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Ralf Nordbeck, Michael Faust

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**Working Paper**

## European chemicals regulation and its effect on innovation: An assessment of the EU's White Paper on the strategy for a future chemicals policy

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# **UFZ Discussion Papers**

**Department of Economics,  
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**4/2002**

**European chemicals regulation and its effect on  
innovation: an assessment of the EU's White Paper on the  
Strategy for a future Chemicals Policy**

Ralf Nordbeck and Michael Faust

July 2002

UFZ Centre for Environmental Research,  
Department of Economics, Sociology and Law  
PO-Box 500136, 04301 Leipzig, Germany

e-mail: [nordbeck@alok.ufz.de](mailto:nordbeck@alok.ufz.de)  
phone: +49 341 235-2895  
fax: +49 341 235-2825

## **European chemicals regulation and its effect on innovation: an assessment of the EU's White Paper on the Strategy for a future Chemicals Policy**

<sup>1</sup> UFZ-Centre for Environmental Research Leipzig-Halle

<sup>2</sup> Faust & Backhaus Environmental Consulting GbR

### **Abstract:**

In February 2001, the European Commission published its White Paper on a Strategy for a Future Chemicals Policy. The publication launched a heated debate on principles, aims, instruments, implementation, and management of future chemicals control in the European Communities. The White Paper came in wake of massive criticism of current chemicals legislation. Various parties involved repeatedly expressed their concern about a tremendous lack of effectiveness. Furthermore, comparisons with other industrialized countries outside the EU indicated that the current regulatory framework actually discourages innovation in the European chemicals industry. This paper examines current European chemicals policy and main elements of the White Paper strategy with a special focus on the impact of chemicals regulation on innovation towards sustainability. The claim that chemicals regulation tends to block innovation is rejected for lack of conclusive proofs. In contrast, the paper reinforces the view that the White paper strategy is an important step forward towards sustainability in the chemicals sector. However, with the aim to make it pay for companies to pursue environmentally orientated innovation strategies, supporting measures and instruments need to be developed further.

### **Contact:**

Ralf Nordbeck, UFZ-Centre for Environmental Research Leipzig-Halle, Department of Economics, Sociology and Law, Permoserstr. 15, 04318 Leipzig, Germany.

E-mail: [nordbeck@alok.ufz.de](mailto:nordbeck@alok.ufz.de)

Dr. Michael Faust, Faust & Backhaus Environmental Consulting GbR,  
c/o Universität Bremen, NW2 / B 3241, Leobener Straße, 28359 Bremen

E-mail: [mfaust@biology.uni-bremen.de](mailto:mfaust@biology.uni-bremen.de)

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## 1. Introduction

In February 2001, the European Commission launched a far-reaching debate on exactly what form its policy for controlling chemicals should take by publishing its White Paper on the Strategy for a future Chemicals Policy. The White Paper is the culmination for the present of a three-year evaluation phase of European chemicals policy known as the EU Chemicals Review. The reform mooted by the White Paper has been welcomed on the whole by the EU's Council of Environment Ministers, the Member states of the EU, the chemical industry and other stakeholders. During the past 12 months heated discussion has taken place over the reform proposals contained in the White Paper, which are ultimately designed to change the very direction of European chemicals policy. At the June 2001 public hearing organised by the European Parliament, the representative of the VCI (*Verband der Chemischen Industrie* / German Association of the Chemical Industry) stated that rarely before had a political initiative generated so much attention and so much concern for chemical companies as the change of tack intended for European chemicals policy. The White Paper will shortly be followed by proposals for new chemicals legislation at Community level.

The EU's White Paper came in the wake of massive criticism of current chemicals legislation, whose lack of effectiveness was repeatedly criticised by various parties, most notably several Member states. Furthermore, international comparative studies indicated that the current regulatory pattern actually discourages innovation on the part of the European chemical industry in a number of ways.

Therefore, this examination of European chemicals policy will focus on the effect regulation has on innovation towards sustainability<sup>1</sup>. It starts by summing up experience of the current European chemicals policy, and then outlines the main reforms of the strategy behind the proposed chemicals policy based on the European Commission's White Paper. It concludes by assessing the extent to which this restructuring of European chemicals policy will encourage innovation.

## 2. The current regulatory pattern of European chemicals control

Over the past 30 years, policy-making for chemicals control has almost completely been transferred to the European level. European chemicals regulation began back in 1967 with the Europe-wide harmonisation of legal and administrative regulations for the classification, labelling and packaging of dangerous substances, at first solely for the purpose of protecting human health. The Europeanisation of chemicals law then took place in three stages starting off with Directive 67/548/EEC (Köck 2001: 303):

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<sup>1</sup> This paper presents an outcome of the ongoing project "Impacts of Chemicals Regulation on Innovation towards Sustainability". The project is funded by the German Federal Minister for Education and Research" as part of its "RIW" research program on "Frameworks for Innovation towards Sustainability", supervised by "GSF project management for environment and climate" – grant no. 07 RIW 2A, 2B, 2C.

- 1) The sixth amendment to Directive 67/548/EEC dated 18 September 1979 which came into force on 18 September 1981 introduced a notification procedure for new chemical substances about to be launched onto the market involving testing requirements on the part of the applicant. It also included the environment for the first time as a second aim of protection alongside human health.
- 2) The testing and labelling requirements were increased and uniform principles introduced for official risk assessment in the seventh amendment in 1992. Moreover, notifications of new chemical substances in one Member state were deemed to apply throughout the European Community.
- 3) The Directive covering existing chemicals which came into force on 23 March 1993 placed existing chemicals – i.e. all chemicals which were declared to be on the EU market on or before 18 September 1981 and listed in the EINECS (European Inventory of Existing Chemical Substances) – under the control of the European Community. Existing chemicals are not subject to the notification procedure; instead manufacturers and importers have to provide the competent authorities with the available chemicals' basic data depending on the volumes in which they are produced or imported. Only some chemicals which have been set on priority lists continue to be governed by data provision and testing obligations.

The current basic structural feature of European chemicals regulation is the dual system of procedures for new and existing substances. The procedure for the control of chemicals is divided into three main stages: provision of data, risk assessment and risk management. The first stage is controlled by Directive 67/548 for new substances, and Regulation 793/93 for existing ones; the second by Directive 93/67 and Regulation 1488/94; while the third stage is controlled in both cases by Directive 76/769, which limits marketing and use of dangerous substances. During the first, information gathering stage, the manufacturer or importer is obliged to provide a certain amount of information – depending on the chemical's annual production/import quantities – on its properties relevant for risk assessment. These obligations have to be met for new substances prior to their launch on the market, i.e. the chemicals have to be notified first. By contrast, chemicals already available on the market can continue to be sold, the information obligations being conducted simultaneously (Winter 2000: 248). Information procurement is initially followed by an official risk assessment, which forms the basis for any restrictions on marketing and use. Whereas administratively speaking the first two stages are the responsibility of DG Environment, decisions concerning the third stage are up to DG Enterprise.

## **2.1 The procedure for new substances**

Ever since the sixth amendment to Directive 67/548 came into force in September 1981, chemicals have legally been divided in the European Union into existing and new substances. The term 'new chemicals' applies to all chemicals not listed in the EINECS. New chemicals which are sold in an amount exceeding 10 kg per annum must be notified in the EU before

they can be marketed. The extent of testing to determine the dangerous characteristics of new substances depends on their marketing volume (Table 1) and covers their physico-chemical, toxicological and ecotoxicological properties.

Table 1: Quantity thresholds for the notification of new substances

Marketing volumes		Type of notification
Per annum	Total per manufacturer	
10 kg < 100 kg	-	Reduced notification dossier
100 kg < 1 t	≥ 500 kg	Reduced notification dossier
≥1 t	≥ 5 t	Base set of data
≥100 t	≥ 500 t	Level 1
≥1,000 t	≥ 5,000 t	Level 2

The testing requirements for small quantities of chemicals concentrate on acute hazards, whereas those for high-production volume substances include effects of long-term exposure such as properties that are carcinogenic, mutagenic, or toxic for reproduction. The set of test data required for chemicals with a marketing volume exceeding 1 tonne is referred to as the ‘base set’.

Around 2,700 new substances have been notified in the EU since 1981. In the first few years following the introduction of the Directives, hardly more than a dozen new substances were notified each year. However, in the second half of the 1990s, notifications of new substances rose to an annual average of 300. Sixty per cent of new substances are marketed in quantities of between 1 and 10 tonnes, about 30 per cent in quantities less than a tonne, and about 10 per cent exceed 10 tonnes. Just under 3 per cent of new substances are marketed in annual quantities exceeding 100 tonnes, while merely 0.6 per cent are sold in volumes exceeding 1,000 tonnes.<sup>2</sup> Some 70 per cent of all new chemicals are classified as dangerous, the two properties most frequently relevant being ‘irritating’ and ‘dangerous for the environment’. Of the 1,000 new chemicals notified in Germany by 1997, 514 were classified as irritating, or sensitising substances, while 502 were classified as dangerous for the environment (BMU 1998).<sup>3</sup>

On the whole, the procedure for new substances enjoys a relatively good reputation. The European Commission’s report reviewing European chemicals policy describes the results of regulation as “satisfactory”, while an evaluation under the SLIM initiative<sup>4</sup> concludes that all in all the system functions up to standard (COM 2000: 8). Unfortunately, in both cases exactly

<sup>2</sup> Cf. the website of the European Chemicals Bureau: <http://ecb.jrc.it>.

<sup>3</sup> The total number of classifications is higher than the number of chemicals owing to multiple labelling.

<sup>4</sup> SLIM stands for “Simpler Legislation for the Internal Market” – an initiative by the Commission designed to simplify legal regulations on the single market.



what criteria were used to judge the success of the Directive and how the reports' authors reached their conclusions are unclear. This positive opinion appears to be based on the creation of a good stock of data on the new chemicals, enabling risk assessment. However, both reports independently concluded that reform is needed regarding the Directive's overall structure, as well as that the complex system of classification and labelling needs to be simplified, and that the division of working procedures and responsibilities among the Member states, the European Chemicals Bureau, the European Commission and manufacturers need to be reorganised.

## **2.2. The procedure for existing chemicals**

Whereas under Directive 67/548 new substances are to be tested and assessed in terms of their dangerousness for human health and the environment, existing ones are not subject to the same testing requirements. The control of existing substances at European level began in 1993 with Regulation 793/93 dated 23 March 1993 on the evaluation and control of the risks of existing chemicals. Its aim is for information on existing substances to be compiled, distributed and made accessible, and for the risks of existing substances for humans and the environment to be properly assessed so that risks can be better dealt with.

Previous years have seen continuing discussion over reforming European chemicals policy. One cause of concern has always been the lack of effectiveness of the regulations covering existing substances.<sup>5</sup> The EINECS lists 100,195 substances, about 30,000 of which are sold in annual quantities exceeding 1 tonne (COM 2001: 4). Of this amount, 20,000 are sold in quantities of 1–10 tonnes every year; 5,000 of the substances have annual production levels exceeding 100 tonnes, and 2,500 of them are produced in quantities of more than 1,000 tonnes. This underlines the striking numerical imbalance between existing and new substances, as well as the scale of the problem regarding existing chemicals. Existing chemicals make up more than 99 per cent of the total amount of chemicals substances on the market which may in principal be freely bought and used.

The EU's Regulation on existing substances tries to deal with the problem of existing substances in four steps: data collection, priority setting, risk assessment and measures for risk reduction. The first phase – collecting available information, initially for existing substances produced or imported in quantities exceeding 1,000 tonnes annually, and later for existing chemicals in quantities of 10–1,000 tonnes – is now complete. The database for existing substances marketed in large volumes is maintained by the ECB. Existing chemicals with a marketing volume exceeding 1,000 tonnes, whose data are incomplete (necessitating further testing), or whose available data indicate the need for regulation, are in the second step

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<sup>5</sup> In December 1997, the Netherlands' delegation to the EU Council of Environment Ministers submitted a declaration expressing its concern at the considerable shortcomings in the implementation of Regulation 793/93 on existing substances in the previous two years. The main reasons were cited as the ECB's lack of resources, excessively rigid procedures and red tape, and the Regulation's lack of enforceability. This position was supported by Denmark and Germany (EU Council of Environment Ministers, Brussels 16/12/1997 – Press: 399 no. 13373/97).

included on a priority list. Since 1994, the European Commission has passed four priority lists with a total of 140 existing substances.<sup>6</sup> The third and fourth steps (risk assessment of priority substances and measures for risk reduction) have not yet been completed.

So far, the Regulation on existing substances has on the whole proved unsatisfactory and exhibits considerable weak points. Whereas the priority lists under the Regulation for existing substances have so far been limited to just a few substances, there is a general lack of knowledge concerning hazardous properties and use patterns of existing chemicals (Allanou, Hansen, van der Bilt 1999). Current knowledge of toxicological and ecotoxicological characteristics as well as behaviour in the environment are even unsatisfactory for adequate risk assessment for numerous existing substances sold in large quantities (over 1,000 tonnes annually) with high human and environmental exposure. Not enough is known about their main purposes either, since under current legislation only the manufacturers and importers of chemicals – but not the subsequent users – are obliged to provide information about how they are used. The complex procedure of risk assessment places a considerable burden on the competent authorities of the individual Member states, the European Commission and in particular the ECB.

The criticism that the procedure for controlling existing substances is too lengthy is underlined by a glance at the figures.<sup>7</sup> By the end of 2001, the Member states had submitted a draft proposal for risk assessment for 88 of the 140 existing substances listed in the first four priority lists under the existing chemicals Regulation. Conclusive risk assessment had been drawn up for 56 of these 88 substances, while further risk reduction measures had been deemed necessary for 45 substances. Initial proposals for risk reduction strategies existed for 24 of these 45 substances. Only 11 existing substances had by this time completed the entire assessment procedure specified by Regulation 793/93. A period of 18–29 months passes from the publication of a priority list until an initial draft risk assessment is submitted to the Technical Committee. Discussion and agreement until final risk assessment take another nine months (KOM 1998: 13). According to the European Commission's report, the main reasons for this delay are the lengthy, difficult stages and procedures specified by the Regulation such as the selection of chemicals for the priority lists, the choice of reporting Member state, data collection, risk assessment, technical evaluation of the risk assessment reports, and drawing up strategies for risk reduction (KOM 1998: C22). According to current opinion, the control of existing substances has become bogged down in the ponderous procedures of information gathering, assessment and decision-making (Köck 2001: 304). Another complicating factor is that the Regulation does not provide any deadlines for risk assessment or possibilities of sanctions. This poor incentive structure has meant that in practice member states and industry are often poorly motivated to participate. Furthermore, under the current regulations the authorities have to provide convincing reasons before restrictive measures can be introduced.

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<sup>6</sup> For more details on the four priority lists of the Regulation on existing substances between 1994 and 2000 see the following EU Directives: (EC) 1179/94, (EC) 2268/95, (EC) 143/97, (EC) 2364/2000.

<sup>7</sup> Cf. the ECB's website: <http://ecb.jrc.it>.

This is difficult since the current system does not provide any incentive for the industry to support assessment. On the contrary: delaying the procedure is rewarded by the substance being allowed to remain on the market (Winter 2000: 267; COM 2001: 19).

### **2.3 Risk assessment**

The test data already provided by industry form the joint basis for two different but closely interconnected elements of chemical regulation. One of these is the classification and labelling of chemicals by certain hazardous properties, while the other is the regulatory assessment of the risks they pose. The principles of risk assessment were initially stipulated in 1993 and 1994 separately for existing and new substances respectively (Regulation 1488/94 and Directive 93/67), although in fact there are only minor differences. Consequently, the European Commission harmonised the instructions, uniting them in 1996 within the 700-page Technical Guidance Document (European Commission 1996). Risk assessment boils down to comparing a chemical's possible harmful effects and the reasonably assumed exposure of humans and the environment to it. The assessment procedure is therefore divided into three main steps:

- i) 'Effect assessment', i.e. identifying the harmful effects a certain substance may cause and if necessary determining the concentration-effect or dose-effect relationships for these effects;
- ii) 'Exposure assessment', i.e. estimating the concentrations or doses of a substance to which humans are or could be exposed and which occur or could occur in environmental compartments such as water, soil and air;
- iii) 'Risk characterisation', i.e. estimating the probability of harmful effects occurring with the predicted or actual exposure levels. This risk characterisation is carried out separately for humans and the environment, including for different types of effects and exposure pathways.

The first step is largely the same as the procedure for the classification of dangerous substances, while steps two and three make the difference between hazard assessment and risk assessment.

Major limitations are imposed on the possibilities for risk assessment by the specification of testing requirements and methods. The risk of effects which are not the subject of testing or which cannot be identified with the methods used cannot of course be assessed. The most prominent examples in this respect are the hormone-like effects of environmental chemicals observed in humans and animals for which so far no standardised test procedures are available. On the other hand, risk assessment may be superfluous if the tests carried out do not indicate any hazardous effects – which appears to be the case for around 30 per cent of new substances.

The establishment of test criteria and methods already contains the explicit or implicit weighing-up of a series of conflicting demands, especially:

- i) Low time and resources;
- ii) Minimising animal testing;
- iii) Low variance, high reproducibility and good comparability of data;
- iv) The relevance of the results for the risk to be assessed and the protection goals to be achieved.

The minimum requirements in the EU for a stock of data for risk assessment meeting (at least partly) the comprehensive aim of protecting humans and the environment are defined by the 'base set'. The average costs of drawing up a base set have been quoted by the European Commission at €85,000. In order to indicate possible chemical effects on humans, the base set usually contains laboratory findings on the impact on rats following one-off administration as well as administration daily for 28 days, augmented by test findings on the irritant and corrosive effects on rabbits and sensitising effects on guinea pigs. In addition, test findings are available on bacteria and cell cultures, which could provide indications of carcinogenic or mutagenic characteristics. The diversity of biological species in human environments is represented in the base set by only three freshwater organisms. The fatal effect on a species of fish, the immobilizing effect on a species of water-flea, and the inhibition of the reproduction of a species of green algae are each tested over 96 hours. Furthermore, data are provided on the short-term effect on the bacteria population of a sewage treatment plant. However, the risks for marine and terrestrial organisms remain largely impossible to assess on this basis. The same goes for effects which only manifest themselves at the level of biocoenoses and ecosystems. Providing a basis for exposure assessment, the base set delivers information on substance quantities, use categories, physicochemical characteristics and biological degradability. The expectable exposure of humans and the environment has to be calculated from this on the basis of simple, standardised scenarios and models.

The central aspect of effect assessment is the derivation of NOAEL and PNEC values. The NOAEL (No Observed Adverse Effect Level) refers to the highest dose or concentration of a substance for which the existing test data do not indicate any harmful effects. The NOAEL plays a crucial role in risk assessment for humans. When assessing the risk for organisms in the human environment, the yardstick used is PNEC (Predicted No Effect Concentration), which is estimated from test findings taking into account an extrapolation factor designed to express the uncertainties resulting from the transfer of laboratory data covering a few species to the real environment (Directive 93/67). The exposure assessment delivers not only the reasonably foreseeable exposure level for humans (concentrations in the air or amounts absorbed) but also the expectable concentrations in certain environmental media and compartments (e.g. surface water), a parameter known as PEC (Predicted Environmental Concentration). In risk characterisation 'risk quotients' are formed, which refer to the quantitative ratio between the exposure level and the NOAEL as well as between the PEC and the PNEC. If the assumed exposure exceeds the NOEL or the PNEC, there is always cause for concern; otherwise there is room for discretion. Risk quotients are not an absolute measure of

the probability of harmful effects occurring but still enable risk comparisons between different chemicals (Van Leeuwen 1995).

Risk assessment is always based on the isolated impact of one individual substance. The problem of complex pollution situations involving a variety of substances are almost completely neglected (Faust et al. 2000). Risk assessment inevitably contains numerous extrapolations, such as from 'laboratory species' to humans or other species, from relatively short-term exposure to long-term pollution, and from the laboratory environment to actual environmental conditions. The inclusion of uncertainty factors in effect assessment, the assumption of a 'reasonable worst case situation' in exposure assessments and maintaining margins of safety when assessing risk quotients for humans are measures intended to ensure that, given the current state of knowledge, the findings remain on the safe side.

The competent authority responsible uses the results of the three-stage procedure to draw conclusions which may provide a starting-point for risk management. It has different options at its disposal depending on whether new or existing substances are being investigated. As far as the new substances are concerned, the following four assessment categories are used pursuant to Section 3 of Directive 93/67:

- i) No cause for immediate concern and no further need for testing until additional information is available;
- ii) Cause for concern, but further investigation only necessary once the next higher tonnage threshold has been reached;
- iii) Cause for concern; further information immediately required;
- iv) Cause for concern; measures for risk reduction recommended.

According to the ECB, since the seventh amendment (1992), 56 per cent of the some 800 risk assessments for new substances have drawn conclusion (i), 34% have stated the need for more information when reaching the next tonnage trigger (ii), 14% called for additional information immediately (iii), and 10% required risk reduction measures (iv).

As far as existing chemicals are concerned, the TGD (EC 1996: 8 based on Section 10 of Regulation 793/93) provides for the following three types of conclusions:

- i) Further information needed;
- ii) No further information needed; no (other) risk reduction measures needed;
- iii) Risk limitation required (but measures already being applied to be taken into account).

Nine of the 11 assessment procedures so far completed saw the need for risk reduction measures for humans and/or the environment (iii). In the two other cases, it was felt that no further information or action were required (ii). The dossiers on which the conclusions are based are published for existing substances, but are kept secret for new substances.

Risk assessment is an iterative process. Procedures, criteria and methods can and must of necessity be constantly updated with new information and findings. This aspect is a major subject of discussion in environmental sciences. By contrast, debate on environmental policy currently focuses on the question over whether and when the complex methodology of risk assessment should be used in the first place. Should risk assessment be absolutely necessary before restrictive regulatory measures can be imposed? Or should certain substance characteristics regarded as especially dangerous be considered as a sufficient argument for restriction or even ban of a chemical, irrespective of the actual or supposed exposure level? This approach is already used in the existing system for substances which are carcinogenic, mutagenic and toxic for reproduction. Environmental associations are campaigning for this strategy to be enforced and also broadened to include other hazardous characteristics, especially high persistence, high toxicity and high bioaccumulation potential (EEB 2000). Industry is vociferously against such a move; politicians and scientists are divided.

## **2.4 Risk management**

The third stage of chemical regulation, namely decision-making under Directive 76/769 relating to restrictions on the marketing and use of dangerous substances, also appears in need of reform. This 'Limitations Directive' is equally relevant for both existing and new chemicals, and regulates the possibilities for limiting the use of and even banning substances. By 2001, the Directive had been amended 25 times and now covers about 900 substances. As a rule, measures taken under this Directive simply specify controlled use, i.e. they only limit the use of substances for certain purposes. Bans with exceptions or even complete bans such as in the case of PCB are rare. The overwhelming majority of substances regulated in this way are carcinogenic, and so most of the restrictions aim to protect human health (KOM 1998: 9).

The Directive's most serious drawback is the lack of any automatic link between the risk assessment of new and existing substances and the resulting risk management (Köck 1999: 84). Another complicating factor is that risk assessment and risk management are administratively divided at European level between DG Environment and DG Enterprise. As a result, the extensive preliminary work undertaken by DG Environment in the form of risk assessments and proposed risk reduction strategies are not sufficiently taken on board by DG Enterprise (Winter 2000: 257). Instead, these documents are supplemented by DG Enterprise's own independent analysis of the advantages and disadvantages of the proposed measures, resulting in additional economic and social criteria being included in the decision-making process. In the European Commission's view, risk assessment only provides part of the information necessary for risk management, and therefore the Commission has undertaken to conduct cost-benefit analyses before proposals for risk reduction affecting the chemical industry are passed (KOM 1998: D10). On the whole this procedure appears to be suffering from overregulation and to be unnecessarily complex. Indeed, restrictions and bans are often only imposed after lengthy procedures lasting a number of years for chemicals for which member states have already taken the regulatory initiative. Krämer (2000: 25) even argues

that there is virtually no active Community policy regarding the banning and restriction of dangerous substances.

### **3. The EU White Paper – a new strategy for European chemicals policy**

The problems of European chemicals policy and how to proceed were discussed by the EU environmental ministers at informal meetings in Chester (UK) in April 1998 and Weimar (Germany) in May 1999. Widespread concern was voiced over the lack of progress in the risk assessment of existing chemicals, and so the ministers welcomed an offer by the former Commissioner for the Environment Bjerregaard to submit the EU Chemicals Review, a report on the implementation of the central Directives and Regulations of Community chemicals policy. The report was handed to the European Commission on 18 November 1998 and revealed serious drawbacks in parts of European chemicals regulation.<sup>8</sup> In its conclusions on chemicals policy in June 1999, the EU Council of Environment Ministers stated that the European Community's current approach to the assessment and regulation of chemicals contained a string of conceptual and operational shortcomings.<sup>9</sup> The Council stated the current practice could not be expected to solve the problems stemming from existing chemicals by adequately limiting the risks to humans and the environment. The Council accordingly called upon the European Commission to submit a proposal for a new strategy for European chemicals policy by the end of 2000. The European Commission complied by submitting the White Paper on the Strategy for a Future Chemicals Policy on 27 February 2001.<sup>10</sup>

The White Paper sets out the European Commission's proposals for a future Community chemicals policy designed to contribute to the overriding goal of sustainable development. The new chemicals policy is supposed to protect the environment and human health while ensuring the proper functioning of the single market and the international competitiveness of the chemical industry. Given the analysis of the drawbacks of its current chemicals policy, the European Commission is developing a new system of chemicals control comprising five key points:

- 1) The creation of a single coherent system for both existing and new chemicals by the year 2012 with the gradual integration of existing chemicals;
- 2) Shifting the burden of proof for testing and risk assessment from government agencies to chemical companies;
- 3) Including the 'downstream users' into the requirements for data provision and substance testing;
- 4) The introduction of an authorisation procedure for especially dangerous substances;
- 5) More public openness by granting easier access to information on chemicals.

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<sup>8</sup> Working document of the Commission SEC (1998) 1986 final.

<sup>9</sup> Conclusion by the EU Council of Environment Ministers dated 24.6.1999, pp. 9f

<sup>10</sup> KOM (2001) 88 final.

### 3.1 REACH: the new chemicals control system

Based on the procedure for new chemicals, the White Paper calls for the creation of a uniform system for existing and new chemicals to be set up until the year 2012. The core of this future chemicals policy comprises a new system for chemicals control to be known as 'REACH' (**R**egistration, **E**valuation, **A**uthorisation of **C**hemicals), which is designed to deal with the challenge posed by the sheer quantity of existing chemicals. The REACH system consists of three main components: registration, evaluation and authorisation (COM 2001: 16):

- i) The registration of all chemical substances which are produced in amounts exceeding 1 tonne per annum. The European Commission estimates this will cover some 30,000 substances. The basic data submitted by the chemical industry will be stored in a central database.
- ii) The evaluation of the registered information for all substances produced in quantities exceeding 100 tonnes per annum, which should account for some 5,000 substances or 15 per cent of all registered substances, as well as for substances sold in smaller quantities if there is special cause for concern. This assessment is to be carried out by the competent authorities and will include the development of specially tailored testing programmes.
- iii) The authorisation of certain substances with hazardous properties that give rise to very high concern. This mainly applies to substances that are carcinogenic, mutagenic and toxic for reproduction (CMR substances of categories 1 and 2<sup>11</sup> along with persistent organic pollutants (POPs) as listed in the UN Convention). The number of chemical substances for which authorisation are required is estimated by the European Commission to be 1,400, corresponding to 5% of the registered chemicals.

The White Paper puts forward an ambitious timetable for the transfer of existing chemical substances to the new system (Table 2), especially bearing in mind the given experience of the assessment of existing substances.

Table 2: Timetable in the EU White Paper for existing chemical substances

<i>Substances produced / imported in quantities exceeding ...</i>	<i>Registration dossier to be submitted by ...</i>	<i>End of testing and official assessment</i>	<i>Estimated no. of chemicals</i>
1,000 tonnes	End of 2005	End of 2010	2,600
100 tonnes	End of 2008	End of 2012	3,000
1 tonne	End of 2012	No general official assessment	25,000

Source: COM 2001, AHRENS 2001

<sup>11</sup> Pursuant to the definition in Directive 67/548.



A report on the White Paper by the British House of Lords stresses that many of those questioned representing the agencies and stakeholders involved doubted it would be possible to meet the registration deadlines (House of Lords 2002: notes 91f). Reservations were above all expressed regarding the available laboratory capacities. The UK's Department of the Environment believes the only way to meet the tight schedule would be to limit the data to be provided to the necessary minimum.

The European Commission estimates that testing for existing chemicals required by the introduction of the new system will cost the chemical industry €2.1 billion (including the additional personnel needed by industry). Distributed over 11 years, this will correspond to an annual burden of €200 million. For its part, the chemical industry puts the costs of the White Paper at €7.8 billion. Additional personnel costs will be created by the need to expand the ECB as the first port of call in the future. The European Commission assumes that the member states will not incur any additional expenditure due to the White Paper since the personnel currently tackling other tasks will be released to provide the additional staff required for assessment. The White Paper emphasises that reliably estimating the total costs is very difficult owing to the lack of experience and the uncertainties in the test data.

### **3.2 Registration: changes to the disclosure obligation**

To close the current gaps in data on existing chemicals, the Commission rearranged the phase of data provision in the White Paper. During registration (the first step of the REACH system), the manufacturer or importer will now be obliged to inform the competent authorities of its intention to produce or import a chemical. This registration obligation applies to all existing and new chemicals produced or imported in quantities exceeding 1 tonne per annum. This basic threshold is a compromise between the existing regulations for new chemicals requiring data on quantities exceeding 10 kg to be provided, and those for existing chemicals, under which this obligation only applies to quantities exceeding 10 tonnes (Ahrens 2001: 4). Chemicals which the company produces or imports in quantities of less than a tonne will not be routinely tested. This still means that of the 100,000 existing substances, 30,000 chemicals with a marketing volume exceeding 1 tonne per annum will have to be registered by the end of 2012. As far as new chemicals are concerned, the number of registrations will fall, since nearly 30 per cent of new chemicals are marketed in quantities of less than a tonne. The deadlines for the submission of registration dossiers depends on the quantities to be marketed. In the Commission's view, registration for chemicals exceeding 1,000 tonnes per year should be completed by 2005, whereas those exceeding 100 tonnes only need to be completed by the end of 2008, and the rest by the end of 2012. Registration entails submitting a dossier to the agencies responsible containing details of the physico-chemical, toxicological and ecotoxicological properties of the substance (hazard assessment), information enabling human and environmental exposure to this substance to be estimated (production quantity, use categories), a provisional risk assessment taking into account its intended uses, and if necessary proposals for risk management measures. The information submitted will be centrally stored and managed on an electronic database belonging to the ECB. The general

conformity test currently prescribed for newly registered chemicals in quantities exceeding 1 tonne per annum will in future be replaced by spot-checks and computerised screening. The principle of quantity gradation governing the provision of further test data already provided for in the current regulations for new chemicals (base set, level 1 testing, level 2 testing) will largely be retained in the new chemicals policy. However, under the REACH system the base set<sup>12</sup> will only be required for substances produced or imported in quantities exceeding 10 tonnes per year, the level 1 test<sup>13</sup> for chemicals as of 100 tonnes, and the level 2 test as of 1,000 tonnes. However, the White Paper also intends to ensure that the future system is flexible by not making additional tests mandatory if a new quantity threshold is reached, dispensing with superfluous testing depending on chemicals' characteristics and exposure scenarios, and allowing 'substance-tailored testing programmes' to be carried out (COM 2001: 13, Ahlers et al. 2001: 76).

The registration dossiers and in particular having the companies carry out provisional risk assessment themselves relieves the national authorities of much of the time-consuming task of collecting data and carrying out risk assessment required of them by current chemical legislation. In future, industry will be responsible for these tasks, leading to greater responsibility by the chemical industry for its own products. In the European Commission's view, this new role and responsibility should be extended to the entire processing chain for chemicals. The White Paper therefore also makes provision for information rights for subsequent users and even ultimate consumers. Moreover, the registration dossier entails new obligations for subsequent users, who are to provide manufacturers with details concerning the usage of chemicals, since otherwise the authorities may call for additional tests whenever the uses of chemicals differ from those originally envisaged by the manufacturer (COM 2001: 21). This is very likely to promote a new information and communication structure in the chemical industry and all in all result in extensive stocks of data concerning the uses and the health and environmental risks of 30,000 substances.

### **3.3 Accelerating risk assessment**

Risk assessment has been redesigned by the European Commission in a number of respects. This concerns not only the role of manufacturers, importers and users, but also that of the competent authorities involved. One key element of the White Paper is transferring risk assessment from the official authorities to the chemical industry. During registration, companies will now have to provide a provisional risk assessment, which will merely be verified by the agencies. Subsequent users may also be obliged to carry out additional tests and risk assessments. The European Commission estimates that the procedure will end with registration for 80 per cent of chemicals, with them not needing to be assessed any further. The competent authorities will concentrate on the risk assessment of chemicals sold in quantities exceeding 100 tonnes per annum, as well as chemicals which provide particular

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<sup>12</sup> Basic description of chemicals pursuant Annex VIIa of Directive 67/548.

<sup>13</sup> Substance-tailored tests to determine long-term effects.

cause for concern since they pose a health or environmental risk, irrespective of the quantities in which they are produced or imported. The agencies will also have to decide on chemical-specific testing programmes based on the information received. Decisions over necessary additional tests will then be made by the national assessment agencies (as is already the case in current legislation for new chemicals). This mechanism is designed to overcome the extremely slow, ponderous procedure to obtain additional test data for existing chemical substances under the EU's Regulation for existing chemicals (COM 2001: 24). The information provided during registration, the provisional risk assessment and any necessary additional tests and data will enable the agencies to determine what chemicals are relevant and then to carry out 'tailored' official risk assessment. In many cases, this will replace the previously customary extensive risk assessment by targeted risk assessment. All in all, the European Commission hopes to save considerable time in the risk assessment of chemical substances by the four factors comprising the extensive provision of data during registration, companies' obligation to carry out an initial risk assessment, the chemical industry's greater responsibility for their products' safety, and finally targeted risk assessment. The procedure will be further accelerated by applying the principle of precaution in the case of unduly delayed risk assessment processes which in particular occur when manufacturers delay the submission of information or test data (COM 2001: 20). The precautionary principle will also be applied if there are indications of unacceptable risks.

### **3.4 *Improving risk management***

The area of risk management has doubtless been conceptually restructured more than any other aspect of the existing regulations. One completely new item is the proposed authorisation procedure for substances of very high concern. For these substances, authorities will have to give a specific permission before they can be used for a particular purpose, marketed as such or as part of a product (COM 2001: 18). Uses which do not provide cause for concern such as controlled use within industrial processes or in research laboratories may be exempted from the authorisation procedure. According to the European Commission, chemicals requiring authorisation include those which are carcinogenic, mutagenic or toxic for reproduction (CMR substances in categories 1 and 2) as well as substances with POP characteristics under the UN Convention of persistent organic pollutants. The authorisation procedure might also covers the vast majority of endocrine disruptive chemicals (COM 2001: 18). In the European Commission's view, this concerns a total of 1,400 substances which would be affected by use-related authorisation. The White Paper also keeps open the question concerning the inclusion of other groups of chemicals such as persistent, bioaccumulative and toxic substances (PBT chemicals) as well as very persistent and very bioaccumulative substances (vPvB chemicals).

One problem concerning the introduction of the authorisation procedure is that a considerable proportion of chemicals subject to an authorisation obligation are currently freely available as existing chemicals on the market, and can only be identified as particularly dangerous by level 1 and level 2 testing. In order to solve this problem, the European Commission proposes

introducing a two-stage decision procedure to implement the authorisation procedure (COM 2001: 19). In the first step, all substances and their special uses for which the White Paper prescribes authorisation will be identified. Transition periods will be established, after which all non-authorised uses of a substance will be banned. In the second step, the manufacturers and importers can then apply for the actual authorisation for certain uses.

Authorisation is to be granted if the use merely poses a negligible risk (COM 2001: 19). The decision is to be taken depending on the expected effects either by the competent authority of the responsible Member state (in charge of occupational health and safety or local environmental impact) or at EU level (for chemicals used in products). In addition, the White Paper mentions the possibility of conditional authorisation whenever this is justified by the socio-economic benefits arising from the use (COM 2001: 19). This evidently refers to cases in which for example substances cannot be substituted for certain needs. In contrast to the previous legislation, in future companies will have to present cost-benefit analyses demonstrating that the socio-economic benefits of the continued usage of a substance compensate for the risks of harmful effects on human health and the environment.

Regarding substances which are not subject to the authorisation procedure but still require measures of risk management owing to their risk assessment, the decision-making process is to be accelerated by resorting more often to the committee procedure provided for in Directive 76/769 to introduce restrictions or bans on these substances in place of the previously usual complete legislative procedure.

### **3.5 *The effectiveness of the new strategy in the White Paper***

Evaluating the European Commission's White Paper against the background of the shortcomings of current chemicals regulation listed above, the general assessment – apart from a few details which still need to be tidied up – is on the whole very positive. In producing the White Paper, the Commission has succeeded in initiating broad discussion over future European chemicals policy. Given the considerable problems of implementation for existing substances under current chemicals control policy, by abolishing the existing dual system for existing and new chemicals the White Paper is pointing out the correct route to an effective, efficient chemicals policy encouraging innovation. Thanks to the REACH system, the new strategy contains a suitable mechanism equal to the challenge of dealing with existing substances with the limited control resources available. Compared to the previous organisation of the individual procedural steps, the REACH system has a number of advantages regarding the procedural structure of chemicals management (Ahlers et al. 2001, Köck 2001):

- i) It reduces information gaps affecting existing chemicals relatively quickly by switching to a single coherent system.
- ii) It reduces the workload of risk assessment for the official agencies involved by transferring the burden of proof to industry owing to the introduction of provisional risk assessment, and opens up the possibility of targeted official risk assessment.

- iii) It accelerates the decision-making process by strengthening the competences of the national authorities in procuring information, the usage of the committee procedure for imposing restrictions on chemicals, the use of deadlines for authorisation procedures, and ultimately by exercising the precautionary principle should insufficient data be provided by industry.
- iv) It transfers the burden of intervention in the case of substances of very high concern by introducing the authorisation procedure and shifting the burden of proof to industry.

Irrespective of the reorganisation of the process, the White Paper contains new, inter-procedural aims for chemicals policy geared towards achieving sustainable development:

- It creates incentives for substituting substances by introducing the authorisation procedure for especially hazardous chemicals, the inclusion of downstream users of chemicals within registration and risk assessment obligations, and strengthening the rights of consumers and the general public to information and transparency.
- It promotes the development of the new information and communication structure by strengthening industry's own responsibility (manufacturers, importers and downstream users).

In addition to the positive elements of the REACH system enabling the control of chemicals to be generally organised more effectively, the new strategy for chemicals policy still contains a number of open questions. One especially problematic aspect is that the currently relatively well functioning notification system for new chemicals will practically be abolished owing to the compromise between current regulations for existing and new chemicals, since 90% of new chemicals will be below the required 10-tonne threshold and so will no longer require the base set of data. Furthermore, the White Paper largely fails to answer the key question over the new system regarding quality assurance for test data and provisional risk assessment. In addition, it can also be feared that the consequences for the planned timetable resulting from the inclusion of downstream users in the White Paper have largely been underestimated.

## **4. European chemicals regulation: barrier or incentive to innovation?**

### **4.1 *Innovation effects of the procedure for existing chemicals***

The testing and registration of chemicals inevitably impose costs and time delays on the companies concerned. The previous dual system divided into existing and new chemicals prompted considerable evasion regarding these burdens. Innovative activity was shifted away from the development of new chemicals requiring notification to the use of the extensive inventory of existing substances, which was mostly subject to no restrictions whatsoever. R&D projects were sometimes transferred abroad. These conclusions were reached by Staudt et al. 1993 on the basis of discussions with experts and case studies of German chemical companies. However, the authors emphasised that the regulation of chemicals is but one of

many determinants for such strategic corporate decisions and was therefore usually not the main cause of such results, instead usually having a cumulative effect in conjunction with other factors. Nevertheless, this combined effect still counteracted the aim of chemicals regulation, namely that of swiftly advancing the safe use of chemicals by obtaining information about their potentially dangerous characteristics. This failing in terms of environmental policy is to be dealt with by the White Paper by creating equal conditions for working with existing and new substances – and hence for innovation – within 12 years. This approach is welcomed by many stakeholders. Establishing the same conditions also includes imported products not containing any untested substances not notified in the EU, at least such that are released upon usage and disposal. Although the White Paper mentions this problem, it cannot offer a specific solution to it.

#### **4.2 Innovation effects of the procedure for new chemicals**

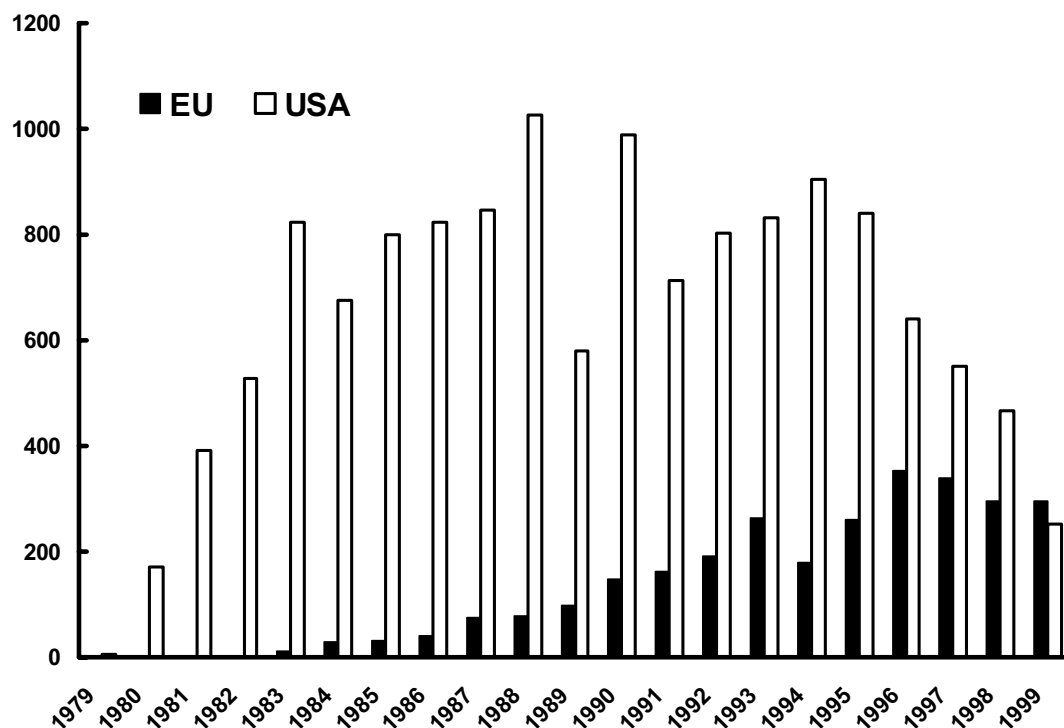
Fleischer et al. (2000) published a comparative analysis of the effects on innovation of different systems for the notification of new chemicals in the EU, Japan and USA. They reported that the Japanese system imposes much lower obligatory test requirements than the EU system, concentrating on identifying especially persistent substances. More extensive tests are only demanded if a test for biological degradability provides cause for concern. The US American system does not oblige those registering chemicals to produce any sort of test data whatsoever. The responsible agency can only demand such data if it can substantiate suspicion of unreasonable risk in individual cases, the legal yardsticks being rather high (GAO 1994). Fleischer et al. (2000) tried to quantify comparisons of the effects on innovation of the three systems by using four different indicators:

- i) R&D productivity (influence of R&D expenditure on the operating result);
- ii) Patent productivity (influence of R&D expenditure on patent output);
- iii) Innovation count (number of innovations reported in corporate annual reports);
- iv) Notification of new chemicals (the number of new substances registered in the respective regulation system).

Although the first two indicators – R&D productivity (i) and patent productivity (ii) – indicate US chemicals companies to be superior, the suspicion of a causal link with the regulation of new chemicals in the USA cannot be statistically underpinned by the authors with the data available. Counting reports of innovations by companies (iii) does not reveal any significant difference between the European, Japanese and US chemical industry. The only positive indicator of different effects on innovation in the three regulation systems hence remains the number of new chemicals notified annually (iv). According to Fleischer (2001:21), this is the decisive indicator for judging how the regulation of new chemicals affects the efficiency of innovation. Using notification statistics, Fleischer et al. (2000) calculated means covering for the USA the period 1979–99 (21 years), for Japan 1974–98 (25 years) and for the EU 1983–97 (15 years). The authors take into account different regulations for the registration

obligation for polymers by reducing the figures for the USA by 25 per cent. As a result, they found that in the USA an average of 425 new chemicals are notified per year, compared to just 154 in Japan and 143 in the EU. However, this raises the question of whether these means suitably and comparatively reflect actual developments or merely disguise them instead.

Fig. 1: Number of new chemicals notified for commercial manufacture or import per annum



Data sources: EU – European Chemicals Bureau (<http://ecb.ei.jrc.it/new-chemicals/>, date of access 4 October 2001). USA – Fleischer *et al.*, 2000 (there cited as personnel communication of the Office of Pollution Prevention and Toxics of the US Environmental Protection Agency); for years 1991 to 1996 Fleischer *et al.* report two different figures each, the higher ones being displayed in the figure.

The registration of new chemicals in the EU started in 1983 on the basis of the inventory of existing chemicals previously compiled containing over 100,000 substances. The notification figures were initially low, but grew constantly as the years progressed, and since 1996 have stabilised at a level of over 300 new chemicals per year (Fig. 1). The US TSCA Inventory (Toxic Substances Control Act) started four years earlier. It was also based on an inventory of existing substances, albeit one which, containing around 62,000 chemicals, was much smaller than its European counterpart. The number of newly marketed chemicals rose faster than in Europe in the first few years, peaking in 1988 with around 1,000 chemicals (Fig. 1). After 1988, the figures tended to decline. Towards the end of the period surveyed (1999), they actually converged with the European figures. This does not take account of different polymer regulations which may justify a further the reduction of the US data by an average of 25 per cent by way of correction for comparison (see above).

*Hence, considering the dynamics reveals a completely different impression than the simple comparison of means. In recent years at least, these data do not demonstrate considerably higher innovation productivity on the US chemicals market.*

However, the drastically higher US registration figures in previous years remain striking. Secrecy of chemicals' identities in the inventories of new substances on both sides of the Atlantic impedes precise analysis of their content and allows much leeway for conjecturing interpretations. The much greater 'existing chemicals cushion' in Europe may be just as responsible as the very different registration requirements. Due to the lack of test data, the US EPA (Environmental Protection Agency) generally has to derive its assessment of the dangerousness of chemicals solely from their chemical structure by comparing them with the properties of known substances with similar structures. Initially, neither sufficient databases nor the forecasting models derived from them were available for this SAR (Structure Activity Relationship) method. In a 12-year project, the EPA had for example 651 different chemicals tested in terms of fish toxicity (Geiger et al. 1990) and used the results to develop structure-effect relations for numerous groups of chemicals. Hence this method was only able to become effective in the late 1980s for official substance assessment. Further development in the 1990s was accompanied by critical stocktaking which found the TSCA to be lacking in effectiveness regarding the attainment of the protective aims, and recommended the US Congress to introduce changes more akin to the European system (GAO 1994, EDF 1997).

In contrast to these recommendations, Fleischer et al. rate the US system with its lack of test requirements as the most efficient and most effective, and recommend its adoption by the EU without restrictions. It must be objected, however, that the SAR method is still unable to reliably detect the risk-relevant properties of new chemicals as efficiently as direct testing. Within the framework of European chemical regulation it is regarded as an important aid, for example for setting priorities, identifying additionally necessary tests, the planning and quality control of experiments, and reducing the extent of animal experiments (TGD: 505 pp). However, it is not yet suitable to completely replace experimental tests (BAuA 2001). By the way, when comparing the regulatory systems, it should be borne in mind that the TSCA places practically the entire burden of work and proof of risk assessment on the EPA. By contrast, the European White Paper strategy pursues exactly the opposite aim: compelling industry to carry out initial risk assessment, and encouraging innovation designed to boost efficiency of hazard and risk assessment procedures to become aims of industry.

### **4.3 Scope for innovation from exemption rules and quantity thresholds**

Staudt et al. (1997) also examined the extent to which minor changes to the existing regulatory framework could open up innovation scope for chemical companies. They concluded that this is possible to a considerable degree without having to give up protective or precautionary aims. They collected arguments from companies and agencies regarding contentious regulatory items. After balancing the arguments, they identified three areas where barriers to innovation could be removed without losing the protection aims:



- i) Expanding the special exemptions from the notification procedure for substances which are only used for scientific or process-orientated R&D;
- ii) Reducing the testing programme and targeted risk assessment for substances which are only to be used for further processing within the chemical industry ('intermediate products');
- iii) Simplifying regulations for the notification of polymers (group registration of polymer varieties or the dependence of notification on certain hazard indications).

Whereas the 'polymer dilemma' still appears unsolved, progress appears to have been achieved regarding the other two items. The White Paper strategy makes provision for increasing the registration quantity threshold for chemicals used for scientific R&D from 100 kg to 1 tonne, as well as for extending the exemption deadline for substances in process-orientated R&D from 1 year to 3–5 years. Regarding strictly controlled intermediate products, the 28th amendment designed to bring Directive 67/548 in step with technical progress provides for a reduced test programme. This change will come into force in summer 2002. Whether the expectations of greater innovation will be fulfilled remains to be seen.

According to Fleischer et al. (2000: 154f), the high registration costs for new chemicals compared to the USA and Japan, especially for substances with relatively low market volumes, contain considerable potential for limiting innovation and distorting competition compared to the Japan and the USA. They therefore recommend raising the quantity threshold for basic testing from 1 tonne to 10 tonnes. This is in fact provided for by the White Paper strategy, albeit for another reason. The tonnage thresholds for experimental tests need to be raised if there is to be any realistic chance of dealing with a reasonable proportion of existing chemicals within the proposed 12-year plan. The 10-tonne threshold suggested will result in approximately 10,000 existing substances remaining for which at least the base set will have to be provided. In 12 years, this will mean an average of some 830 chemicals tests per year being additionally incurred. The only reason for raising the tonnage threshold for new chemicals requiring a base set from 1 tonne to 10 tonnes is as a countermove to ensure equality. Hence relief in the area of new chemicals is offset by additional burdens regarding existing chemicals. However, it is almost impossible to assess any sort of net possible effect on future innovation productivity on this basis. Then again, clear new scope would result from raising the quantity threshold whenever the development of new substances were planned right from the start for special applications in relatively low quantities.

There is however resistance to dealing with existing substances at the expense of reduced informations on new chemicals. In its joint paper drawn up with the VCI and the IGBCE (Mining, Chemical and Energy Industrial Union) dated 11 March 2002, the German government urged that at least a reduced dataset be demanded for substances produced or imported in amounts of 1–10 tonnes per annum, providing information in the event of accidental release and for occupational safety. Other member states and groups of stakeholders have echoed this view. Therefore, considerable cost reduction for companies in connection with new chemicals appears unlikely.

In addition, raising the threshold tonnage for new chemicals may in actual fact run counter to the aim of the White Paper of creating conditions and incentives for the substitution of high-risk chemicals by low-risk ones. This aspect is dealt with below.

#### **4.4 Directing innovation towards sustainability**

The point of regulating chemicals is to protect human health and the environment. The current regulation of new chemicals is based on identifying the hazards and risks attached to chemicals early on. It is tied to the political expectation that this will encourage innovation towards less risky or ideally completely safe chemical products and procedures. *An assessment of innovation productivity which completely ignores these aims and simply rates each new substance on the market as marking innovative progress misses the central point of chemicals regulation and the attempts to make it more effective.* It would have to end in the trivial conclusion that all the costs connected with registration could lead to a barrier to innovation, since it cannot place the costs in relation to the desired benefits for the preservation of human health and environmental resources. This sums up the clear weaknesses of previous studies on how chemicals regulation affects innovation. However, it must be admitted that methodological problems and the lack of suitable databases have so far largely stood in the way of the comparative cost-benefit analysis of different regulatory systems or regulatory options.

The current regulatory systems for new chemicals in both the USA and the EU have focused on identifying and isolating especially hazardous and risky chemicals. The White Paper's strategy goes one step further by rating the substitution of hazardous chemicals by safer substances as a new, important goal. However, substitution decisions require comparable, generally accepted bases for discussion which enable a new substance to be classified in a comprehensible manner as relatively low-risk. The system of rigid test requirements in the EU criticised as inefficient by Fleischer et al. (2000) ensures the provision of such a basis of information, at least for substances with a production volume of at least 1 tonne per annum. This also provides an important way of pursuing innovation productivity geared towards the desired minimisation of the conflict between economic and ecological aims.

So far, the information situation for new chemicals has proved favourable for advancing the substitution approach. It was on this basis for example that the Federal German Agency for Labour Safety and Occupational Medicine began publishing lists of recommendable substances for certain purposes and areas. They contain chemicals which during the notification procedure were not found to have any dangerous properties necessitating classification and labelling, and for which no indications of toxic effects have been found which could provide cause for concern (BAuA 1999). As new chemicals are generally initially used in low market volumes, it is important for such promotion strategies that the tonnage thresholds for test requirements also be set relatively low. However, based on previous experience, the uniform rise from 1 to 10 tonnes proposed in the White Paper would mean that some 90% of the substances would drop below the threshold required for the

production of a base set of data. And this could knock the bottom out of the substitution approach.

Substance identity and test data from the new chemicals procedure are currently subject to strict secrecy. The public and users are expected to trust the results, while valuable collections of information for the validation and development of methods and models for predictive hazard assessment remain off-limits to environmental scientists. Furthermore, the quality assurance of secret data is also beset by serious problems. Occasionally re-analyses of datasets made anonymous have in some cases revealed considerable shortcomings in the performance of biological tests as well as the statistical evaluation of experimental data (Ratte 1998). Therefore the question has also been raised as to whether transparency and publicity are perhaps important and effective elements of an environmental innovation strategy in the chemicals sector. Experience with the Toxic Release Inventory in the USA has shown that merely the free availability of information can release enormous stimulus towards the reduction of environmental pollution (EDF 1997). This effect could also be useful to increase the safety of chemicals and to boost environmentally innovative chemical applications. The initial approaches outlined in the White Paper move in this direction, but the protection of property rights to substance and exposure data currently appears to be an almost insurmountable obstacle. Solutions need to be found in order to push ahead with innovation for sustainable economic activity.

## **5. Concluding remark**

On closer examination, there is no conclusive proof for the claim that the current European regulation of the chemicals tends to discourage innovation. It is the current regulatory pattern involving separate regulation for existing and new substances which has resulted in evasive possibilities slowing down innovation. The strategy contained in the White Paper for unifying the level of information required for existing and new chemicals is designed to close the gap. It defines the aim of sustainable development as a desirable direction of innovation, although its strategy for achieving this aim remains largely focused on impeding market access for risky chemicals and hence fostering the pressure for environmentally orientated innovation. Simultaneously, it is intended to expand the scope for innovation by raising the threshold values for test requirements and enlarging the conditions for exceptions in R&D. These are important steps for sharpening the focus on innovation of chemicals policy.

From the perspective of encouraging innovation, one of the main things still missing is approaches for the complementary development of positive innovation incentives by strengthening market chances for relatively low-risk chemicals and processes. The threat of restrictions has proved necessary in the past, but is by itself a ponderous means for implementing environmental policy aims. The idea is to make it pay for companies to pursue environmentally focused innovation strategies. For this purpose, supporting measures and instruments need to be further developed.

## 6. Literature

- Ahlers, J.; Schwarz-Schulz, B. und H.-C. Stolzenberg (2001). Strategie für eine zukünftige Chemikalienpolitik. Das neue EU-Weißbuch. Umweltwissenschaften und Schadstoffforschung 13 (2), 75-78.
- Ahrens, Ralph (2001): Neuordnung der Chemikalienpolitik in Europa - das Weißbuch der EU-Kommission. Dokumentation des Workshops III der Reihe "Gesprächsstoffe - Dialog zu Chemikalien, Mensch und Umwelt". Eine gemeinsame Initiative von VCI und IG BCE, Frankfurt am Main.
- Allanou, R.; Hansen, B. and Y. van der Bilt (1998): Public Availability of Data on EU High Production Volume. European Chemicals Bureau: Ispra, Italy.
- BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) (1999). Farbmittel – Auswertungen der Anmeldungen nach dem Chemikaliengesetz. <http://www.baua.de/prax/chem/posli.htm>
- BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) (2001). Toxikologie von Gefahrstoffen: Anwendbarkeit von Struktur-Wirkungsbeziehungen. Amtliche Mitteilungen der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin 2/2001, 6-7.
- BMU (1998): In Deutschland wurde der 1000. Neustoff angemeldet. Umwelt Nr. 3/1998, 128-129.
- Commission of the European Communities (2000): Report from the Commission to the European Parliament and the Council: Results of the Fourth Phase of SLIM. COM (2000) 56 final.
- Commission of the European Communities (2001). White Paper: Strategy for a future Chemicals Policy. COM (2001) 88 final.
- European Commission (1996). Technical guidance document in support of Commission Directive 93/67/EEC on risk assessment for new notified substances and Commission Regulation (EC) No 1488/94 on risk assessment for existing substances. Office for Official Publications of the European Communities, Luxembourg.
- EDF (Environmental Defense Fund) (1977). Toxic ignorance: the continuing absence of basic health testing for top-selling chemicals in the United States. EDB National Headquarters, New York, USA.
- EEB (European Environmental Bureau, Federation of Environmental Citizens Organisations) (2000). What is wrong with EU's chemicals policy? EEB Office, Bruxelles, Belgium.
- Faust, M., Altenburger, R., Backhaus, T., Bödeker, W., Scholze, M., and Grimme, L. H. (2000). Predictive assessment of the aquatic toxicity of multiple chemical mixtures. J. Environ. Qual. 29, 1063-1068.

- Fleischer, M. (2001). Regulierungswettbewerb und Innovation in der chemischen Industrie. Discussion Paper FS IV 01-09, Wissenschaftszentrum Berlin.
- Fleischer, M., Kelm, S., Palm, D. (2000). The impact of EU regulation on innovation of European industry: regulation and innovation in the chemical industry. Report EUR 19735 EN, The European Commission Joint Research Center, Institute for Prospective Technological Studies, Sevilla, Spain.
- GAO (United States General Accounting Office) (1994). Toxic substances control act: legislative changes could make the act more effective. Report GAO/RCED-94-103 to Congressional Requesters, Washington D.C., USA.
- Geiger, D. L., Broke, L. T., Call, D. J. (1990). Acute toxicities of organic chemicals to fathead monnow (*Pimephales promelas*), Volume V. Center for Lake Superior Environmental Studies, University of Wisconsin Superior, Superior, Wisconsin, USA.
- House of Lords (2002): Reducing the Risk: Regulating Industrial Chemicals. Select Committee on European Union. Thirteenth Report, UK. <http://www.parliament.the-stationery-office.co.uk/pa/ld200102/ldselect/ldeucom/81/8101.htm>
- Köck, W. (1999): Risikobewertung und Risikomanagement im deutschen und europäischen Chemikalienrecht - Problemanalyse und Reformperspektiven. In: Hansjürgens, B. (Hrsg.): Umweltrisikopolitik. ZAU Sonderheft 10, 76-96.
- Köck, W. (2001): Zur Diskussion um die Reform des Chemikalienrechts in Europa. Das Weißbuch der EG-Kommission zur zukünftigen Chemikalienpolitik. ZUR 5/2001, 303-308.
- Kommission der Europäischen Gemeinschaften (1998): Bericht über die Durchführung der Richtlinie 67/548/EWG, der Richtlinie 88/379/EWG, der Verordnung (EWG) 793/93 und der Richtlinie 76/769/EWG. Arbeitsunterlage der Kommission SEK (1998) 1986 endg.
- Krämer, L. (2000): Introduction into the European chemicals regulation: Basic structures and performance. In: Winter, G. (Hrsg.) (2000): Risk Assessment and Risk Management of Toxic Chemicals in the European Community, 14-34.
- Staudt, E., Auffermann, S., Schroll, M., Interthal, J. (1997). Innovation trotz Regulation: Freiräume für Innovationen in bestehenden Gesetzen - Untersuchung am Beispiel des Chemikaliengesetzes. Innovation: Forschung und Management, Band 13, Institut für angewandte Innovationsforschung, Bochum.
- Staudt, E., Kriegesmann, B., Schroll, M. (1993). Innovation und Regulation – Gesetzesfolgenabschätzung am Beispiel des Chemikaliengesetzes. Berichte aus der angewandten Innovationsforschung No 126, Institut für angewandte Innovationsforschung, Bochum.

- Ratte, H. T. (1998). Influence of the growth pattern of the EC50 of cell number, biomass integral and growth rate in the algae growth inhibition test: Volume I – Anonymised Version. Umweltbundesamt Project No. 360 030 10, RWTH Aachen University of Technology, Chair of Biology V, Aachen , Germany.
- Van Leeuwen, C. J. (1995). General introduction. In: Van Leeuwen, C. J., Hermens, J. L. M. (Eds.), Risk Assessment of Chemicals: An Introduction. Kluwer Academic Publishers, Dordrecht, The Netherlands, 1-17.
- Winter, G. (2000): Chemikalienrecht - Probebühne und Bestandteil einer EG-Produktpolitik. In: Führ, M. (Hrsg.): Stoffstromsteuerung durch Produktregulierung. Baden-Baden: Nomos, 247-276.