposes in order to protect human or animal health should not be restricted merely because one or more of the matters referred to above cannot be established as a reasonable probability, as opposed to a mere possibility. *Current medicines and consumer protection legislation should be reviewed with a view to giving the Government power to act swiftly and comprehensively to ban the use of any substances or processes which might pose a risk to human or animal health.* " (Volume I, 1329).

industries would instead accept the more complicated regime defined by the four measures, in exchange for being exempt from liability due to development risk. A negative side to this scheme would be that low risk firms would be aggravated with limited insurance costs and would not have the "guidance" currently provided by the "state of the art principle".

2.11 From risk management to liability

An administrative system for "development risk management" can be very costly and ineffective.

The position above is clearly in line with the traditional European approach of demanding complex societal matters of appropriate regulating bodies, and is coherent with EU policy of issuing numerous safety directives and promoting associated agencies over recent years. It should however be noted that many doubts can be raised on regulations and regulators concerning both their effectiveness and efficiency. Concerning the former, the quality of a regulator's actions will depend on the knowledge of the people who work for them (managers and technical personnel) and on their ability to provide objective and fair opinions not influenced by economic and political pressure. Concerning efficiency, the costs needed to set up and operate a well-working "product safety and liability agency" would imply a major burden on the EU, and indirectly on European Members States having to finance it and companies in having to deal with it.

With these problems in mind, it is possible to imagine an alternative (or even complementary) regime for coping with development risk, which is similar to the approach favoured in the United States, where regulation of complex societal matters is generally left to the judicial system.

As an alternative approach, it is possible to suggest a liability regime in which firms are strictly liable up to the state of the art, but subject to a "negligence rule" for defects unknown to it. A defendant firm would therefore be judged on the efforts made in order to assess and manage development risk.

The previous discussion highlighted how, under the regime based on the DRC, the "state of the art" provides a watershed between "strict liability" and "no liability", and this "all or nothing" status sets misleading incentives to firms concerning the growth of knowledge on product safety. The alternative proposal would consist of using the "state of the art" to provide a watershed between a "strict liability regime" for defects known to the current SOTA (as in current legislation), and a new "negligence in development risk regime" for defects unknown to it. In other words, a company would be allowed to defend itself by showing that, given the technical and scientific

state of the art and corresponding development risk, (i) the decision to place the product on the market was not reckless and (ii) that it had done reasonable research (obtaining reasonably well-founded results) to advance the state of the art thus enabling development risk to be appropriately evaluated and reduced.

The advantage of this "negligence in development risk" regime is that firms would no longer have the incentive to restrain their safety-related research and/or hide negative outcomes from the same research. In fact, a firm's ability to defend itself in court in a liability suit would be proportional to the resources spent on the research compared to the positive findings that came out of it. On the producers' side, there should be no argument against the spirit of this regime which is designed to punish reckless behaviour; there could however be some concern about how it is applied.

This would do away with incentives to restrain safety-related research and keep defects secret.

Consumers would enjoy greater protection thanks to these incentives; not full protection however, as a firm's liability would still be constrained by bankruptcy in the case of catastrophic events (unless sector-specific funds were established to provide compensation).

Another problem would be a court's difficulty in ascertaining liability when evaluating "reasonable actions" in complex technical and scientific matters during a different time-frame from when the issue reaches court. However, since development risks are generally associated to rare catastrophic events with resounding impact, policy-makers should be able to accept the occurrence of a limited number of landmark cases, even if these individually lead to significant use of judicial system resources and expert witnesses. Coherently with this line of thought, in order to avoid petty litigation and focus on the main design defects, the "negligence in development risk" regime could be imposed on firms only for significantly large liability suits (e.g., when the number of damaged individuals exceeds a given limit).

Consumers would still not be granted full protection. The judicial procedure would become more complex, and the law should therefore be worded so to restrict applicability of the "negligence in development risk" criterion to major cases only.

The following table 12 provides a summary view of the positions stated above, with the centre row describing the current regime.

Table 12

Policy orientation	Scenario	Effect on consumers	Effect on producers	Other effects
GREATER USE OF REGULATION (E.U. – STYLE)	Introduce a "safety and liability system" with administrative measures complementary to GPS legislation[56]	- Consumers granted greater protection, depending on the capability of the "safety and liability system" to provide objective guidance	- Increased administrative burden when dealing with the "safety and liability system" - Need to contribute to the compensation fund	- Costly "safety and liability system"
CURRENT	Current status (DRC as option)	- Consumers may be supplied with unsafe products and without liability coverage in a few instances	- Firms tend to align their production to the state of the art - There are instances in which being aligned to the state of the art is not enough, and the DRC does not provide an incentive to advance it	- Product liability insurance provided at low cost (0.02 – 0.2 % of sales)
GREATER USE OF LITIGATION (U.S. -STYLE)	Introduce the concept of "negligence" in development risk	- Consumers granted greater protection as far as product safety is concerned, but without full compensation in case of catastrophic events	- Firms given an incentive to advance the state of the art where it is lacking	- Negligence in advancing a lacking state of the art difficult to ascertain in courts - Insurance on development risks provided only where such risk is not an issue. Coverage for development risk would not be provided where it would be most needed
	Take the DRC out	- Consumers granted a higher level of protection only in theory (see "impact on producers" to the right) but anyway not fully compensated in case of catastrophic events - Adverse effect on innovativeness of goods (particularly critical in the case of life-saving products)	- Firms lose the clear-cut reference to the state of the art provided by the DRC. - Firms would tighten safety procedures up (in some cases advancing the state of the art) and simply keep the residual risk - Firms would not be able to adapt their product strategy rationally and would either under-react (reducing product safety or "taking chances") or over-react (reducing innovation)	- Leaving firms defenceless would induce greater amounts of litigation - Insurance on development risks provided only where such risk is not an issue. Coverage for development risk would not be provided where it would be most needed

[56] Schemes for product monitoring and recall, industry-specific and European-wide compensation funds, creation of and sharing of knowledge on product safety.

3. *Development risk and producers' insurance*

3.1 The Economic Nature of Development Risk.

First, it should be specified that we are dealing with innovation-related risks (or development risks). Such risks are often unpredictable, i.e. it is very difficult to predict their occurrence in the future, due to lack of historical data and experience. Moreover, this report presents a survey of accidents which demonstrates that accidents and related damages are concentrated and particularly relevant in specific industries, such as agriculture, food, health and medical appliances, chemical products, vaccines and human derivatives. The nature of accidents in such industries is often very close to so-called "large accidents". In fact, reported accidents generally display some, if not all, of the following features:

Statistical nature of developmental risks.

1) damages are in excess of the injurer's assets;

2) several countries may be involved;

3) the probability that the accident will occur is normally very low;

4) since the number of very large accidents in the past is low, it is difficult to determine the probability of an accident occurring in the future.

The consequences to these features are straightforward. Firstly, since liability has an upper limit, this can, in principle, limit the incentives to take enough care in preventing damages. This argument is possibly very relevant in cases within the state of the art defence discipline. Secondly, victims are likely to be under-compensated in such circumstances. Thirdly, it may be difficult for insurance companies to define best practices and behavioural standards which companies should conform to when subscribing insurance policies. Finally, in consideration of this statement but not only, it may be difficult to have such risks insured. We now focus on these aspects that are strictly related to the impact of liability on producers' insurance.

Consequences of developmental risks' statistical nature.

3.2 Insurance against development risk.

Producers' insurance is certainly one way to provide victims with compensation while also allowing companies to afford high risk activities such as innovation and product development. Nevertheless, insurance policies also affect company incentive in taking adequate care in product safety. The effect of insurance policies on product safety is unclear and multi-faceted. The classic moral hazard argument may be formulated as follows: if the purpose of strict liability is to provide incentives for precaution, insurance clearly undermines those incentives and the conclusion is that insurance should be forbidden. This conclusion relies on the theory that insurance implies less precaution.

The moral hazard problem.

Such arguments may usually be contested on several grounds.

First, insurance companies' monitoring policies may create a *de facto* negligence rule. The theory tells us that if the insurer is in the position of monitoring the injurer's procedures, the injurer will have an incentive to take efficient care. Nevertheless, it is possible to argue that, especially during product development, information asymmetries almost entirely prevent efficient monitoring of those activities. In such circumstances, the insurer's control over company activities is not efficient to provide product safety.

Second, insurers may try to resolve information asymmetries by acquiring information and setting premium-performance schemes. This in principle should align insurers' and injurers' objectives, guaranteeing that the insured company complies to the safety standards set by insurance companies. Once again the peculiar nature of development activities and related risks defines an environment in which it is almost impossible for the insurance companies to set behavioural standards and monitor compliance to them. Product development and innovation are by definition non-routine, where it is very difficult to apply any sort of negligence rule *ex-ante*.

The combination of the two arguments implies that, in the specific contest of development risks, liability insurance may spoil one important dimension which the strict liability regime is designed for, namely providing incentives for investing an efficient amount of resources in product safety. In fact, when information asymmetries prevent effective monitoring, moral hazard may induce companies to under-invest in product safety.

Liability insurance may not provide incentives for investing an efficient amount of resources in product safety.

The insurability problem.

The second argument relates to the insurability problem, i.e. whether companies are able to find insurance coverage for development risk, especially when concerning large accidents. Insurance companies' core business is to provide financial indemnity for losses arising from a defined set of causes. There are constraints on the types of risks that can be insured and on the magnitude of risks that can be transferred to insurance markets. Attempts have been made to formalise criteria for the insurability of risks. The most important are the probability of events occurring, the maximum total loss associated with an event, the average total loss associated with an event, the average time span between two events and the level of insurance premium required.

As far as development risks are concerned, they seem to fall in the area of non-insurable risks, due to the fact that they are rare and often imply severe damages. Under these conditions, it is highly likely that, should the risk development clause be removed, insuring themselves against development risk would not be feasible, simply because a market for development risk insurance might not exist.

Before discussing such theories empirically, we should stress that one more relevant issue is related to the problem of high insurance rates being reflected in higher prices for consumers. This would have two major consequences.

Over-insurance.

On one hand, this may cause over-insurance: consumers obtain greater coverage than they would from accident insurance. In other words, if insurance costs were fully reflected in prices, consumers would be forced to take out full insurance cover, without any option of different levels of risk cover. It should be stressed that mandatory bundling may be desirable when consumers are affected by systematic misperception of risks and damages. One might argue that innovation and product development are indeed situations where consumers do not have full perception of the risk and therefore over-insurance (mandatory insurance) should not be indicated as a drawback of strict liability.

Impact on market structure.

On the other hand, an increase in production costs deriving from higher insurance costs could have an impact on market structure. First, if the theory that insurance costs are fully reflected by prices, this could have an impact on industry size. The effect will be determined mainly by actual perception of development risk by consumers. If consumers are ignorant

about the risk, i.e. product safety features are not a dimension of competition, strict liability is bound to reduce demand for that product by increasing costs and prices. This is not strictly true when consumers perceive product safety as a quality feature of the product. In this case consumer's utility will be decreased by higher prices but increased by the perception of a safer product, therefore the effect on aggregate demand cannot be predicted *ex-ante*. Once again, a shared view emerges between the industry and consumers that product development and innovation are characterised by strong information asymmetries about safety features and there seems to be some credit in the theory that insurance against liability might negatively affect demand and industry size. Having said that, we need to stress that the theory that an increase in insurance costs will definitely be reflected in prices it at least debatable. This will depend largely on market structure and in particular on the degree of competition in the final market.

Finally, an upward shift of production costs might also change industry structure, in terms of concentration and barriers to entry. High fixed and sunk costs deriving from insurance policies might cause new barriers to entry and therefore contribute to creating concentrated industries. Smaller incumbent companies could find it impossible to stay in the market and small firms wanting to enter would in practice be prevented. The result of this process would eventually be a less competitive and more concentrated market structure in many selected industries.

On a final note, it should be remembered that the liability regime is defined regarding the destination market, i.e. the market in which the product is actually sold to consumers. The European market, especially in industries where product development risk is relevant, is indeed integrated, as market leaders sell their products to many different Member States. This implies that even though the Development Clause is not in force in every Member State, no major asymmetry in production costs should arise between companies from different Member States. On the contrary, should liability be enforced with respect to the State where the product is manufactured, the non homogeneous application of Development Risk Clause would determine competitive asymmetries and yield serious damages to European Industry besides being in open contrast with the principle of free

competition in the internal market that inspires EU's industrial policy.

3.3 Empirical evidence and results

When empirically assessing the impact of DRC on the insurance market, one cannot but consider a number of contingencies that have characterised such market in the past decade.

In some Member States, the development of contingency fee agreements, often supported by extensive media advertising by lawyers, has fuelled the so-called "compensation" culture, increasing the number and cost of claims. Moreover, a series of government changes to the law on damages has significantly changed the scenario faced by insurance companies, particularly due to the retrospective impact they have had.

It is the industry's opinion that, throughout these changes, some of which have been adverse and costly for insurers, the certainty of DRC has played an important role in maintaining a viable market for product liability risks.

In this section, we present a summary of the results that were drawn from interviews, case studies, questionnaires and workshops. In all circumstances, companies were given a set of questions drawn from the theoretical analysis presented above, in order to understand their perception of the relationship between liability regime and insurance.

As we mentioned in the introduction, there seems to be very little evidence that insurance rates have increased with the strict liability regime in Europe. Companies seem to share the view that this is one major benefit of the development clause, which allowed them to face development risks without relying too much on insurance policies. To support such results, we should mention that insurance rates imposed on European firms dealing with North American companies are higher than those firms which limit their business to the European market. A rough estimate, derived by qualitative estimation from those people interviewed, tells us that Europe's exports to the United States can be between two and ten times (especially for pharmaceuticals) more expensive than exports to other

Impact on exports.

countries[57]. This, besides confirming a potential effect of different liability regimes on insurance costs, seems to represent a major political issue, since it imposes *de facto* non-tariff barriers to international trade.

Differences in Member States.

On the contrary, different liability regimes within Europe do not seem to be reflected in specific insurance policies. Companies that export to countries like Finland, Luxembourg where no Development Risk Clause is in force or to countries where the development clause is not in force for specific products, have declared almost unanimously that they do not have any specific insurance policy for products that are exported to those countries. One explanation that seems to emerge is that differences among Member States are only partially determined by the application of the Development Risk Clause but such differences are more often mediated by special provisions contained in national legal provisions. In other words, Finland and Italy, for example, are not that different in terms of product liability, since the Italian legal system provides victims with a variety of protection beyond state of the art defence, thus mitigating the effect of the Development Risk Clause itself.

Another issue that was strongly debated in both interviews and workshops is the possible rivalry between insurance policies and R&D expenses. In fact, insurance and R&D compete for the same financial resources, and in this respect should be treated as rival goods. One major argument from the producer's side was that the huge resources they would be forced to pay in insurance, could be more efficiently invested in safety-related research and development activities. Although this in principle is true, from another point of view we might observe that R&D and insurance can also be viewed as complementary activities, since they share the same objective of reducing development risk.

[57] Current rates for product liability insurance range from 0.02% of sales for low risk product such as textile to 0.4-0.5 % for high risk products, such as pharmaceuticals, life saving devices and so forth.

PART II -

CONSUMER PROTECTION

4. *Practical cases*

The following pages analyse the cases where the DRC was applied and the cases where it could have been applied but was not.

The cases are divided into two groups:

- cases that occurred before the approval of the Directive;
- cases that occurred after the approval or the implementation of the Directive.

The former include some cases that were brought before national courts. Studying such cases allows for an understanding of how the courts ruled in the absence of the DRC, and what their legal reasoning was. Although the DRC was not applicable, judges referred to the "state of the art" available either at the time when the product was placed on the market or at the time when the damage occurred. The majority of these cases were decided on the basis of the rules applying the tort liability, and the burden of proof of the producer's negligence was on the consumer.

There are some cases where judges made a reference to the liability for *dangerous activities* for which the burden of proof is on the producer. The courts examined the knowledge available at the time when the product was put on the market, in order to establish whether or not the producer was liable. They are all cases that, had they occurred after the implementation of the product liability directive, they could have been decided on the grounds of the DRC.

The practical cases are also classified in relation to the type of products which caused the damage:

- blood and blood derivatives
- pharmaceuticals and vaccines
- foodstuffs
- chemicals.

This classification in understanding if and how the DRC is/was applied for each type of product, and what the solutions for the compensation of damages are. The analysis shows that both before and after the implementation of the Directive, the majority of the practical cases involved large scale damage (e.g.

blood transfusion in France, rape-seed oil in Spain, and blood products infected with the HIV virus in Germany and Denmark). In these cases, neither the Directive nor national legislation was sufficient to compensate victims[58].

4.1 Practical cases that occurred or were ruled on before the Directive was approved or implemented in national laws.

A - Blood and blood derivatives

Courts' decisions on damages caused by blood products

Before the approval of the EEC Directive on product liability, many cases concerning damages caused by blood transfusions were brought before national courts. These decisions are comparable because they applied the national rulings on tort liability and/or the liability for dangerous activities; the state of the art at the time when the products were placed on the market was also analysed. However, the final decisions of the judges differed. Some of the courts found the producers liable for the damages caused to people who underwent blood transfusion. In **Spain,** the judges found INSALUD (the National Institute of Health) and the hospital liable for the damages caused by blood transfusions, even if at the time when the product was used, the hospital was not obligated to check for Hepatitis B[59]. On 9 July 1996, The **French** Cour de Cassation, in relation to the "contaminated blood" affair, ruled on the applicability of the DRC before its transposition into national law. It stated that the blood transfusion centre was required to provide products that were untainted. The centre could claim exemption from liability for any reason other than external cause; the internal defect of the product, even if undetectable, did not constitute external cause for the supplier. The supplier tried to invoke the exemption clause under Article 7(e) of the Directive, despite the fact that it was not yet transposed into French law. The court responded that, even if the judge was required to interpret domestic law in light of the purpose and text of the Directive, it was on condition that the latter was binding on the Member States, and did not allow any option for adapting national law to Community law. The court added that the Directive actually stated nothing on the matter, since Article 15(1)(b) allowed the Member States to decide for themselves

[58] Commission of the European Communities (2001), 11.
[59] Audencia Provincial de Asturias, 7.10.1993.

whether or not to introduce exemption for development risks[60]. In a previous proceeding, the French Supreme Court held that the obligation of the medical laboratories to reveal the side effects of pharmaceuticals and their contraindications had to be evaluated in relation to what was known at the time when the product was placed on the market[61].

In each of these cases, the judges examined the state of the art available at the time the product was in circulation, which is exactly what the DRC requires. In order to establish whether the producer was negligent not, it was necessary to know what tests, scientific and technical knowledge could have been used or referred to at that time.

Special compensation funds for damages caused by blood and blood derivatives

There were many other cases dealing with damages caused by blood and blood derivatives that were not brought before national courts. In some analogous cases that took place also in other Member States, special compensation funds were created before the approval of the Directive to compensate victims and/or their families. This occurred in **Spain**, **France** and **Austria**. The analysis of these funds is dealt with later in the section dedicated to special compensation funds.

B - Pharmaceuticals and vaccines

Courts' decisions on damages caused by pharmaceuticals

Pharmaceutical products have been the subject of many court proceedings before the product liability directive was implemented in national laws. There were some cases against pharmaceutical producers in **Italy** in the 1980s requesting compensation for damages caused by Trilergan, a medicine which contained immunoglobulin[62]. The courts found that liability for the production of medicines is based on the Article 2050 of the Italian civil code which rules on the liability for dangerous activities, stating that anyone carrying out a potentially dangerous activity (classified as dangerous on the grounds that the either activity itself the instruments being used are dangerous) is responsible for compensating the injured person unless they can prove they had taken all the proper precautions to avoid the damage.

The Trilergan cases arose when some people who were administered the medicine were infected with Hepatitis B,

[60] Cour de Cassation, 9.7.1996.

[61] Cour de Cassation, 1st, 8/4/1986, Bull civ., 1986, I, 82.

[62] Corte di Cassazione, 15/7/1987 n. 6241, Nuova Giurisprudenza Civile Commentata, 1988, I, 476 and Foro Italiano, 1988, I, 144; Tribunale di Milano, 19/11/1987, Responsabilità Civile e Previdenza, 1988, 412 and Foro Italiano, 1988, I, 156.

which was found to be contained in the medicine's components. The infected patients sued the producer, Crinos, asking for the compensation for damages. The courts ruled that, since the production of pharmaceuticals is a dangerous activity, producers must prove they have used all the technology available at the time of the production and not only those that the law considered to be compulsory for checking the safety of the products. In these cases, it was presumed that the producer was liable, and thus the producer had to prove that they used all the available techniques to verify the product's safety. However, the producer did not manage to satisfy the burden of proof and was held liable.

Special compensation funds for damages caused by pharmaceutical

Some **special compensation funds** were set up for pharmaceutical related damages. In the **United Kingdom** a fund was created to compensate the thalidomide victims. There are two other countries where special compensation funds for defective pharmaceuticals were set up before the approval of the EC directive: **Finland** (where the DRC does not apply), and **Germany** (where section 84 of the Drug Act approved on 24/8/1976 introduced a form of strict liability that applies to medical products put on the German market that are produced for human use. In Finland, there is a pharmaceutical injury insurance financed by producers, which was created 19 years ago as a voluntary insurance; it is based on a contract between insurance companies and the pharmaceutical industry. In Germany, there is the "**pharmapool**" which was created in 1978. The analysis of these funds is dealt with later in the section dedicated to special compensation funds.

Special compensation funds for damages caused by vaccines

There were many cases where defective vaccines caused damages to consumers. In order to provide the injured people with compensation, in the **UK** the Vaccine Damage Payment Act came into force in 1979, compensating the children that were and are still vaccinated within the UK territory. In **Austria** the vaccination Damage Act approved in 1973 found the government liable for damages caused by wrongful compulsory vaccinations. The analysis of these funds is dealt later in the section dedicated to special compensation funds.

C - Foodstuffs

Special compensation funds for damages caused by foodstuff

Before the approval of the Directive on product liability there were cases in which consumers were harmed by foodstuffs, as happened in **Spain** twenty years ago. Thousands of people

were poisoned by an unknown element in colza oil, many of which died, and others were disabled. Criminal proceeding were brought before the Spanish courts and a special compensation fund was set up in 1982. The analysis of these funds is dealt later in the section dedicated to special compensation funds.

4.2 Practical cases that occurred or were ruled on after the Directive was approved or implemented in national laws

A - Blood and blood derivatives

Courts' decisions on damages caused by blood derivatives

The court proceedings concerning the damages caused by infected blood and blood products continued to occur after the approval of the product liability Directive. It is interesting to note that the judges did not refer to or decide on the basis of the product liability system and the development risk clause in all of these cases.

In 1998, the Court of Appeals (Italy) found the Ministry of Health liable, on the basis of the rules on tort liability, for the damages caused to citizens from HIV and Hepatitis B and C originating from infected blood, which was supplied by the Ministry itself. No express reference was given to the development risk clause. However, the judges analysed the scientific and technical knowledge available at the time when the product was put into circulation, and held that producers must not only take the measures established by the law, but also all precautionary measures that are called for by general criteria of prudence, skill, diligence and by the state of technique[63]. The same ruling was found in similar case that followed in 2001,[64] where Italian judges held the Ministry of Health liable for the damages caused to people that had been infected with HIV and Hepatitis B and C resulting from blood transfusion. All the plaintiffs were forced to have a blood transfusion as a result of an illness. This occurred during the timeframe in which the Italian Ministry of Health was the producer and distributor of blood (from 1974 to 1995), that was

[63] Tribunale di Roma, 27/9/1998, Danno e Responsabilità, 1999, 214. .This sentence has been appealed before the Court of Appeal and is currently before the Italian Supreme Court.

[64] Tribunale di Roma, 4-15/6/2001, Guida al diritto, 14/7/2001, 45. This sentence was appealed and is currently pending before the Italian Court of Appeals.

imported from other countries such as the United States, as well as various African and Central America countries. The court looked at the scientific knowledge available at the time when the infection was said to have occurred and established that, at that time, the Ministry could have used tests available for screening Hepatitis B, C and HIV, since they were already well known and used elsewhere. Although court did not mention the state of the art defence or the product liability Directive, the Ministry of Health was found liable on the basis of Article 2043 of the Italian civil code, which rules the tort liability (and not on the grounds of dangerous activities). However, it examined the knowledge available at the time when the product was in circulation, trying to establish whether or not there was a possibility for the Ministry to escape liability on the basis of the available state of the art.

A similar scenario unfolded in **Denmark.** The judges, following a claim filed by a number of people who had contracted HIV from blood transfusions, found the Ministry of Health liable on the basis of the Act of Liability and the general principles of torts law - not on the basis of the Product Liability Act. The claimants said that they had been treated with products that were not screened or heat-treated. The court dismissed the claims against the producers, since at that time, the Ministry of Health did not prohibit the use of such products. However, the Ministry of Health was found liable for having authorised the use of foreign un-screened products that had not been heat-treated. Nothing was mentioned about the scientific and technical knowledge available at that time[65].

In a **Spanish** case,[66] the public administration was not held liable for the infection of Hepatitis C caused by blood transfusion because the virus was unknown at the time of the transfusion. The court did not consider that, according to the Spanish law on product liability, the state of the art defence can not be applied to medicines including blood derivatives.

The state of the art defence was highly analysed in a legal proceeding that started in the **United Kingdom** against the English Ministry of Health, by a group of people infected by blood derivatives. The trial was composed by 114 claimants

[65] Supreme Court, 3/10/1996, UfR, 1996, 1554 H.

[66] Tribunal Supremo, Sala de lo Contencioso 25/11/00, in Diario Medico, 8 March 2001. The same principle is established in the sentences of the Tribunal Supremo, Section 6 (administrative Court) of december 21, 2001; november 25, 2001 and January 30, 2001.

seeking recovery for damages. Said damage was due to their infection with Hepatitis C from blood and blood products through blood transfusion from 1 March 1988, while undergoing surgery. The court analysed Article 7 (e) of the Directive and said that its purpose is to exclude the development risks from the Directive succeeding in its purpose because the risks cease to be development risks and become known risks not if and when the producer in question has the requisite knowledge, but if and when such knowledge was accessible anywhere in the world outside Manchuria. Therefore, it protects producers against the unknown. Finally, the judge found that "*the Article (Article 7 (e) of the Directive) should be construed purposively, that it is in order to assist the purpose of the Directive (…), such that the existence of the defect is discovered in the actual product if it is eliminated or removed or prevented from arising. Even if the nature of the defect is not specifically identified, the defect to my mind would be discovered if the precaution was taken which in fact eliminated the defect*"[67]. The state of knowledge was construed as "*as to include all data in the information circuit of the scientific community as a whole, bearing in mind, however, on the basis of a reasonableness test the actual opportunities for the information to circulate*." According to the court, the producer can use the development risk defence only before the time when the defect of the product materializes or is published about. After that time, once the risk in known the defence does not apply any more, and if the product is supplied and the defect occurs the producer will be liable. The court declared that the Ministry liable from the time when the routine screen was available.

Dutch courts also analysed the state of the art defence in cases where patients got HIV from contaminated blood. The judges took into account the vital interest of the blood transfusion and held that the development risks defence applied because the Sanquin Foundation - which had supplied the blood - proved it had acted in compliance with the scientific and technical knowledge available at the time when the blood was administered[68]. According to the court, it cannot be required that a blood supplier does a third test after they have already done two required control tests in order to avoid the danger that the blood may be infected with HIV. This is for the two following reasons: the equipment for this third experimental

Special legal proceedings

[67] A. and others v. the National blood Authority and others, case n. 1998 A458, (2001) Lloyds (Med) 289.
[68] Distric Court of Amsterdam, 3.2.1999, in Nederlandse Jurisprudentie, 1999, 621.

and laborious test was not available yet and the fact that there was a small chance that HIV could be transmitted via a blood transfusion did not constitute general knowledge.

Special tribunal were set up in **Portugal** and **Ireland** to decide cases concerning damages derived by the infection of HIV and Hepatitis. In the former country, in 1993 a special arbitration convention was created, for those who had been infected by the blood imported in Portugal in 1986. The Decree Law 237/93 allowed the government to appoint the referees of the Volunteer Arbitration Centre of the Portuguese Bar Association in order to decide on the compensation of damages caused by the infected blood. Consequently, the law permitted the injured people to adhere to the Arbitration Convention, granting them the indemnities without a legal proceeding in a judicial court. In order to enter into the Arbitration Convention, it was necessary that the following conditions were fulfilled (as established in Article 3 of the Decree Law 237/93):

- to authorize the referees to judge according to equity, considering the age and the family responsibility of the injured party;
- to grant the referees the powers to choose the procedure rules to be used in the arbitration;
- a three month deadline for the arbitration court's decision;
- the maximum amount of the indemnity;
- prosecution waiver if there is a law suit going on in a judicial court, on the same cause of action.

In **Ireland**, on the 1st November, 1997, the statutory Hepatitis C and HIV Compensation Tribunal was established in accordance with the Hepatitis Compensation Tribunal Act 1997. The tribunal was created in order to process the claims of the people who suffered Hepatitis C infection from contaminated blood products. The tribunal has made a series of recommendations which the executive has pledged to implement. The tribunal is now the preferred way of resolving a multitude of claims arising from alleged negligence by the government. Whilst the courts have their own difficulties, and very high legal costs, this method is considered preferable to defending every action individually in the courts. However, recipients of compensation from the tribunal have subsequently sought to take High Court proceedings seeking further compensation.

Compensation funds for damages caused by blood derivatives

Funds for damages caused by infected blood were set up also after the implementation of the Directive on product liability. They were created in **Denmark**, **Italy** and the **UK**. In 2001 the **Belgian government** decided to compensate all the people who were infected with HIV from 1 August 1985 to 30 June 1986 resulting from blood transfusions and the use of blood products. The analysis of the functioning of these special compensation funds is dealt with in the relevant part concerning the special compensation funds.

B - Pharmaceuticals and vaccines

Court's decisions on damages caused by pharmaceuticals

Regarding pharmaceuticals, recently the Spanish Tribunal Supremo, in its sentence dated March 6, 2002, denied the liability of the Spanish public administration for authorizing the use of the medicine called Protectona which have an active ingredient called deictilestilbestrol (DES) [69]. This ingredient was synthesized in 1938 and was given to thousands of pregnant women to prevent spontaneous abortion. In 1971 suspicions that DES causes vaginal cancer in the daughters of these women arose. The court established that, on the basis of the scientific knowledge when this medicine was given to the patients, it was impossible to know that it caused cancer. The judgment does not refer specifically to the development risk clause, but it is based on the idea that the scientific knowledge at that time did not allow for detection of the medicine's defect. This decision is very interesting and has a double peculiarity: it was the first time that a Spanish court decided on medicines whose active ingredient is DES; the action was brought against the public authorities instead of following the usual procedure to bring the action against either the pharmaceutical company who placed the medicine on the market or the holder of the marketing authorization.

In two **French cases** although the French judges analysed the development risks defence, they did not apply it since at the time when the damaged occurred, the Directive 85/374/EEC, had not yet been implemented in France. In the first case,[70] the pharmaceutical manufacturer was held liable. The UCB Pharma was sued by Ms Bobet, alleging that its product had caused her to get cancer. The product was distilbene, distributed in the late 1960s as a treatment for pregnant women against miscarriage. It was subsequently discovered that this product was likely to

[69] National Audience, Tribunal Supremo, 6 march 2002, in Aranzadi Jurisprudenica and La Ley Jurisprudenica.
[70] Tribunal de Grande Instance de Nanterre, 24/5/2002, Bobet/UCB Pharma, Dalloz 2002, IR, 1185.

have brought about cancer or abnormalities in children exposed to it in the womb. The plaintiff's mother was treated with this product during her pregnancy in 1968, and, as a result, Ms Bobet got cancer. The UCB Pharma argued that when distilbene was distributed there was no scientific evidence of any possible side-effects of the product, which was commonly prescribed in the late 1960's. This lack of evidence could have supported a development risk defence. However, since the product was marketed before the implementation of the Directive, the defence was not available.

In a later action[71], the family of a young woman sued the manufacturer and the supplier of growth hormones, which had caused her to die of Cretzfeldt-Jakob disease. The action was brought under Article 1147 of the French civil code on the basis of the principles of contractual liability. The Court, taking into account the state of the art defence, found that the producer could have not invoked it, because the effective application of the Directive's provision was available only where the provision was mandatory according to the terms of the Directive itself. Since the defence was not mandatory and it was not implemented at the time of the infection, it could not be applied.

Special compensation funds for damages caused by pharmaceutical

After the implementation of the Directive on product liability in national legislations, compensation funds were also created for pharmaceuticals. This is the case of **Denmark** where there is a fund financed by the government and **Sweden** where the fund is financed by the pharmaceutical companies. The analysis of the functioning of these special compensation funds is dealt with in the relevant part concerning the special compensation funds.

Special compensation funs for damages caused by vaccines

Because of the many problems and damages caused by vaccines other compensation funds came about in the past few years. For example, in **Ireland** a governmental Commission was created in order to examine the files of those injured by a defective vaccine. In **Italy,** in 1992 a law introduced a fund for compensating the people who must have an obligatory vaccination. The analysis of the functioning of these special compensation funds is dealt with in the relevant part concerning the special compensation funds.

C - Foodstuff

[71] Tribunal de Grande Instance de Montpellier, 2nd ch B, 9/7/2002, JCP ed G 2002, II, 10158.

In **France** there was a case where a person who contracted trichinellosis after eating horsemeat sued the producer[72]. This is the first judgment given by a French Court of Appeal to be affected by the new rules enacted on May 19 1998, when the Directive was implemented. The court ruled out the possibility of the defendant arguing a development risk because at the time the product was put on the market the defect (ie, the existence of trichnins in the horsemeat) was well known.

Courts' decisions on damages caused by defective foodstuff

In the past few years there has been problems due to the BSE and CJD syndromes caused by infected cows. Because of the diffusion of the syndrome in the **UK**, the government, after the publication of the BSE Enquiry Report in October 2000, set up a compensation scheme based on that created for the HIV victims. The analysis of the functioning of these special compensation funds is dealt with in the relevant part concerning the special compensation funds.

Special compensation funds for damages caused by foodstuff

D - Chemicals

In **Austria**, after the implementation of the Directive, a fund for damages caused by asbestos was created for compensating people who allegedly got lung-cancer and pleura-cancer caused by this substance. The analysis of the functioning of these special compensation funds is dealt with in the relevant part concerning the special compensation funds.

Special compensation funds for damages caused by chemicals

E - Other cases

There are other cases where the development risk clause was examined by national courts. These cases do not belong to any of the above mentioned groups since the product which caused the damage can not be classified in any of the indicated groups. However, these cases are important because the courts expressly referred to the Directive on product liability and the state of the art defence, trying to explain how it should be interpreted and applied. In **Germany,** the defence was referred to in a case[73] in which the plaintiff sued the producer of a carbonated mineral water bottle, claiming that, when she was nine years old, she fetched two bottles of thicker glass from the cellar of her parents' house, placed them on the floor outside the cellar in order to close the door, and was about to pick them up when one of the bottles exploded. Splinters of glass entered her left eye and caused serious injuries which, despite an

Other courts' decision on damages caused by defective products

[72] Cour d'appeal Toulouse, 22/2/2000 in www.internationallawoffice.com/nl.cfm.
[73] German Federal Supreme Court, BHG 129, 353, VI, Civil Semate, 9/5/1995.

operation, reduced her sight to 60% and left her with astigmatism. According to the German court, the purpose of the state of the art defence is to exclude liability for what is known as development risks. The term covers only cases where at the time a product was put into circulation none of the means offered by the current state of science and technology rendered it possible to detect its dangerous quality. Therefore, the strict liability of the producer is to be limited by what is objectively possible in light of the knowledge of risks available at the time the product is put into circulation. Moreover, according to the court, the only dangers which can be treated as development risks are dangers inherent in the design and construction of the product, which in the current state of the technology could not be avoided, not those that were inevitable at the stage of production. The court stated that when the EC Directive on product liability was written, it was agreed that the defence under Article 7 (e) would apply not to manufacturing defects, but only to defects in design and construction, and the only dangers emanating from a product which the German legislator wanted to exempt from the scope of product liability law were dangers, undetectable even when taking extreme care, arising at the stage of design and construction. Therefore, the judges said that liability is to be excluded only if the potential danger of the product was not obvious due to the fact that at the time of circulation it was not possible to recognize it yet. Since, at the time of the accident, the potential danger of glass bottles filled with carbonated liquids had long been recognized and, according to the court, the danger of using such bottles are that even a tiny hairline crack which spread causing it to explode, the judge concluded that such a defect was not to be considered a fault of design or construction. Therefore, it was not impossible to exclude liability.

In 1996 a **Belgian court** ruled on the liability of a producer of an aerated bottle that exploded. The court held that this explosion proved an abnormal product feature that was incompatible with the safety that consumers were entitled. The court stated that the producer offered no evidence of abnormal use of the bottle nor any other evidence for which there is provision under Article 7 of the Directive. The judge held that, despite the quality checks the defendant claimed to have implemented, he

did not offer any proof of the "absolute impossibility" of detecting the existence of the defect that caused the damage[74].

5. *Damages covered by the social security systems*

There are social security schemes in all Member States that protect people who have been injured for various reasons and provide them with a monetary sum to cover the economic loss. It is important to note that in no Member States there is a special social security scheme which specifically applies only for damages caused by defective products. Therefore, when a defective product causes damages serious enough that reduce the working ability, affects the earning capacity and increases the worker's needs, the general schemes applies and the injured person can ask for sickness benefits, incapacity or disability/inability allowances.

The above mentioned emoluments are not the same for all the categories of workers since in the majority of the Member States, different compensation amounts are provided for civil servants, employees of private companies, self employed and unemployed.

5.1 Sickness benefits

Payment of sickness benefits

Sickness benefits compensate for the loss of income due to an illness caused by reasons that are not work related. They are often paid after the waiting period (after a few days of illness). For example, in **Greece, Ireland, Italy, France, Austria** and **Portugal** there is a three day waiting period; in **Spain** they are paid after 4 days and in **Finland** after 9 days. They are always paid to employees of private companies. As for civil servants and the self-employed, they are not always entitled to sickness benefits.

[74] Cour de Namur, 5e ch., 21.11.1996.

5.2 Incapacity and invalidity benefits

Payment of incapacity and invalidity benefits

Besides sickness benefits, other allowances can also be paid when working ability is decreased as a result of an injury caused by the defective product, for a longer period or even in some cases, indefinitely. They are the incapacity benefits and the invalidity or disability pensions and they are calculated on the basis of the earned income.

Not in all the Member States is there a difference between the last two categories of allowances. In fact, in some countries only the invalidity benefits apply. In other countries, such as **Italy**, the two benefits apply according to the type of injuries. Thus, the incapacity occurs when the working ability is reduced of at least 2/3; the invalidity occurs when the damaged person becomes completely unable to work. In same cases, the "civil invalidity" can be applied, as in **Italy** where an allowance for life is paid when someone's working ability has been reduced to at least 1/3 due to a congenital or acquired disability (that may have been caused also by a defective product). The pension will be paid if the injured person has an anatomical or functional loss of an organ or an apparatus and the missing organ or apparatus is important for the working activity.

5.3 Voluntary social security protection

Voluntary social insurance

In some countries a voluntary insurance can be applied. In **Luxembourg** workers can get an insurance which covers the damages caused by a prolonged sickness when the working capacity has been reduced to such a degree that the injured person is unable to carry on an occupation.

In **Portugal**, voluntary social security schemes guarantee the right to social protection for the people who can work, who are not compulsorily covered by any social protection scheme or who are covered by schemes that are not relevant to the Portuguese social security. The risk covered is invalidity.

In **Austria,** all those who are not covered by any compulsory social security scheme can voluntarily join the Austrian pension scheme.

In **Denmark,** the self-employed may have recourse to a voluntary insurance scheme which grants sickness benefits from the 3rd day of illness or beginning from the first day.

In **Germany,** those who are not covered by a compulsory pension insurance scheme may join sickness insurance schemes on a voluntarily basis.

In **Italy,** if a person paid employment or self-employment temporally or permanently tax contributions, they can preserve or tip up their sickness by paying voluntarily tax contributions.

5.4 Special security schemes.

Schemes for particular categories of workers

Special security schemes apply in some countries for some categories of workers. For example, in **France** there are special schemes for agricultural, clergy, mining, railroad, public utility and seamen. In **Italy,** a special fund has been recently created for housewives. It is financed by the taxes paid by housewives, and it allows them to have a disability pension in the event that they can not do any job because of some serious illness or injuries.

Social security benefits for the unemployed people

As for the unemployed people, they are not always covered by the social security schemes. Only in a few cases they are paid sickness benefits, and sometimes they are entitled to the incapacity or disability allowance. For example, in **Ireland** there is a disability allowance, a weekly allowance paid to people not in the work force who are disabled. It must medically proven that they have an injury - that is, have a disease or illness or have a physical or mental disability, which has continued or may be expected to continue for at least one year. As a result of this condition, they must be "substantially handicapped" in undertaking work which would otherwise be suitable for a person of the same age, experience and qualifications. Finally, they must be over 16 years old and under 66. In **Luxembourg**, people who are unemployed have the right to invalidity benefits if they are under the age of 65 providing that they have been insured for 12 months within a period of 3 years before the invalidity is declared.

Special social security benefits for people with disabilities

A special fund exists also in **Austria**. Since 2001, there has been an assistance fund for people with disabilities established on the basis of the Bundesbehindertengesetz. To a great extent, the fund is financed by the government in addition to tax contributions. Beneficiaries are Austrian citizens or permanent residents in Austria who are disabled. The amount of the allocations depends on the fund's financial situation. There is no information available on the length of the procedure, which is highly formalized.

In **Portugal** there is a special type of protection for people who are disabled as a result of HIV. According to this scheme, the qualifying period is 3 calendar years and the rate of the pension is 3% of the average earnings for each calendar year with earning registration.

Special social insurance benefits for people infected with HIV proceedings

All the above mentioned benefits cover only the loss of income. No compensation for other kinds of damages is provided for, since the social security systems do not award damages for suffering and pain. The only exception is **Austria** where the "Integritätsabgeltung" was set up. This institute constitutes a first step in the direction of the compensation for immaterial damages (pain, higher working pressure). However, despite the intention to formulate a compensation for pain and suffering ("Schmerzengeld") it is only realised partly, as the new legal term "limitation of integrity" covers only corporal and mental functions, but not necessarily pain and suffering.

Damages covered by the social security benefits

All these means of compensation are summarised in table 13:

6. Damages covered by special compensation funds

Other alternative/cumulative ways of compensation for damages resulting from development risks are the special compensation funds set up in many Member States. The classification of the funds have been made according to the products they refer: funds for damages caused by infective blood and blood derivatives; funds for damages caused by defective pharmaceuticals, funds for damages caused by defective vaccines, funds for damages caused by defective foodstuff and funds for damages caused by defective chemicals. Finally there are few special funds, which are not part of any of the above-mentioned groups. However they have been indicated because the damages they cover may be caused by development risks.

Compensation funds are alternative/cumulative ways of compensating for damages caused by development risks

6.1 Funds for damages caused by infected blood

These special funds have been introduced in the past few years, following the scandals of HIV and Hepatitis. The only requirement that must be fulfilled is to have been infected with

Funds covering damages caused by Hepatitis and HIV are not strictly connected with product liability law

Hepatitis or HIV as a consequence of blood transfusion and the use of human derivative and so they are not strictly connected with the law on product liability. That means that in many Member States where they have been applied, compensation has been granted irrespective of whether the government or the producer had been held liable on the basis of the product liability system. These funds now exist in **Spain**, **UK**, **France**, **Italy** and **Austria** and they cover: those who have been treated with infected blood products before medical checks to detect HIV and Hepatitis were compulsory; their partners or members of the family in case of the death of the damaged person; the infected children born before their mother was diagnosed with HIV and Hepatitis.

In **Belgium** in 2001, the Federal Government of Belgium decided to give compensation to all the persons contaminated by the HIV virus during the period from 1 August 1985 to 30 June 1986 following a blood transfusion and the distribution of blood products in Belgium. It was only clear at that time that the virus contained in the blood of donors could have been possibly detected from the 1 August 1985 checking for the presence of antibodies in the blood. However it was only systematically done from 30 June 1986, which is why the Ministry put in place the following measure to compensate the infected persons. A compensation of Euro 124.000,00 was provided for the patient himself. In case of death a compensation of Euro 62.000,00 was provided for the partner living with him/her and a compensation of Euro 6.200,00 for the other relatives and for each son. A non-profit organization called AAPS was created in order to evaluate all the applications and to be responsible for the payment of the compensation financed by the Federal Government.

In **Ireland** on 15 December 1995, a non-statutory scheme was set up to compensate certain persons who had contracted Hepatitis C and HIV from the use of human immunoglobulin-anti-D, whole blood or other blood products. In 1997, the statutory Hepatitis C Compensation Tribunal was established in order to grant compensation to those who suffered Hepatitis C infection from contaminated blood products. The fund is 100% government financed; producers do not pay any of this compensation. The government may pursue the producers for the compensation paid when all the compensation claims have been satisfied by the Tribunal. Payments to date by the tribunal are approximately Euro 90 million.

6.2 Funds for damages caused by pharmaceuticals

Funds for damages caused by pharmaceuticals in case of development risks are financed publicly, privately or by both public and firms

Special funds were created also for the damages caused by pharmaceuticals which pay compensation even in cases of development risks.

One of the oldest **publicly financed funds** created in order to compensate the victim of defective medicines was the one set up in **UK** in 1973 as an immediate response to the thalidomide disaster. The fund is financed by the English government and compensation is granted to those families whose income does not exceed the indicated limits.

Besides the Thalidomide fund in the UK, other special funds for damages caused by defective pharmaceuticals were set up in other Member States, some of which are financed by the government; others are financed by the pharmaceutical industries.

Publicly financed funds were created in **Denmark** where a compensation scheme was implemented from 1 January 1996 under the Act on damages from pharmaceuticals for those who have been damaged by defective drugs. The compensation is limited to pharmaceuticals administered by doctors or hospitals and having been legally distributed from a pharmacy, hospital or doctor domiciled in Denmark.

Privately financed funds were created in **Sweden**, **Finland** and **Germany**.

In **Sweden,** manufacturers or importers of pharmaceuticals who are members of the Swedish Pharmaceutical Insurance Association have undertaken liability for drug-related injuries in accordance with the Indemnity Rules from 1 January 2000. The rules state that compensation shall be paid in accordance with the undertaking for an injury caused by a pharmaceutical that a manufacturer or an importer who is a member of the Swedish Pharmaceutical Insurance Association distributed in Sweden. Compensation is determined in accordance with the Tort Liability Act (1972:207), except as otherwise stipulated: compensation for bodily defect or other permanent harm is paid in accordance with the rules determined each calendar year by the Swedish Pharmaceutical Insurance Association. When determining the amount of the indemnity, a deduction shall be made for, beside the benefits mentioned in the Tort Liability Act - compensation that can obviously be received through social security insurance. Compensation is not paid for

any additional costs that may arise as a result of benefits provided for by the government, county council or municipality being debited in a greater amount or lapsing because the injured person is entitled to reimbursement for costs under this undertaking.

In **Finland** there is a pharmaceutical injury insurance that is financed by the producers themselves and has existed for 19 years as a voluntary insurance based on a contract between insurance companies and the pharmaceutical industry. The insurance covers pharmaceuticals manufactured, imported or marketed by entities that are members of the Finnish Cooperative for the Indemnification of Medicine-Related Injuries. The Cooperative is the policyholder and the insurer is the Finnish Pharmaceutical Insurance Pool, which is made up of insurance companies. Pharmaceutical injuries insurance covers unexpected side effects sustained by users of pharmaceuticals sold or supplied for consumption in the country. Personal injury is compensated providing that there is a likelihood of a causal link between the use of medicine and the injury and that the injury is unreasonable in relation to the treatment. Since compensation does not presuppose the existence of a deficiency of a medicine but only that the injury is "unreasonable", the coverage of the scheme is much wider than that of the Product Liability Act (and the Directive) and of the general product liability insurance schemes provided for by the insurance companies. Pharmaceutical injury insurance also covers the clinical trials carried out in Finland in accordance with instructions issued by the National Agency for Medicines, providing that the entity carrying out the trial is a signatory to the insurance contract through the policyholder. Consequently, the companies do not need to have separate liability insurance for clinical trials. The insurance also covers blood and blood products and intrauterine contraceptive devices. Homeopathic and anthropomorphic products are excluded.

Compensation is paid for pain and suffering, permanent defect and handicap, permanent cosmetic injury, medical treatment expenses, home-care costs, clothing costs and loss of income. In case of death, funeral expenses are also covered up to a reasonable amount, and so is the survivor's pension in cases where anybody entitled to a said pension is left without support. The amount of compensation paid is determined on the basis of the provisions of the Damages Act (412/74). With regard to the compensation of costs, the principle of full

compensation applies. No compensation is paid for minor injuries. When the amount of compensation is calculated, any compensation or benefits likely to be due to the injured out of public funds or under the statutory insurance schemes are deducted.

Finally there is the **pharmapool**, created in **Germany** in 1978. § 94 AMG states that German pharmaceutical industry is legally obliged to financially provide for liability claims up to the maximum amounts indicated in § 88 AMG. Such a provision for coverage can either be made by means of a third party insurance or by an exemption or warranty obligation issued by a German a bank. Consequently the German insurance companies established a special pool in order to deal with high impact liability claims that go beyond usual insurance coverage. This pool does not only represent an institutionalized system for reinsurance, but can also be considered an indirect insurance company. In fact, it pays for damages that go beyond the ordinary pharmaceutical liability insurance.

In case of a pharmaceutical liability claim, the responsible pharmaceutical manufacturer's insurer has to cover damages up to a total amount of Euro 10.000.000,00, further damages up to Euro 110.000.000,00 will instead be compensated by the funds of the pharmapool, so that claims up to a total of Euro 120.000.000,00 will be mutually compensated by the insurer of the pharmaceutical company and the pool. Since there is joint liability between the pool and the single insurance companies that make the relevant contributions to the pool, it could be misleading to identify this multifaceted structure as a sole reinsurance system. The practical relevance of payments of the pharmapool still is relatively low. So far, the significant damages have only been paid in cases of contaminated blood products, but the pharmapool is also very likely to cover the damages induced by Lipobay of Bayer.

6.3 Funds for damages caused by vaccines

In some Member States damages caused by defective vaccines are compensated by special funds, which are financed by the government.

Damages caused by vaccines are compensated by special funds financed by the governments

It is the case of the **UK,** where the law provides for a Vaccine Damage Payment Scheme. Under this scheme, a one-off payment is available if a person has been severely disabled as a

result of a vaccination against certain diseases. The disabled person may also be eligible for compensation if:

a) they are thought to be severely disabled because while she was pregnant, their mother had the vaccination for one of the diseases recognized in the list

b) they were in close physical contact with someone who was vaccinated against poliomyelitis with vaccine that was given orally. Children must be 2 years old or more before they can receive payments.

The vaccination must have been given in the UK or the Isle of Man, but the damaged person may still be able to get a payment if they are living abroad at the time of the claim. If the vaccination given was outside the UK, the injured person may still be able to get a payment if the vaccination was given as part of the Armed Forces medical facilities.

In **Ireland** people damaged by a defective vaccine can apply individually or with the assistance of a lawyer to a government commission in order to obtain compensation.

In **Italy**, the same law which introduced the fund for people infected with HIV and Hepatitis also provided for compensation for those who have been damaged by a defective compulsory vaccination which has caused a permanently injury.

Austria and **Germany** also have special compensation funds for damages derived by defective vaccinations, financed by the government. The **Austrian Vaccination Damage Act** states that the government is liable for damages caused by compulsory vaccinations, recommended vaccinations, and vaccinations named in the so called "Mutter-Kind-Pass". Compensations cover the costs of curing the damage (inter alia medical aid, orthopaedic tools and transport costs), the costs of rehabilitation and periodical money allocations. If the vaccination has provoked a grave bodily injury as defined in the criminal code, the person injured must be paid in a lump sum ("pauschalierte Entschädigung"). According to the report on the situation of people with disabilities by the Austrian BMSG (see Annex for full description), at the end of 2001, 75 persons were beneficiaries of periodic money allocations on the

basis of the mentioned law. The general costs were approximately two millions Euro in 2001[75].

In **Germany**, according to § 60 of the Law concerning protection against infections (Infektionsschutzgesetz), it is possible to get compensation when a health damage occurred after a vaccination. The claim requires that the vaccination has been recommended by the competent regional authority, has taken place in the same region, has been ordered by reason of the law concerning protection against infections and has been legally prescribed. In order to get compensation it is sufficient to prove the probability regarding the causality between vaccination and damage. The obligation to pay the compensation falls on the government in favour of which there is a *cessio legis* regarding the claim of compensation against a third person.

6.4 Funds for damages caused by foodstuffs

Publicly financed funds for damages caused foodstuff were set up only in Spain and in the UK

The only Member States where a fund for defective foodstuffs was set up are **Spain** and the **UK**. A complementary compensation fund for people affected by poisoning has been created by the Spanish Real Decree 1276/1982 of June 18, 1982 for the Toxic Oil Syndrome[76]. The Resolution of December 11 of 1986 from the Ministry of Labour and Social Security's undersecretary established a procedure in which it was declared the state of grand invalidity for the people affected by the Toxic Oil Syndrome who didn't belong to the Social Security system or any other public social service system.

In the **UK**, following the publication of the BSE Enquiry Report in October 2000, a compensation scheme for victims of vCJD has been developed by the government in consultation with representatives of families affected by vCJD. An interim Trust fund was set up on 12 April 2001 and interim payments of £25,000 have already been made to most of the families. The payments have been directly paid to the victim or his/her surviving spouse or partner or parents, brothers or sisters[77].

[75] BMSG, Bericht über die Lage der behinderten Menschen in Österreich from 14.03.2003.

[76] Twenty years ago twenty thousand people were poisoned by an unknown agent, more than three hundred people died and many others became disabled or with severe *sequelae*. The case of massive poisoning by the consumption of colza oil (contaminated oil with denatured aniline) gave rise to two criminal trials which were the most important trials without any doubt in the Spanish Law of the last century not only for the number of victims but also for the amount of money given as compensation (three thousand million euros). There were two criminal trials, the first one against the businessmen, and the second against the civil servants, the latter in order to obtain a verdict in which the administration was held as civil liable.

[77] See www.gov.uk.

6.5 Funds for damages caused by chemicals

Austria is the one country where damages caused by defective chemicals were compensated. A fund for damages caused by asbestos was set up, even if the issue of (lethal) diseases caused by products containing asbestos is still not adequately dealt with: lung-cancer and pleura-cancer (Pleuramesotheliom) were recognized as professional diseases ("Berufskrankheiten") in the social accident insurance branch only in 1976. However, the chance to get a pension is very low: the first "filter" is the proceeding: the AUVA chooses the expert in charge of examination – not surprisingly, the exams are mainly negative. Indeed, a statistic of the AUVA shows that asbestos-specific professional illnesses, namely asbestosis and mesotheliums are very rarely recognized: between 1980 and 1999, the recognition rate for asbestosis was between 7 and 19 cases per year, the rate for mesotheliums between 2 and 27 cases per year. In this context, three deputies of the Parliament of Upper Austria made a legal initiative ("Initiativantrag"), asking among others for the creation of an asbestos-fund, financed by the government, the concerned industry and the AUVA. However, the initiative was refused in the initial phase of the lawmaking process.

6.6 Other special compensation funds

In Austria there is also a special fund for cancer. It is run by the private association "Flora – Viennese Women against Breast Cancer" established to help women that have breast cancer (regardless of the causes), who are residents in Vienna and are in financial distress. It is financed by private donations and proceeds from charity-events. The resources of the fund should cover the costs incumbent as a result of the disease. There is no legal claim for the assistance by the fund. The applicant has to submit a written application with all the necessary documents. The application is examined by an advisory body and the decision is made by the executive committee. The amount of the assistance varies between 360,00 and 3.630,00 Euro. The maximum amount can be increased up to 1.450,00 Euro if the applicant has to care for at least another person. The assistance is generally paid in the form of a lump-sum payment. However, if the assistance is paid more than once, it can not exceed 7.270,00 Euro per year. If the applicant has to care for at least one other person, this sum can be increased up to 3.630,00 Euro.

A synoptic table of the special compensation funds in relationship with the different kind of products is made in the following table 13.

Table 13

STATE	PHARMACEUTICAL	CHEMICALS	AGRICULTURAL	FOOD	BLOOD DERIVATIVE
AUSTRIA	Compensation for wrongful vaccination fund	Fund for damages caused by asbestos	-	-	HIV Fund and hepatitis fund
BELGIUM	-	-	-	-	HIV Fund
DENMARK	Compensation fund for damages caused by pharmaceuticals	-	-	-	HIV Fund and hepatitis Fund
FINLAND **The state of art defence does not apply**	Finnish Cooperative for the Indemnification of Medicine related injuries (producers and insurance companies	-	-	-	-
FRANCE	-	-	-	-	The development risk clause does not apply Compensation fund for people infected by HIV
GERMANY	The development risks clause does not apply Pharmapool	-	-	-	-
GREECE	-	-	-	-	-
IRELAND	Government Commission for damages caused by defective vaccines	-	-	-	Special Hepatitis C compensation Tribunal
ITALY	Special compensation fund for people injured by compulsory vaccines	-	-	-	Special compensation Fund for HIV and hepatitis
LUXEMBOURG **The state of art defence does not apply**	-	-	-	-	-
NETHERLANDS	-	-	-	-	-
PORTUGAL	-	-	-	-	Special security scheme for people affected by HIV and Volunteer Arbitration Centre for procedures caused by administration to haemophiliacs
SPAIN	The development risks clause does not apply	-	-	The development risks clause does not apply Fund for toxic oil syndrome	Special compensation fund for HIV and hepatitis c
SWEDEN	Compensation fund for damages caused by defective pharmaceutical	-	-	-	
UK	Vaccine Damage Payment scheme and Family Found for Victims of thalidomide Fund for defective vaccines	-	-	Fund for vCJD victims	Found for HIV victims

PART III -

SOCIAL SECURITY SYSTEM AND

COMPENSATION FUNDS: ANALYSIS OF THE

FUNCTIONING

7. *The functioning of the social security schemes and their action of recourse*

All the social security schemes are financed partly by the contributions paid by the employers, and partly by the taxes paid by the employees and the self employees or freelancers. In order to be granted the allowances provided for by them it is necessary to fulfil the requirements indicated by the national laws such as: the belonging to the categories of workers as indicated above; the number of years of contributions paid as provided for by the law and which varies from country to country; the proof of the sickness or incapacity and the percentage of inability and invalidity.

Social security schemes are financed by contributions of employers, by the taxes paid by the employees and the self-employees or freelancers. It is necessary to fulfil the requirements indicated by the national laws.

7.1 Relationship between Social Security Benefits and compensation paid by producers

The emoluments paid by the social security schemes may substitute or be added to the compensation that the damaged person can ask the producer.

In the **UK,** the social security scheme is based on the principle that a person should not be compensated twice for the same accident, injury or disease by getting social security benefits and compensation from a liable third party. As a consequence when an insurance company pays out compensation or damages to a claimant, the total of any social security benefits paid or payable to the victim will be set out in a schedule which the insurance company then deducts from the actual amount paid to the victim.

Emoluments paid by the social security schemes may substitute or be added to the compensation that the damaged person can ask the producer

The **Belgian law** on product liability rules that compensation via the product liability regime is justified only when the welfare state provisions are not sufficient. The law that implemented Directive 374/85/EEC states that producer liability must be considered as a complementary instrument in respect to other means of compensation. It means that the damaged person will have to ask for compensation first to the social security institutes and, only after, he/she will have the possibility to ask the producer to be compensated of those damages which have not been paid out by the social security system.

In the other Member States, even if the law does not state anything, it has been established that the victim should not be compensated twice for the same injury. Therefore, when a damage caused by a defective product occurs, the injured person can ask the producer the compensation for damages, subtracting what he/she has already perceived by the social security schemes. When establishing if the compensation paid by the producer is in addition or in substitution to the emoluments paid by the social security schemes, it is necessary to bear in mind a fundamental principle. The social security schemes pay out only the economic damages whilst the laws on product liability can also take into consideration the non-economic ones. It is not possible to obtain a double compensation for economic damages and the damaged person will be entitled to have just the social security emoluments or the compensation paid by the manufacturer. As concerns the non-economic damages, since they are not compensated by the social security schemes, they will have to be refunded by the producer, when the national law on product liability so establishes and they will be added to the sums obtained by the social security schemes. As a result, in these cases, the damaged person has an active claim against the producer limited to the amount not covered by the social security institutes. The mechanism is the same that is applied in Belgium, with the difference that in this last country it has been expressly introduced by the national law, in the other countries it has been drawn by the general principles of law. This mechanism leads to the conclusion that - in the cases where the development risks clause applies - the damaged person will receive only the social security emoluments if all the requirements provided for by the law have been met, or the compensation provided for by a special compensation fund applied to the defective product. They will not receive any compensation for the non-pecuniary damages.

The time when the social security emoluments can be requested varies. In some Member States they must be required before asking the producer for compensation (the emblematic case is Belgium), in other States the time when they are required is not relevant.

7.2 The action of recourse of the social security schemes

The social security institutes which have compensated the damages caused by defective products may ask for the reimbursement of all the sums paid. However in those States where the state of the art defence applies, if the producer is not held liable for the damages caused by his/her defective product because - according to the state of knowledge at the time when the product was put into circulation - it was impossible to detect the defect, he will not have to pay any compensation.

In most Member States Social Security institutes may ask the producer the sum paid. The producer can avoid the payment using the state of art defence

In many cases the action of recourse of the social security institutes has been set out by the national laws and repeated by the case law.

In **Spain** the recourse action is recognised in Article 43 of the Insurance Contract Law 50/1980 and in Article 83 of the General Social Security Law which allows public administrations that have attended the users to claim back the expenses from the party responsible. Later the principle was held by the Spanish Supreme Court of Justice, which ruled that the State has the right to make good its losses at the expenses of the responsible person.

In **France** Article 29 of the Law 5/7/1985 recognises the social security institutes the right to recover the hospital fees and the expenses for drugs, treatments and sickness benefits. Non-pecuniary losses are excluded with the exception of the so called "incapacité fonctionelle" that, even if considered a non-pecuniary loss, is included in the general incapacity and subject to the third party right of recourse. Also in **Greece** the action of recourse of the social security institutes is expressly ruled by the law[78].

In **Italy,** the recourse action has been expressly recognised for one of the social security institutes and then extended by the case law to all the other institutes. In **Denmark,** section 17 of the Act on Liability states that payments under the social security legislation including daily allowance, medical assistance, pensions under the social pension legislation that an injured party is entitled to cannot constitute a basis for a right of recourse against the liable party, except in the case of illness emoluments. Following this rule, in a case the municipality was

[78] Law n. 4104/1960 and Royal Decree n. 226/1973.

entitled to relief in respect of partial indemnity for illness emoluments due to the serious breach by the producer. [79]

The **English Social Security Act 1997** has introduced a compensation recovery scheme according to which any social security payment paid to an individual by reason of an accident, injury or disease can be recovered by the government from the compensator that is, in the case of a defective product, the manufacture's insurance company. This scheme is based on the principle that taxpayers, who finance the social security schemes, do not have to subside a liable third party in their obligation to fully compensate a person for the injury or disease they have contracted.

Both in **Austria** and **Germany**, the law rules commonly refered to practise of *cessio legis* according to which the tort claims of the damaged person are transferred automatically to the social security institutions. In the former country the *cessio legis* in favor of the Sozialversicherungsträger takes place at the time of the accident. In Germany the *cessio legis* applies if: the department of social benefits has paid the injured person; the claim is based on the law of product liability; a real benefit has been granted in order to compensate the damage[80].

In **Luxembourg** after granting social security or health care benefits to victims of defective products, the social security institutes may obtain a refund of all the emoluments from the responsible person[81].

In other Member States, such as **Portugal**, there is not any special provision and the action of recourse is only possible on the basis of the general legal rules. There are no cases concerning proceeding against producers.

In Netherlands and Finland the Social Security Institutes do not have action of recourse against the producer

There are only a few Member States where recourse action is not granted. This is the case of the **Netherlands,** where on the basis of the existing laws, claims concerning product liability are not susceptible of subrogation, and **Finland** where, according to the law, social security institutes do not have any right of recourse if the damages have not been caused by a criminal offence.

[79] UfR 2003, 792.
[80] § 116 SGB.
[81] UCM (Union des Caisses de Maladie) Statutes

Table 14 - Relationship SSS (*) emoluments and PPL (**) compensation

MEMBER STATE	TIME OF THE REQUEST OF THE EMOLUMENT	ACTION OF RECOURSE OF THE SOCIAL SECURITY INSTITUTE AGAINST THE PRODUCER	CASE LAW
AUSTRIA	Before PPL compensation	Yes (Cessio Legis)	-
BELGIUM	Before PPL compensation	Yes	-
DENMARK	Before PPL compensation subject to reimbursement when compensation has been awarded or after the award of PPL compensation if the victim is in need	Yes in respect of sickness emoluments.	The municipality was entitled to relief in respect of partial indemnity for illness emoluments due to the serius breach by the producer (UfR 2003.792)
FINLAND	-	No	-
FRANCE	Before PPL compensation	Yes	Defective health products; An affaire regarding presumed trichinoses due to ingestion of contaminated horse meat, imported from Yugoslavia.
GERMANY	Before PPL compensation	Yes	
GREECE	After or before	Yes	-
IRELAND	Before PPL compensation	No	-
ITALY	After or before	Yes	The recourse action is recognized to all the social security institutes (Corte di Cassazione 9/7/1991 n. 7587)
LUXEMBOURG	At the same time of PPL compensation	Yes	-
THE NETHERLANDS	Before, at the same time or after the PPL compensation	No	-
PORTUGAL	After or before	Yes	-
SPAIN	Before PPL compensation	Yes	The State has the right to make good its losses at the expenses of the responsible person (Supreme Court of Justice, 26/9/1997)
SWEDEN	Before PPL compensation	-	-
UK	After or before	Yes	-

8. *The functioning of the special compensation fund*

Compensation funds for damages caused by infected blood. The benefits generally consist of a lump sum. Their functioning varies.

The special compensation funds for damages caused by infected blood created in **Spain**, the **UK**, **France** and **Italy** are financed by the government and the benefits generally consist of a lump sum. Their functioning varies.

In **Spain** an application together with the medical record must be submitted to the public administration. The benefits may consist of a lump sum of Euro 60.101,21 to be paid in two annuities, or in a monthly payment which is: equal to minimum wage for people infected who are under 18, people who are over 18 are entitled to twice of the minimum wage, children dependent on infected people are entitled to 2/3 of the minimum wage until they reach the age of 24. If the child is handicapped, the benefit is paid for their entire life. These pensions are compatible with any other pension. It is compulsory to waive any claim for contamination by HIV against any public sanitary administration or staff of the same to get these pensions. Consequently the injured is not entitled to receive the benefit if he/she has sued any public sanitary administration for contamination by HIV and a verdict of guilty has been passed.

In the **UK**, it is the hospital which has to apply to the National Health System and has to confirm that, on the balance of probabilities it was blood supplied by them that lead the patient being diagnosed as HIV positive.

In **France**, the person infected with HIV can claim compensation under Article 1147 of the Civil Code which provides for the award of damages in the event of the non-execution of a contract. It is a form of strict liability and the transfusion centre can not allege that it was impossible to discover the defect in the blood at the time of its supply. The plaintiff must establish infection by HIV caused by the transfusion of blood products or injections of products derived from the blood. The fund should compensate the victims for the damages suffered within three months from the date on which the fund received complete documentation in support of the alleged damage claim. The offer shall indicate the assessment

made by the fund in relation to each head of damage. There shall be full compensation for all pecuniary and non-pecuniary damages sustained by the direct and indirect victims of contaminated blood transfusions carried out in France. Three-quarters of the compensation due is payable upon diagnosis of the HIV infection, and one-quarter at stage IV of the illness, provided that the development of full-blown AIDS has been established. Any proceedings against the fund (when a claim is rejected, there is a failure to make an offer, or the victim has rejected an offer) must be brought before the Court of Appeal of Paris. When a victim accepts an offer from the fund for full compensation, he/she is prevented from seeking further compensation for the same injury.

The same applies in **Italy,** where it was established by courts that the law introducing such an indemnity has not excluded the possibility for the injured person to obtain other forms of compensations in addition to the indemnity. The proceeding is ruled by the law n. 210/92. The damaged person has to submit, within 10 years for damaged caused by HIV and 3 years for damaged cause by Hepatitis, his/her request of refunding to the AUSL, the local health authorities, together with the medical documents required for by the law. A medical body will decide whether compensation can be granted. It is possible to appeal against the medical body's decision before the Ministry of health. This same proceeding applies for damages caused by defective vaccines, but compensation must be asked within 3 years. Because of the many proceedings started by those who have been infected by HIV and Hepatitis, the Italian Parliament recently approved a new law(n. 141/2003) whose Article 3 indicates the total amount of money that will have to be paid, in an out of court settlement, to those who have sued the Ministry of health.

The fund for the victims of HIV introduced in **Austria** in 1988 is different because it is financed by the State in part and in part by the pharma-industry. Therefore the applicant will receive an amount of money from the Government and an amount of money from the pharmaceutical companies.

In **Belgium** on the 12 of July 2001 a non-profit organization called «Association pour l'octroi d'une allocation aux personnes contaminées par le virus du Sida à la suite d'une transfusion sanguine ou d'administration de produits sanguins ayant eu lieu en Belgique du 1 août 1985 au 30 juin 1986 » (AAPS) was

created in order to evaluate all the applications to handle payment of government financed compensation for HIV damages. The application must be an official ad hoc form provided by the organization's secretariat. All the requested fields (names of relatives, medical data, doctor references, etc… including bank accounts to which the compensation sum can be transferred) must be properly filled in for the application to be processed. A compensation of Euro 124.000,00 is provided for the patient. In case of death a compensation of Euro 62.000,00 is granted to the partner living with him/her and a compensation of Euro 6.200,00 to the other relatives and for each son. It covers the material as well as moral damages caused to the contaminated person or his/her relatives, namely the pain and troubles in everyday life caused by being HIV positive and the eventual appearance of the disease. The association makes its decision regarding the compensation application after receiving the motivated advice of the Experts Committee. If the person receives an allocation, they renounce the possibility to claim any other possible compensation in the future from the government or any other organization located in Belgium that was responsible for the blood transfer or the administration of the blood products in the given period.

The proceeding to be followed before the Hepatitis C Compensation Tribunal established in **Ireland** is ruled by the Act 1997. The action before the tribunal can be brought by a person who has been diagnosed for Hepatitis C resulting from the use of human immunoglobulin anti D or from a blood transfusion or blood products within Ireland. Children, spouses and any dependant of such people can also obtain compensation. The making of the claim does not involve the waiver of any other right of action by the claimant. Written medical or other written reports should be submitted. The application must be made within 3 years form the date upon which he/she first became aware of the infection. The tribunal awards compensation on the basis of the principles which govern the measure of damages in the law of tort and any relevant statutory provisions, taking into account also the aggravated or exemplary damages, the impairment of sexual relations and any reasonable costs and expenses the claimant has incurred in taking the claim. Compensation is paid in the form of a lump sum or a provisional award. The claimant has a period of one month during which he may decide to either accept or reject the award (decision must be in writing) or to

appeal before the High Court whose decision will be final. If he/she accepts the award he/she has to waive in writing any other right of action.

The compensation fund for the damages caused by defective drugs created in **Denmark** is financed and awarded by the Danish government. Authority to administer the scheme is delegated to the association of patients who equally administers the scheme for insurance against medical liability. A complaint board is set up to hear appeals on decisions concerning compensation or refusal to pay compensation. The payment of the compensation presupposes an application by the injured, which is processed within 6 months. The compensation scheme covers cases where liability for producers or importers is excluded under the state-of-the-art-defence under the Product Liability Act. Proof of cause and extent of damage still has to be provided by the applicant. Expenditure of medical examination necessary is to be carried by the applicant. When paid out, compensation will be considered a part of the means of support of the victim and be accounted for in connection with the allocation of social benefits. It also substitutes the compensation paid under the Product Liability Act.

Compensation funds financed by pharmaceutical industry.

The private funds created by the pharma industry in **Sweden** and **Finland** work differently.

In **Sweden** liability is limited to the amount of money provided for in the law. A person who claims compensation shall address his claim to the insurer, and has to submit such investigative material that can reasonably be required to him/her in order for the insurer to be able to determine whether an indefinable drug-related injury has occurred. A person who desires to claim compensation shall, within three years from the time when he became aware of the injury, give written notice to the insurer. If the person who claims compensation starts or pursues litigation in a court for compensation against the party who manufactured or imported the pharmaceutical, the right for compensation for the injury lapses. Questions of principle and claims for compensation that are disputed, are, at the request of the person who claims compensation or of the insurer or of the Swedish Pharmaceutical Insurance Association, be referred to a specially appointed panel – The Pharmaceutical Injury Panel – for an opinion. Disputes between the insurer and the person claiming compensation are settled by arbitration in accordance with the Arbitration Act (1999:116). The arbitration proceedings

shall be based on the written documentation adduced. The parties shall present their cases in writing. The arbitrators may decide whether an oral hearing shall also be necessary to elucidate the material issue. If an arbitrator so requests, the arbitrators shall call in an expert and provide him with the opportunity to present his views. A person who accepts an offer of compensation is liable to assign to the insurer his right to damages from any party who may be held liable for the injury. However this duty shall not apply as regards compensation from social security insurance or road traffic insurance that has been deducted. If the person claiming compensation does not assign his right to damages within six months, he loses his entitlement to compensation for the injury under this undertaking.

In **Finland** any claim for compensation for a pharmaceutical injury must be made within three years from the date when the claimant became aware of the injury. In no case, however, may a claim be made later than 15 years from the date when the injured person stopped taking the pharmaceutical that caused the damage. Any applicant who is dissatisfied with the insurance institution's decision can bring the matter to the Pharmaceutical Injuries Board's resolution, which is comprised of neutral experts. The Board issues its opinion free of charge. The applicant can also initiate an action before the District Court of his/her domicile, or bring the matter before an arbitration tribunal, if it has been agreed with the insurance institution. In practise, only rarely have the two latter alternatives been chosen.

The **German Pharmapool** is a private institution that was founded in Germany by the national insurance companies in 1978. There are no legal provisions ruling the procedure. It is mainly a re-insurance, and therefore has no direct impact on damage claims and on the court proceedings. Injured people can only sue the pharmaceutical producer, because there is no legal foundation of a direct claim against the insurer. Hence, the patients cannot file any actions against the insurer or the pharmapool. Only after the judge's decision on the producer's liability, the pharmaceutical producer will be reimbursed by the insurer and the pharmapool, according to the insurance terms. It should be stressed that the terms and conditions affecting the relationship between the pharmaceutical industry, the insurance companies and the pharmapool as reinsurance are not relevant for the injured patient, because according to the

German law, there is no joint liability between the pharmaceutical manufacturer and the insurer. Hence, the pharmapool can be said to be an insurance for insurance companies. It is not a fund that covers damages caused by defective medicines in general, but it makes reimbursements in case of concrete, proven liability of a specific insured pharmaceutical company. It has no other functions and does not affect the relationship between the pharmaceutical manufacturer and the consumers. Besides various recommendations of political parties and consumer lobbies, the German Legislator has always decided against the introduction of a general reimbursement fund for damages caused by defective pharmaceutical products.

Functioning of funds covering damages caused by vaccines

The Vaccine Damage Payment Unit, on behalf of the Department of Work and Pensions, administers the fund that covers the damages caused by defective vaccines in the **United Kingdom**. The assessment of claims is undertaken by a medical agency sub-contracted to work for the DWP, with a right of appeal to the Vaccine Damage Appeal Tribunal on both facts and law. In theory there are two routes for victims of vaccine damage to receive financial compensation as a result of vaccine damage: they can claim under the VDP scheme or bring a claim in the civil courts. Although in the paste there has never been a successful claim on these grounds, multi-party litigation has recently begun on behalf of over one thousand children who claim to have been damaged by the MMR vaccine (Measles, Mumps and Rubella vaccine). Their claim is under the Consumer Protection Act 1987. The trial was scheduled for October 2003. In order to get compensation, the vaccination must have been given before the person's 18th birthday unless it was against poliomyelitis or rubella (German measles), or during an outbreak of the disease in the UK or the Isle of Man. The individual must claim within 6 years and a lump sum is paid.

In **Austria** the decision whether to grant the allowance is to be taken by the “Bundessozialamt”, and in the second instance by the “Bundesberufungskommission”. If there are claims based on other laws that exceed the compensations provided for by the “Impfschadengesetz”, the damaged person may pursue those damages additionally.

Table 15 - Relationship SSS (*) emoluments and PPL (**) compensation

MEMBER STATE	TIME OF THE REQUEST OF THE EMOLUMENT	ACTION OF RECOURSE OF THE SOCIAL SECURITY INSTITUTE AGAINST THE PRODUCER	CASE LAW
AUSTRIA	Before PPL compensation	Yes (Cessio Legis)	-
BELGIUM	Before PPL compensation	Yes	-
DENMARK	Before PPL compensation subject to reimbursement when compensation has been awarded or after the award of PPL compensation if the victim is in need	Yes in respect of sickness emoluments.	The municipality was entitled to relief in respect of partial indemnity for illness emoluments due to the series breach by the producer (UfR 2003.792)
FINLAND	-	No	-
FRANCE	Before PPL compensation	Yes	Defective health products; An affaire regarding presumed trichinoses due to ingestion of contaminated horse meat, imported from Yugoslavia.
GERMANY	Before PPL compensation	Yes	
GREECE	After or before	Yes	-
IRELAND	Before PPL compensation	No	-
ITALY	After or before	Yes	The recourse action is recognized to all the social security institutes (Corte di Cassazione 9/7/1991 n. 7587)
LUXEMBOURG	At the same time of PPL compensation	Yes	-
THE NETHERLANDS	Before, at the same time or after the PPL compensation	No	-
PORTUGAL	After or before	Yes	-
SPAIN	Before PPL compensation	Yes	The State has the right to make good its losses at the expenses of the responsible person (Supreme Court of Justice, 26/9/1997)
SWEDEN	Before PPL compensation	-	-
UK	After or before	Yes	-

9. *Cases where consumers could remain without protection*

Considering the damages covered both by social security schemes and compensation funds, there are some cases in which consumers receive little or not protection.

The study of social security schemes and of special compensation funds shows that there may be cases where consumers receive little or not protection. Such cases are described in the following analysis making a distinction among the different product groups.

9.1 Blood and blood derivatives

Blood and blood derivatives

Unemployed people

Unemployed people. Social security benefits are not always granted to people who are unemployed. There are two possibilities:

a) social security benefits are granted

b) social security benefits are not granted.

When social security benefits are granted (option a) - injured people can:

I) ask the producer for further compensation

II) apply for a special compensation fund where it exists.

In option I), they can not receive any type of compensation from the producer if the state of the art defence applies. As a result, if it is not possible to apply for a special compensation fund, people in this situation will only be entitled to social security benefits. For example, Greek social security benefits are paid to people who are unemployed, but there are no compensation funds for HIV and Hepatitis victims. If the producer is not liable, the injured people will be entitled to social security benefits but will not receive any other compensation.

In option II), in addition to social security benefits, injured people can apply for the special compensation fund if such a

funds exists. In Austria, for example, unemployed people are entitled to sickness benefits. They can also obtain compensation from the HIV fund.

In the second scenario - social security benefits are not granted - injured people can do the following:

III) ask the producer for compensation

IV) apply for a special compensation fund where it exists.

In option III), they will not receive any compensation from the producer if the state of the art defence applies. As a result, if it is also not possible to apply for any special compensation fund, they will not receive any compensation.

In option IV), the injured people can obtain compensation if a special compensation fund exists. If no compensation funds exist for HIV and Hepatitis, and producers are not liable, unemployed people will not be entitled to any form of protection.

The fact that development risks and the resulting damages are usually discovered after the product was on the market for many years must be taken into consideration. As a result, it is possible that those who are liable for the damages according to both the product liability Directive and the national laws, are not in business any more or have gone bankrupt. In this event, the level of consumers' protection will decrease, except in the cases where a special compensation fund exists and social security benefits are granted.

Blood and blood derivatives

Employed people

Employed people. People who are employed usually receive social security benefits when the requirements provided for by the law are fulfilled (number of years of contribution, kind of work done, kind of invalidity, etc.). The possible scenarios are as follows:

a) injured people are entitled to social security benefits because all the requirements are fulfilled. As a result they are granted the either sickness benefits or the invalidity or inability allowance. They can also do the following:

   I) ask the producer for further compensation

II) apply for a special compensation fund where it exists.

If the producer is not held liable, the only possibility is to apply for the compensation fund. If no compensation fund is provided for, the injured people will only receive the social security benefits. Let's evaluate this possibility using a Greek employee as an example. He/she undertakes a blood transfusion and as a result is infected with HIV or Hepatitis. No compensation funds for such damages are provided for by the Greek government. Therefore the only possibility for the injured person is to ask the producer for compensation. If the producer does not want to pay and the case is brought to the national Courts, no compensation will be granted in the event that the producer is not held liable for the HIV or Hepatitis infection.

b) injured people are not entitled to social security benefits because the requirements established by the national law are not fulfilled (for example because he/she has not paid all the required contributions). Therefore, they are not granted any social security benefits. However, they can do the following:

III) ask the producer for compensation

IV) apply for the special compensation fund where it exists.

In the event that no compensation funds for HIV and Hepatitis victims exist and the producer does not compensate for the damage caused because of the development risk clause, there could be a low level of protection.

It is possible that those who are liable for the damages (according to both the product liability directive and the national laws) are no longer in business or have gone bankrupt. In this event, the level of consumers' protection will decrease, except in the cases where a special compensation fund exists and social security benefits are granted.

9.2 Pharmaceuticals and vaccines

Pharmaceuticals and vaccines

Unemployed people

Unemployed people. In Member States where social security schemes grant sickness and/or invalidity benefits to injured people who are not employed, they can do the following:

a) ask the pharmaceutical producer for further compensation

b) apply for a special compensation fund where it exists.

Using Finland and Sweden as an example, they can be said to grant unemployed people a good level of protection. As a result, the unemployed can obtain the social security benefits and also apply for the compensation funds financed by producers. However, the emoluments paid under the social security schemes will be deducted from the compensation granted by the special fund for damages caused by pharmaceuticals.

The situation is different in other countries. For example, in Italy no social security benefits are paid to the unemployed (except for the civil invalidity benefit where it applies) and no special compensation funds for pharmaceutical victims were set up (except for defective vaccines). The only possible solution for injured people who are unemployed is to ask producer for compensation. However, if the producer is not liable because of the application of the state of the art defence, the injured people can not obtain any form of compensation except in the event that they are entitled to the so called civil invalidity.

It is possible that those who are liable for the damages, according to both the product liability directive and the national laws, are not in business any more or have gone bankrupt. In this event, the level of consumers' protection will decrease, except in the cases where a special compensation fund exists and social security benefits are granted.

Pharmaceuticals and vaccines

Employed people

Employed people. If employed people who are injured by a defective pharmaceutical fulfil all the requirements provided for by the national law for the payment of the social security benefits, they will be entitled to such emoluments. They can do the following:

a) ask the producer for further compensation

b) apply for the special compensation fund when available.

If no special compensation funds exist and the producer cannot be declared liable, the damaged people will only be entitled to the social security benefits. If such benefits cannot be paid because the requirements are not fulfilled, the damaged people will receive a minimum level of protection. This is what happens for example in Portugal, except in the event when, according to the law, the injured people could take advantage of a form of voluntary insurance.

9.3 Chemicals

Chemicals

Unmployed people

Unemployed people. A relevant fund for damages caused by chemicals was set up in Austria. In the event that unemployed people are damaged by a defective chemical product, they can:

a) obtain compensation from the social security schemes when available and

b) ask producer for (further) compensation, or

c) apply for the special compensation fund in Austria if they are Austrian citizens and the damaged occurred in Austria.

When no social security schemes for unemployed apply, they will be entitled only to the compensation paid by the producer. If the producer is not liable, no compensation will be granted, except in the event when an allowance for civil invalidity is granted (this is what happens in Italy) or a voluntary social security scheme applies (for example in Portugal).

It is possible that those who are liable for the damages, according to both the product liability directive and the national laws, are not in business any more or have done bankrupt. In this event, the level of consumers' protection will decrease, except in the cases where a special compensation fund exists and social security benefits are granted.

Chemicals

Employed people

Employed people. If employed people fulfil all the requirements provided for by the law, they are entitled to the social security emoluments. In addition further compensation

can be claimed from the producer. However, in Member States where the producer is not liable because the state of the art defence applies, there are two possibilities:

a) the damaged people will only obtain the social security allowances

b) the damaged people can not obtain any social security emoluments except in the event when an allowance for civil invalidity is available or a voluntary social security scheme is provided for.

It is possible that those who are liable for the damages, according to both the product liability directive and the national laws, are not in business any more or have gone bankrupt. In this event, the level of consumers' protection decreases, except in the cases where a special compensation fund exists and social security benefits are granted.

9.4 Agricultural and foodstuff

Agricultural and foodstuff

Unemployed people

Unemployed people. Relevant funds for foodstuff were set up in Spain (for the toxic oil syndrome) and in the UK (for the BSE and vCDJ syndrome). Unemployed people who are injured by an agricultural product or by defective food (other than the colza oil in Spain or contaminated beef in the UK) can obtain the social security emoluments when possible. The scenarios are:

a) the social security schemes apply and the producer pays compensation either because the state of the art is not implemented in the national law (as in Luxembourg and Finland) or because the producer did not manage to prove that, according to the scientific and technical knowledge at the time when the product was placed on the market, the defect was not known or able to be identified;

b) the social security benefits are granted but the state of the art defence applies and the producer is not liable;

c) the social security schemes do not apply but the producer pays compensation;

d) the social security schemes do not apply and the producer does not have to pay compensation. Unemployed people will receive no compensation

except in the event that an allowance for civil invalidity is granted or a voluntary social security scheme applies.

It is possible that those who are liable for the damages, according to both the product liability directive and the national laws, are not in business any more or have gone bankrupt. In this event, the level of consumers' protection will decrease, except in the cases where a special compensation fund exists and social security benefits are granted.

Agricultural and foodstuff

Employed people

Employed people. If employed people fulfil all the requirements provided for by the law, they will be entitled to the social security emoluments. In addition, further compensation can be claimed from the producer. However, in Member States where the producer is not liable because the state of the art defence applies, there are two possibilities:

I) the damaged people will only obtain the social security allowances

II) the damaged people can not obtain any social security emoluments except in the event that an allowance for civil invalidity is available or a voluntary social security scheme is provided for.

It is possible that those who are liable for the damages, according to both the product liability directive and the national laws, are not in business any more or have done bankrupt. In this event, the level of consumers' protection will decrease, except in the cases where a special compensation fund exists and social security benefits are granted.

10. Compensation Funds at Community Level

There is a different level of protection depending on the type of product

The analysis of the special compensation funds shows that for some of the groups of products indicated, there is a good consumer's protection in many countries (damages caused by

blood derivatives, pharmaceuticals and vaccines), whilst for other groups of products there is little or no protection (damages caused by foodstuff and chemicals). Finally, there are few countries were no relevant funds were found (Greece, Netherlands). Before the approval of the Directive 85/374/EEC there was discussion as to whether or not a compulsory insurance should be provided for producers. In the end, the problem was set aide in order to avoid any further delay in the approval of the product liability rules[82]. An improvement to the current compensation system could be the introduction of compensation funds at Community level which guarantee all consumers at least a reasonable indemnification when damaged by the following products: pharmaceuticals and vaccines, blood and blood derivatives, foodstuff and chemicals. There are two possibilities on what damages the funds could cover:

a) the first possibility that the funds cover also cases where the liability of producers is excluded under the state of the art defence;

b) the second possibility is that funds do not grant any compensation when the state of the art defence applies.

EU fund cover cases where the liability of producers is excluded under the state of the art defence

In the first case, consumers would receive a broader protection and the funds would balance the use of the defence. Moreover, the impact of the funds would not have negative consequences on producers. In fact, if the funds are publicly financed, the producer will not have any further cost. If the funds are financed by producers alone or by both producers and national governments, the risk is shared. In both cases compensation would be granted if consumers prove: the damage; the defect of the product and the casual link between the damage and the defect.

EU fund do not grant any compensation when the state of the art defence applies

In option b) consumers would have to prove also that, according to the scientific and technical knowledge at the time when the product was put on the market, the defect was able to be identified. However, the second solution does not seem to be feasible. In fact, it reverses the burden of proof, thus contrasting with the purpose of the state of the art defence. As a result it

[82] Cerini D, *1996*, 54.

lessens the level of protection that the Directive on product liability as a whole and the development risk clause aimed at granting to consumers. The analysis of the special compensation funds shows that in the most cases compensation is also granted also for the unexpected side effects of products and the unknown risks. For example the special compensation fund which was set up in Denmark for the damages caused by pharmaceuticals also covers cases where liability is excluded under the state of the art defence. The same level of protection is granted in Sweden and Finland for damages caused by pharmaceuticals.

On the basis of the results of the research there are three possible solutions:

First solution. It would be possible to create special funds for the damages caused by the products analysed at the Community level. The funds could be introduced with a Community legislative measure. Regarding the content of the legislative measure the possibilities are:

a) It could simply indicate the products which would be covered; the minimum and maximum amount of compensation; the creation of a body within each Member State whose purpose is to administer the money and to analyse the application deciding whether compensation should be granted. Member States could be left free to establish how the fund should be financed and what the procedure to obtain compensation is. In the States where such a fund already exists, it might be integrated with the provisions of the EC legislative measure.

b) In addition to the above mentioned indications, the legislative measure could also establish in detail the procedure to follow in order to obtain compensation. As a result, there would be uniformity in all Member States. The request should be made within a certain number of years (to be decided) from the time when the damage occurred. It should be submitted to the competent national authority along with the applicant's medical records. Both the applicant and the medical records should be examined by an expert appointed by the authority and the request should be processed within a reasonable time. The payment

should be made within a reasonable time. Similar procedures were introduced for many of the funds analysed: for damages caused by blood and blood derivatives in Spain, France, Italy, Belgium, Austria; for defective vaccine in the UK, Austria, Italy; in Denmark, Germany, Sweden and Finland for defective pharmaceuticals.

In both cases a) and b) the funds should cover the damages which occurred within the country were the product was placed on the market. For example, if a person who lives in Italy is infected with HIV because of a blood transfusion that he/she underwent in the UK, compensation should be paid in the UK and not in Italy. The purpose is to avoid that a government may be asked to pay compensation for damages that occurred in another country. Compensation should cover personal injuries. Medical treatment expenses, homecare costs, loss of income, permanent defect and handicap should also be included as it is provided in the existing analysed funds. If the injured person is entitled to social security benefits, they should be deducted from the compensation granted. This is what happens in Finland and Sweden where, when compensation is granted under the special compensation fund for pharmaceuticals, any compensation or benefits that are paid by the social security schemes are deducted. Compensation could be paid in a lump sum payment or in periodical payments. If the injured person dies, compensation could be granted to his/her spouse or partner, children, parents, sisters or brothers.

The consumer may be left free to decide whether to ask for the compensation provided by the fund or to sue the producer. However, he/she can not obtain a double compensation. That is what happens in Spain, where the injured person has to waive any other claim for compensation when claiming compensation under the special compensation fund for HIV. In the UK the injured person who accepts the payment offered under the fund for HIV victims must sign an undertaking that he/she will not sue the National Health System. Another possibility is that consumers could only ask for compensation from the fund and can not sue the producer. As a result, producers would receive economic advantages because they would not have to pay for the damages.

An example of a fund provided for by a European Community legislative measure which was introduced in all Member States, is the one created with the Directive 84/5/EEC. The fund was set up in order to guarantee that the victims of road accidents did not remain without compensation when the vehicle which caused the accident was uninsured or unidentified. For this reason the Directive invited Member States to create or authorize a body with the task of providing compensation. However, it left them free to regard compensation by that body as subsidiary or non-subsidiary and apply their laws, regulations and administrative provisions to the payment of compensation by this body, without prejudice to any other practice which is more favourable to the victim. Nothing is said in relation to the way the fund should be financed. The fund also aims at compensating people who are injured by third parties. It is not related to product liability; however, it could be used as an example of fund introduced at the community level.

Second solution: Another solution could be the creation of compensation funds partly financed by producers and partly financed by the governments, as exists in Austria for HIV victims. Using this system, the economic expenses would be shared between the governments and producers and among the producers themselves. There are two possibilities:

a) to set up the fund leaving Member States free to decide the procedure to follow in order to obtain compensation

b) to establish the procedure in detail.

Another problem that must be solved is determining the percentage of compensation that would be paid by the governments and the percentage that should be paid by producers. There are two possibilities:

1. leave Member States free to establish this percentage
2. decide it with an European Community legislative measure.

In the first case, there could be countries where producers are required to finance the fund in high percentage and countries where the funds are principally financed by the Governments. This difference could have negative economic effects on the

producers based in the various Member States. In the second case uniformity in all Member States would be assure and there would not be any disparity.

Regarding the procedure to be followed in the event that it has to be established at the Community level, the same idea mentioned above could apply.

Third solution. Another solution could be for the European Institutions to oblige the producers to finance special compensation funds. The Community could:

a) leave producers free to establish the procedure to be followed in order to obtain compensation,

b) indicate the procedure in detail.

The way for financing the fund could be established either by allowing producers to indicate it or by ruling it with a legislative measure.

An example is the oil pollution compensation fund set up by the Convention on Civil Liability for Oil Pollution and the following protocols. The IOPC Fund is financed by contributions from companies or other entities receiving oil carried by sea. Proposals have been made to introduce the IOPC Fund at Community level

11. Some economic remarks on compensation funds

Compensation schemes are one possible institutional arrangement that could settle damages, particularly when the magnitude of an accident is such that the liable party's total assets are insufficient to cover the losses. We have already argued that this is the case for most damages concerning development risk. In such cases, neither strict liability for the injurer, nor joint liability for industry, provides enough incentives to make the liable party take efficient care. The reason is, the magnitude of accidents previously studied, is so great, that industry's total assets are insufficient to pay the damages. To ensure victims are compensated in case of an accident, mandatory liability insurance has been introduced,

Incentives to take care.

even though it might in turn, reduce the incentive to take care, due to moral hazard problems. Such conditions imply that most systems implemented in Europe concerning victims' compensation are relatively efficient, but are not suited to provide appropriate incentives for taking efficient care in safety matters.

This report is an extensive survey of different compensation schemes, both private and public and widely used in Europe. Here we should also discuss such schemes' basic properties against the background of the objectives such funds are expected to achieve. Such requirements can be summed up as follows: they should resist political and economical environment changes and be unambiguous concerning all parties' obligations and rights. Besides these requirements, we also want our compensation system to fulfil the goals of the liability system, i.e. create incentives to take care, induce the efficient level of hazardous activity and compensate victims.

Objectives that compensation funds are expected to achieve.

The compensation systems generally in use, do not meet the liability system's requirements. Whichever the solution imagined in the previous paragraph, neither part of this system concerns the injurer's welfare, and hence cannot affect incentives to take care or moderate activity level. Solution a) where the fund is set up from public subsides; it is certainly efficient in compensation terms, since there is no major liability constraint, but does not provide any incentive whatsoever to take adequate care in product safety matters. The public nature of the fund, on the contrary, is prone to moral hazard phenomena, both on victims and injurers. On the other hand, solution a) defines a system where innovative activity is not affected by the fund's existence, since no contribution is expected by private companies.

Compensation systems in use do not meet the liability system's requirements.

This latter statement does not hold true for the remaining solutions; b) and c). In these cases, contributing to the fund rivals investing in R&D and therefore innovative activity might react negatively to the setting up of the fund. This situation is equivalent to the one mentioned in solution a) as far as moral hazard is concerned.

In other words, the three solutions differ as far as risk allocation is shared between industry and public authorities. In theory, there are reasons that justify industry's burden to co-finance the fund, since it enjoys some benefits from establishing a compensation fund covering development risks. This is the

Arguments in favour or against private financing of the fund.

ratio that inspires many funds privately financed by industry (also voluntarily) all over Europe. Nevertheless, the argument of financial rivalry between financing the fund or investing in R&D, suggests that it may be advisable to foresee some State role in co-financing the fund. In this perspective, solution b) may emerge dominant.

The relevant aspect is, however, that none of the solutions currently available can guarantee sound incentives for potential injurers in product safety matters. Under this perspective, the only answer to this problem would be to create an industry-specific and industry-funded compensation system; the basic idea in funded systems is to connect system payments with system benefits, thus creating incentives for efficient behaviour. With this scheme, the moral hazard problem may ease, given that damages payments from the fund decrease the injurer's income. This would be the case if the injurer owns the returns from the fund.

The theory of a mutual fund.

Specifically, the injurers, together with their assets, should be the owners of the mutual fund. The fund, in turn, receives its means through payments made by the potential injurers. The compensation system is based on the principle that the injurers earn interest from the fund's accumulated capital, the fund is strictly liable and injurers operate under a negligence rule. If an accident occurs, the fund is strictly liable and the injurer will be liable with his assets if he has not exercised due care. That is, the interest the injurer earned from the fund will be reduced, thus increasing incentives to take care. Such a system would induce each injurer to take more care than is currently the case with prevailing systems.

Whichever the solution proposed, the common feature of the compensation schemes reviewed, is the necessity of setting compensation schemes at EU level. The nature of the risk is such as to fall in the serious accident category, i.e. accidents that are very rare, require huge amounts of compensation and involve different countries. In addition, economic analysis has demonstrated that there might be scope for industry-specific intervention. In these circumstances, given the magnitude of the expected damages to be compensated, a fund that is both industry-specific and country-specific would be largely inadequate to provide victims with full compensation, i.e. to guarantee full liability. For this reason, and also the necessity to harmonise the degree of risk coverage that consumers enjoy in

Necessity of setting compensation schemes at EU level.

Industry-specific intervention.

different Member States, it is highly advisable that a mixed public-private compensation fund is established at EU level.

The creation of a mixed public-private fund at EU level is highly advisable.

PART IV -

CONCLUSIONS AND POLICY GUIDELINES

Fondazione Rosselli, appointed by the European Commission's Directorate for the Internal Market (DG III), has carried out this study on the economic impact of the Development Risk Clause (DRC) as in Directive 85/374/EEC on the liability for defective products. The study focuses on the implications of removing the Development Risk Clause (Article 7 (e) of the Directive – which Member States may derogate from), that excludes liability for damage caused by a defect that could not be foreseen, given the technical and scientific knowledge available at the time the product was developed.

The study focuses on the economic impact of the DRC.

The study was aimed at understanding how the various product liability regulations in the European Union work and what their economic impact is, focusing in particular on the "state of the art" defence regime. Moreover, the research's objective was to assess how consumers are protected by different product liability regimes across Member States and the best strategy for consumer protection. The analysis has made it possible to assess what the implications would be for producers and consumers if the development risk clause was removed.

The first point we would like to stress is the apparent paradox by which the DRC is perceived to be of utmost importance in the minds of stakeholders' although its practical application is still extremely limited. This study, together with others carried out over recent years confirm that the application of the Directive is still very limited in Europe. The use of the specific provisions of the DRC is rare within such a relatively limited number of cases. Evidence that the DRC is still of limited use in courts should not lead us to conclude that the clause's impact is not relevant. Our analysis provides at least three examples that allow us to conclude that the Clause is indeed very relevant. The first example, expressed mainly by producers, concerning the fact that the DRC is not used in courts, demonstrates that the Directive has achieved the right balance between consumer protection and producers' incentive to innovate in safety requirements. The second example illustrates that many of the disputes that have arisen in recent years have been resolved through out of court settlements, which by definition, are kept confidential by the parties involved.

The apparent paradox: the DRC is perceived as crucially important but its use is still limited.

Finally, a third example that seems apparent is that the relative lack of evidence about the application of the DRC is due to interference between national legal systems and the EC

Directive on Product liability. The Directive was conceived in such a way as to allow each country to keep national legislation which is more favourable to consumers, at least in some respects. There is in fact evidence that in many disputes concerning defective products, consumers have been able to rely on country-specific legal provisions, therefore able to obtain a level of protection that was very similar, if not greater, to that which they would enjoy in a strict liability regime (i.e. without a Development Risk Clause).

The application of DRC in different Member States..

When applying the state of the art defence in each Member State, it is possible to distinguish three different models of implementation. Two Member States, Finland and Luxembourg, have decided to exclude the state of the art defence for all products. That means that producers are also liable for development risks, as already provided for by the existing provisions on tort and contractual liability. In most Member States, namely the UK, Italy, Ireland, Sweden, Greece, Portugal, Austria, the Netherlands, Denmark and Belgium, the development risks defence has been introduced, applying to all products with no exceptions. In some Member States, the state of the art defence does not apply to some specific products. Thus in Spain the producer is liable for development risks caused by food, food stuffs, pharmaceuticals and blood derivatives. In France, after the scandals arose due to contaminated blood and in Germany due to defective pharmaceuticals, it was decided that blood derivatives producers in the former country and pharmaceuticals producers in the latter remain liable. This even applies to defects which where not known by the science and technology available at the time when the product was placed on the market.

Practical cases were DRC was applied.

The report also surveyed practical cases where the DRC was applied as well as cases where it could have been applied, but was not, both before and after the approval and implementation of the EEC Directive. Some of these cases were brought before national Courts. Therefore studying them provides an understanding of how the Courts ruled in the absence of the DRC and what their legal reasoning was. It can be noted that in those cases, even if the DRC was not applicable, the judges referred to the "state of the art" available at the time the product was placed on the market or when the damage occurred. The majority of these cases were decided on the basis of the rules applying the tort liability and the burden of proof of

the producer's negligence was on the consumer. However, there are some cases where the judges made a reference to the liability for dangerous activities when the burden of proof is on the producer. The analysis shows that, both before and after the Directive's implementation, the majority of the practical cases concern damages caused by blood, blood derivatives, pharmaceuticals and vaccines. Some of these cases were brought before national Courts, others were settled out of court.

The DRC present in Directive 85/374/EEC has been defined in order to find a satisfactory compromise between the need to stimulate innovation and consumers' legitimate expectations of safer products. In fact, one of the main claims being set forward in the current debate on the DRC, is that removal of this clause would stifle innovation.

The DRC is aimed at finding a satisfactory compromise between expectations for safer products and innovation.

In our study we have focused our attention on the effect of full liability on innovation. Although empirical evidence is indeed very scarce, our findings support the fact that the effect of strict liability on the rate of product innovation is very subtle and unclear, as a result of contrasting effects. In particular, on one hand, less innovative companies incur higher liability costs either in terms of expected value of risk or in terms of insurance costs. Correspondingly, the introduction of strict liability should induce such companies to either increase their level of innovation or leave the market, thus resulting in an increase of aggregate innovation within the industry. On the other hand, it is evident that highly innovative companies face much greater uncertainty when introducing new products than their non-innovative counterparts. Stricter application of liability will result in higher risk-related costs that reflect such uncertainty. Companies would in principle cope with such uncertainty by two alternative strategies: on one hand, they would try to reduce the level of uncertainty by focusing their efforts on more predictable and conventional results and by decreasing the level of radical innovation. On the other hand, they would try to direct their innovation effort towards quality and safety-related product features. Consequently, it is certainly very difficult to assess whether the innovative effort displays a positive or negative relationship with respect to a stricter or looser application of liability. Nevertheless, we can certainly conclude that the kind of innovation performed by industry is bound to change. In particular, we argue, in accordance with current economic literature, that strict liability regimes would encourage greater process innovation, an increased rate of

Strict liability regimes would induce greater process innovation, an increased rate of incremental innovation but a substantial collapse in product variety, radical innovation and basic research.

incremental innovation, but a substantial collapse in product variety, radical innovation and basic research.

Moreover, we were able to demonstrate that the effect on innovative activity is shaped by many different industry-specific characteristics, such as market structure, the pace of innovation, product architecture and the product life cycle. All such findings fuel our suggestion that the Development Risk Clause should be treated as an industry-specific issue, and as such any form of policy intervention should be calibrated according to industry features.

Another line of investigation concerned different stakeholders' belief that removing the Development Risk Clause would yield a steep increase in companies' insurance costs. This was expected to be ultimately reflected in production costs, prices and market structure. There seems to be little evidence that the Directive as such had a relevant impact on insurance rates. The general perception that was put forward by both industry experts and academics is that insurance rates have only increased marginally since the Directive was introduced. Although not much evidence is available on the specific effect of the Development Risk Clause, we may argue that even in this specific case insurance costs did not rise considerably. Similarly, within Europe, there is no extra insurance when products are exported to Member States that have not applied the DRC in specific sectors. This can probably not be presented as supporting evidence though, given the relative irrelevance of the market dimensions where the DRC does not apply. One explanation that seems to emerge is that differences among Member States are only partially determined by the application of the Development Clause, although such differences are more often mediated by special provisions contained in national legal provisions. Contrasting evidence, significantly more relevant, is provided by the fact that exports from Europe to the United States can be between two to ten times more expensive (especially for pharmaceuticals) than exports to other countries. This, besides confirming a potential effect of different liability regimes on insurance costs, seems to represent a major political issue, since it imposes *de facto* non-tariff barriers to international trade.

The removal of DRC would increase companies' insurance costs.

Even more important than the increase in insurance rates which account for a limited burden on sales (seldom over 1%), we stress that the major problem is probably related to insurability.

There is a severe insurability problem: companies might not find insurance coverage for specific developmental risks.

Specifically, companies could be unable to find insurance coverage for development risk, especially when risks of this nature can involve major accidents. As far as development risks are concerned, they generally seem to fall into the area of non-insurable risks, since they occur very rarely and often imply severe damages. Under these conditions, it is highly likely that, should the Risk Development Clause be removed, insuring themselves against development risk will not be feasible, simply because a market for development risk insurance might not exist.

A related argument concerns the possible increase in production costs deriving from higher insurance. In particular this is expected to have an impact on market structure. We have highlighted that, if consumers are not fully aware of a product's safety features, strict liability is bound to reduce demand for that product by increasing costs and prices. Since there seems to be a shared view between industry and consumers that product development and innovation are characterised by significant information asymmetries on safety features, we may argue that insurance against liability might negatively affect demand and industry size. Having said that, we need to stress that speculating that an increase in insurance costs will definitely be reflected in prices, is at least debatable. This will depend largely on market structure and in particular on the degree of competition in the final market.

Removal of DRC might induce a change in market structure.

Finally, we have proposed that an increase in production costs is bound to change industry's structure, certainly in terms of concentration and barriers to entry. High fixed and sunk costs deriving from insurance policies may create new barriers to entry and therefore contribute to creating concentrated industries. Smaller incumbent companies could find it impossible to stay in the marketplace and small firms would in practice be prevented from entering. The result of this process would eventually, be a less competitive and more concentrated market structure.

A review of different compensation schemes.

The report also reviews the different compensation schemes that consumers may use in different Member States in order to protect themselves against potential damages. This includes voluntary insurance, social security schemes, special compensation funds and the relationships between such different means of protection. The general result is that consumers benefit from many different and alternative

protection schemes, which very often offer the same level of protection and compensation which is enjoyed in strict liability regimes. Nevertheless, two relevant matters for concern do remain in this respect: firstly, the disparity of protection levels in different Member States, secondly, the fact that there appear to be some countries and sectors where consumers might be without adequate protection against development risks. In consideration of this, and given the abovementioned problem with development risk insurability, this report envisages the creation of a compensation fund at EU level as an appropriate mean for guaranteeing EU's citizens an equal and adequate protection from product development risks. The nature of such funds should be both public and private, and it is suggested that the option of having different industry-specific schemes is to be evaluated.

This report envisages the creation of a mixed public-private fund at EU level as an appropriate mean for guaranteeing EU citizens harmonised and adequate protection .

In conclusion, the findings presented in this report seem to support the argument that Development Risk Clause is a significant factor in achieving the Directive's balance between the need to preserve incentives to innovation and consumers' interests. There is in fact evidence that the DRC protects incentives to innovation by reducing the innovation related risks, not diverting resources from R&D to insurance policies and pushing firms to acquire state of the art knowledge. Moreover, the Development Risk Clause is probably a key factor in determining the relative stability of insurance costs in European industry. There is also some indication that, in a regime of strict liability, companies in high-tech / high risk sectors would find it very difficult to get a reasonable insurance policy to cover their developmental risks.

Development Risk Clause is a significant factor in achieving the Directive's balance between the need to preserve incentives to innovation and consumers' interests.

The combination of these factors leads us to conclude that the costs of letting producers innovate their products in a full strict liability environment would be extremely high, especially for companies but also, eventually, for consumers.

Letting the producers innovate their products in a full strict liability environment would be extremely high, in particular for companies but also, eventually, for consumers.

It is, of course, almost impossible to effectively compare the amount of the additional costs that companies would incur in a regime of strict liability against the expected benefits consumers would enjoy in a more protected environment (i.e. removing the DRC). These benefits are invaluable and any comparison, if carried out in the presence of an actual risk would induce policy makers to shift the balance of the Directive in the direction of strict liability, especially for product development activities. However, comparing costs and benefit is probably

not the most straightforward approach to this complex policy issue.

An institutional solution that guarantees consumers the same kind of protection that they would enjoy without the DRC, without getting rid of the DRC itself

We suggest the right way to face the dilemma is to assess whether there is any possible institutional solution that would guarantee consumers the same kind of protection they would enjoy without the DRC, but without getting rid of it. The results discussed indicate that there are different alternative protection schemes, some already available and others that might be relatively easy to implement at EU level, and which are in principle able to provide consumers with the protection level desirable for EU citizens. One crucial message is therefore that the Commission should direct its policy efforts to harmonising protection systems in the Member States and implementing innovative protection schemes at EU level, possibly by means of centralised compensation funds. Being successful in such innovative effort would allow the Commission to adhere to its balanced policy approach, including the key element of the DRC. If the option of keeping the DRC in operation is kept, there is nevertheless a number of side issues which should be faced without delay.

A number of side issues must be faced.

Disparities in regimes of application.

Firstly, the non-mandatory nature of the clause included in Article 15 of the Directive was intended to provide political consensus to the Directive. The result of such a provision is the present disparity in enforcement of the clause among Member States. Such disparity no longer seems to be acceptable, and actions should be directed to harmonising application of the DRC among countries and industries.

Definition of state of the art knowledge.

Secondly, a considerable degree of legal uncertainty seems to persist in the clause's application, especially concerning the definition of state of the art knowledge. Different interpretations of the state of the art knowledge concept would imply very different consequences in terms of possibilities of practically using the state of the art defence. A narrow interpretation of what is meant by "available knowledge" would certainly shift the balance in favour of producers, whereas a very broad one is likely to favour consumers. An additional problem lays in the fact that in specific industries the relevant knowledge is privately held by companies by means of secrecy or intellectual property rights. In such circumstances, and in particular in monopolistic or very concentrated industries, the practical application of the clause is indeed extremely difficult and might turn out as rather

disadvantageous for consumers. For these reasons, it is highly recommended that the Commission endorses an initiative aimed at clarifying the implications of different definitions of the state of the art knowledge and provides a set of normative guidelines to be uniformly applied in European courts.

If DRC is kept in operation, complementary actions are need.

The implementation of such guidelines involves a set of complementary policy actions that can be summarised as follows.

Implementation of schemes for product monitoring and recalls.

Firstly, the implementation of measures and schemes for product monitoring and recalls. Under the current liability legislation, companies are required to follow the state of the art guidelines for new products but have no obligation to monitor the products' compliance which they have already released onto the market. There is such an obligation under GPS legislation, but this is not directly connected to liability. This anomaly should be addressed.

Mandatory industry-specific compensation funds.

Secondly, the establishment of mandatory industry-specific compensation funds, with contributions from both public and private stakeholders.

Creation and sharing of knowledge on product safety.

Thirdly, the creation and sharing of knowledge on product safety. The previous discussion has highlighted that DRC revolves around the concept of "state of the art". In the current interpretation this leaves too many loopholes open for firms acting irresponsibly and either hoarding private knowledge on critical aspects of the products they sell, or not investing sufficient resources to increase such knowledge. With this purpose, it is necessary to have sound independent research on product safety, together with mechanisms for an efficient dissemination to all relevant stakeholders: i.e. firms, researchers, the government and the general public. Independent research may be publicly funded, or funded by industry through the previously mentioned compensation funds, and should be accompanied by stringent legal requirements for firms to disclose information that may be relevant "for the public health".

Enforcing compatibility between the regime of administrative authorization and liability.

Finally, an effort should be devoted to enforcing compatibility between the regime of administrative authorisation (including GPS legislation) and liability. It is possible that, in the future, excessive development risks will lead to a greater use of the instrument of administrative authorisation following the precautionary principle. In such cases it is not acceptable that, after the authorisation has been granted (presumably after the

most thorough and diligent processes), the firm should still be held liable for development risk. If the public entity decides to take authority over a product because of concerns over development risks, it should also bear the responsibility of its decision to accept the product.

Harmonisation under Article 153 of the EC Treaty.

The previous discussion has highlighted that consumers currently are provided with different degrees of protection in the Member States, depending on their national social security systems and on the state-level decision to include or not Article 7e on the DRC in national legislation. The ensuing difference in national legislation may be considered negatively from the consumers' position, and also provides a confusing environment for taking business decisions from the producers perspective. Of course, Article 153 of the EC Treaty entitles individual Member States to introduce a stricter degree of consumer protection in national legislation which, together with local political pressure, would make it very difficult to eliminate Article 15 of the current Directive in order to provide greater harmonisation.

On the other hand, all the other policy conclusions stated above lead to a fuller degree of consumer protection, through the introduction of administrative measures. In this way, the achievement of a greater degree of consumer protection across Europe should make it un-necessary for individual Members States to choose to eliminate Article 7e of the DRC.

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