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European proposal for chemicals regulation: REACH and beyond

Synthesis

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This text only commits its author.

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European Proposal for Chemicals Regulation: REACH and Beyond

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FOREWORD

Following a request from the Council of the European Union at its meeting on 24-25 June 1999, the Commission produced a White Paper on the *Strategy for a Future Chemicals Policy*, which was published 25 February 2001.¹ The Council and Parliament reacted positively to this text and proposed amendments aimed mainly at simplifying it and reinforcing its protection of environment and health. The Commission then met with the stakeholders and established expert groups to propose a draft regulation. The proposal was made public on 7 May 2003, posted on the Commission's Internet site that day, and criticized strongly by heads of state and governments in the United States, Asia, and Europe.² In addition to the numerous e-mail responses,³ the media provided wide coverage of the reactions and comments of various special interest groups. The Commission then published a substantially modified text on 29 October 2003—the regulatory proposal widely known as REACH.⁴ This has once again inspired numerous reactions, especially in the debate about the studies commissioned by various stakeholders (the Commission, Member States, and interest groups) to assess the impact of REACH on health, environment and industry.⁵ The REACH proposal will be submitted to the European Parliament for a first reading in the autumn of 2005.⁶

In the text that follows, we detail first the extent to which the REACH proposal is based upon the precautionary principle (I). We then comment on the proposal, discuss some of its specific aspects (II) and consider several suggestions to complete the current text (III). We next return to the situation of the various

stakeholders who have now and will have key roles in either industrial or research chemistry once a resolute commitment to the objectives of sustainable development is made (IV). Finally we report the choices made for this workshop (V) and briefly present the contributions included in this document (VI).

I. Foundations of the Proposed European Regulation of Chemical Products: The Point of the Precautionary Principle

Under the regulatory system currently used by the European Union (EU) for chemical products, we lack substantial information about the hazards and risks that characterise the huge number of chemical products inventoried by the EU today—more than 100 000 (Haigh).

Failure to ensure serious evaluation before marketing led to the discovery of manifest dangers in widely-used products, including asbestos and DDT. They are now banned in many industrialised countries, in particular in the United States and Europe.⁷ The nature of risks for other agents remains only partially identified, and their characteristics are inadequately defined. Endocrine disrupters furnish one example: tests for use in risk assessment have yet to be satisfactorily defined. Our knowledge about the risks associated with chemical products comes from several types of data. A first group involves the diffusion of chemical substances through the environment,

their interaction with ecosystems and concentration in air, soil, plants, and animals, as well as changes in these characteristics over time. A second type of data derives from the monitoring of diseases in humans and other animals.

We know today that the incidence of a wide variety of disorders is rising, especially for vulnerable populations (children and the elderly): chronic diseases, such as asthma and some allergies, fatal diseases, such as cancer, and dysfunctions of the reproductive and hormonal systems. We also know that diffuse pollution by chemical substances continues to rise and is sometimes irreversible for persistent pollutants accumulating in biological systems.

The relations between the developments observed in environmental pollution and those in human health are hotly debated and consensus is far away. Several factors make it hard for these debates to move forward.

First, intense controversy surrounds the conclusions of studies conducted by governments and organisations about changes in population health characteristics, including the incidence of different diseases and their causes. For example, serious methodological difficulties impede the study of trends in different cancers over the past 50 years.⁸ It is complicated and difficult to compare data sets obtained in different settings:

- the number of early diagnoses has snowballed, and their quality improved, thereby enlarging the field of investigation of identifiable diseases
- behavior and habits have changed substantially and differentially by age groups
- the environment of individuals, at home (domestic sphere, urban, suburban, rural) and in the workplace, has also undergone important modifications.

From opposite ends of the spectrum of opinions and sensitivity, two points of view—even two philosophies—face one another. At one end, some argue that pollution, once much more intense and harmful for humans, has diminished considerably, at the same time as human health has improved substantially. This is certainly the case for the industrialised countries. Consequently, it is argued that the inhabitants of these countries, where the levels of air and water pollution are much lower than in the past, have no cause for alarm. This observation is inapplicable, of course, for developing countries or even, for different reasons, for the emerging or ‘transition’ countries. Those at the other end of the spectrum point out that while obvious pollution—that is, present at high levels and easily discernible—is

strongly differentiated by country, diffuse pollution is growing. Correlatively, the rising incidence of some chronic diseases and the strong presumption that incidence of some cancers has also climbed are heard as an alarm and have sparked intense worry. These chronic diseases may be largely attributable to environmental factors and the cancers promoted by them; diffuse pollution by chemicals is among the most important of these factors.

Finally, in many cases we observe a notably slow rate of growth in our knowledge about the causal relations between developing diseases and the environmental factors likely to influence or cause them, directly or indirectly, especially when we seek scientific certainty. The numerous methodological problems are unsurprisingly similar to the reasons that the debates of experts are so inconclusive. Issues include the difficulty of extrapolating the results of toxicological tests on animals to humans and of demonstrating the initiating or promoting effects of any given substance for a specific disease. Another major question concerns collaborative and therefore synergistic effects harmful to health and environment of substances that, alone at low concentrations, are of no concern (Müller-Herold (a)). The concept of a threshold appears inoperative in those cases. Another source of uncertainty is the vast amount we do not know about these substances’ toxicological and ecotoxicological characteristics as well as about conditions of exposure to them.

The current situation—diffuse pollution by chemical substances and acknowledged scientific uncertainty about their effects on health and environment—is precisely what the precautionary principle is intended for. It is inscribed in the European Union Maastricht Treaty and has since been reaffirmed in the Treaties of Amsterdam and Nice as well as the newest treaty currently pending approval by the Member States. The REACH proposal clearly appears to apply it (Heyvaert, Reh binder). There are serious reasons to worry about the potential or recognised harmful effects of pollution on human health and the environment, effects that may be irreversible when possibly dangerous products accumulate in biological materials and widespread if these substances can also cover long distances.

None of this detracts from the severity of diseases that are still very poorly managed and that ravage populations in developing countries across the planet. Responses that measure up to the drama of these human situations are imperative. We note nonetheless that the

solutions to major health and environmental problems lie in mechanisms of international cooperation that are being constructed laboriously and with great difficulty. The problem of fighting malaria with DDT is emblematic. The Stockholm Convention, which commits the parties using DDT on their territory to stringent restrictions of its usage,⁹ also encourages them to use other methods to fight malaria. It is evident that if serious efforts were made to find, produce and distribute drugs against this disease, the situation would be very different. But efforts in this direction remain inadequate, especially measured by the magnitude of the problem.¹⁰

II. The REACH Proposal

What is undeniably new in REACH is the requirement that companies provide data about the hazards and risks of the substances they produce, import or use. This choice nonetheless falls clearly within the application of the precautionary principle, as does the procedure for authorisation of substances of very high concern (Rehbinder). Some consider it praiseworthy that this initiative reverses the burden of proof, as the European Commission's communication about the precautionary principle recommended.¹¹ The liability as well as the burden here lie on the producer. Make no mistake: when the precautionary principle is invoked in situations of scientific uncertainty about the nature or characteristics of a risk, the safety of the product is as difficult to establish as the countervailing risk. Inversion of the burden of proof is therefore, above all, an inducement: substances that may be or are certainly dangerous should be withdrawn from the market by their producer or subject to usage restrictions by the regulator.

The complexity of the text presented by the Commission and still under discussion at the European Parliament matches that of the problem it deals with. The goal is to create a regulatory system that will by 2012 collect information about all the environmental and health hazards and risks of existing and new chemical substances in Europe, by standardised procedures.

Several prerequisites appear from the onset. The chemical substances—there are more than 100 000 in Europe and 30 000 are concerned by REACH—are extremely diverse: mineral and organic products, metals, small molecules, polymers, etc. Estimating the hazards and risks of these substances at the same

time is not an easy task. Although some of their intrinsic properties, such as a given solvent's solubility, can be measured directly in the laboratory, only estimates are possible for other properties. Estimating toxicity for humans, for example, requires interpretation and extrapolation of animal tests; it is simultaneously a complex and sensitive procedure. The risks of substances are related to the characteristics of exposure, therefore to the volumes produced, types of use, number of users, all along the chain from producer to end-user. Most often, these substances travel through a complex network that links producers, users, and consumers. The REACH system, by the way, focuses on substances considered in isolation, whether or not they are part of a preparation or product; accordingly it ignores possible synergistic effects (Müller Herold (a)).

The initial proposal is therefore ambitious. The choice of criteria to ensure that the job can be done efficiently and commensurately is sensitive. For example, while it is tempting to rank the products of greatest concern, which should be dealt with most urgently, according to the risks they present, the available data often do not allow us to estimate these risks. Consequently, taking into account simultaneously the hazards of these substances and the volumes produced appears to be a more realistic choice. Nor is it simple to ensure that all of the stakeholders, from the producer through the user, exercise their responsibilities (Rehbinder). REACH chose to place the final responsibility as well as the duty of substitution on the initial producer. It is not evident, however, that the producer is always in a better position than some of his customers to do this.

The current draft of REACH reflects specific choices that were made. This workshop will try to understand more precisely to what extent the text responds consistently to the initial project and its goals.

III. Moving Forward

Where is the REACH proposal at this stage of the negotiations? Various interest groups—companies that produce or use chemical substances, unions, environmental and consumer protection groups—remain divided today about the desirable level of regulatory constraint to apply towards the goal sought, but their opinions do not seem to call into question the logic and internal consistency of the REACH proposal.

We could certainly have wished for a simpler text, easier for more people to understand, as well as a faster schedule for dealing with the products of very high concern. We could also have hoped for the development or reinforcement of environmental monitoring systems (Macrory), together with more effective exploitation of the physicochemical properties accessible in the laboratory (Hansson, Müller-Herold (b)). All of these would have corresponded more completely to the precautionary policy as it should be applied before products are put on the market. This proposal nonetheless seems to us a very significant step forward. It is therefore our task to help make it a regulation with the most effective, equitable and easiest possible application.

Several kinds of uncertainties remain about and within the proposal.

These involve in particular questions about frontiers. Europe seeks here to function as a role model or example for other large countries that produce chemical substances. The steps taken in several OECD countries (Musset) reflect concerns about the lack of data very similar to those that inspired REACH and they pursue very similar goals. The United Nations Environment Program international strategy for chemical products and the efforts at harmonisation it involves thus become meaningful. These efforts may find technical assistance in the harmonised methods of evaluation, classification and labelling developed by OECD. The European Commission is committed to participating in this harmonisation effort through REACH.

Some more complex questions may not find satisfactory responses immediately. It is thus important that the text allow them, or even plan for them, to be dealt with later or that it include from the beginning some adjustable provisions (Hansson).

Finally other questions will be answered during the current negotiations. These will include important details about the tasks of the European Chemicals Agency that the text establishes and the respective roles of the Member States and the community organs in assessing and managing these risks. Other important points are the pooling of hazard data by companies, while maintaining the confidentiality of trade secrets,¹² and support for small businesses to help them meet their obligations.

The model of community agencies and their network operations (such as the recently operational European Food Safety

Authority) may serve as an example for the relations that the European Chemicals Agency establishes with similar national authorities (or those with adequate expertise). An essential issue is the expert resources necessary, within the competent national and European authorities and in industry. While consideration of the tasks to be committed to the Agency should be separated insofar as possible from that of its resources in experts, it is desirable for the member states to cooperate in sharing their national expertise and resources. Identifying within the member states the domains of highest—and inversely most underdeveloped—skills will make it possible to invest effectively to develop capacity for expertise in risk assessment as early as possible. The establishment of the Agency will very certainly be an essential element in this rationalisation of competence within the 25 member states.

The REACH proposal also presents the question of possible modes of access to privately-collected data. The point of pooling data from companies is to save money, reduce the amount of animal testing, and especially maximise the use of the data that exist. Accordingly, it would be extremely useful to consider how to make public a greater portion of the toxicological data that pharmaceutical companies collect in meeting their regulatory obligations. This would greatly reinforce our toxicological knowledge.

IV. Stakeholders

We focus most specifically on European chemical industries. We then deal with an important motor for the economic development of this industry—research and innovation.

Economic Actors

The REACH proposal was made and is being examined in a background of accelerating international trade and substantial industrial restructuring under the pressure of several factors—search for economies of scale, refocusing by industrial groups on their core business, and a reduction in the cost of labor. These factors, which all work to increase the values of company stock, result in outsourcing, that is, the moving of industrial sites towards Eastern Europe and emerging countries, especially in Asia (Gréau). Regulatory constraints set up to protect health

and environment appear in this context to be one element that determines companies' strategic choices. This is true in all industries and especially in chemistry.

In this constantly changing environment of major social and economic challenges to western nations, another increasingly pressing challenge is emerging: the need to use natural resources better, more efficiently, more effectively, and more economically, by moving towards modes of development that are more environmentally friendly and therefore better for human health.

The large European chemistry companies, while they maintain strong roots in Europe, are international today. In today's economic situation, they are growing strongly elsewhere, especially in Asia, where they are developing not only production sites but also research and development units. One effect of industrial changes has been to reverse the earlier trend towards diversification, with firms combining activities in the domains of food-processing, pharmacy, and chemistry. The three activities, which do not necessarily have the same profit levels, are being separated again, which affects their industrial environment significantly. Although a small production unit for several chemicals can be created by a newcomer to the market at a relatively low cost, the cost increases as we move from simple chemicals past food-processing into pharmaceuticals. Moreover the consequent fragmentation of skills and know-how will have long-term consequences on innovation.

Within this constantly changing industrial landscape subject to intermediate-term trends—diversification *versus* concentration and refocusing—environmental regulations such as REACH necessarily affect companies differently, depending on their size and resources. In France, in particular, chemical producers and users of all sizes coexist, forming a continuum between what are conventionally called small and large companies. This observation militates in favor of equal requirements for all under REACH, but with differentiated support, for companies according to their resources to ensure that the overall system operates effectively. As such, making technical resources available to companies to facilitate not only the regulation's application but also innovations would be highly desirable (Warhurst).

The Role of Research

Research, innovation and technological development together constitute one of the

principal motors of our society, one that drives education, training, and adaptation to the challenges that must be mastered. One of these is sustainable development. Translating these challenges—food supply, energy efficiency, essential services for all, environmental protection, and better public health—into research calls simultaneously for basic and applied research.

For the past five years all the governments of the European Union have systematically affirmed the urgency of reaching their research budget goals: 3% of their GNP on research (public and private) by 2010. Sadly, meeting these commitments is proving difficult. Too often, the first budget cuts touch these areas essential for our future. They evidence a lack of willingness and a recurrent weakness: the state does not keep its commitments to sustained research, despite the strategic importance of long-term strategies for large-scale programs and of adaptability to advancing knowledge and changing situations. The ability to make consistent choices and stand by them over time requires a recognition that all the components of research contribute vitally to a nation's vigor.

From a historical perspective it appears clear that since World War II, nations have associated their research and industrialisation efforts; this was also true between the wars, but the State's role was less important then (Dahan). Today, we witness an increasingly pronounced diminution of the industrial sector in Western Europe and a simultaneous reduction in funding for research. The restructuring underway is not preserving the first-class private laboratories—for example Bell Labs or Dupont in the United States—that flourished when some companies financed top-rate basic research and benefited from the synergy between engineers and researchers.

Chemistry fits this description. Nonetheless, awareness of the stakes of sustainable development is evolving progressively. It is growing among researchers and is expressed in research programs directed towards building a more environmentally-friendly, safer and more effective chemistry, called green chemistry (Lattes). Nonetheless, even if these efforts produce a load of discoveries and promising innovations, these will still need to be developed and produced industrially at acceptable costs. The laboratory shelves are already filled with riches, however. Efforts must also concentrate on instruments to enable the development and industrial use of existing processes and products. This is true

for chemistry and many other sectors. Think of all of the fields involved in finding ways to reduce greenhouse gas emissions.

V. Choices for this Workshop

We have chosen not to deal with the relations between chemical pollution and human health. The technical complexity of these questions (*cf.* I) prevents a serious approach to them in the framework of this workshop. They are at the heart of the research now being conducted in France as part of the Environmental Health Plan¹³ and debate here is increasingly focusing on this issue.¹⁴ Nor will we deal in detail with the question of the impact of REACH on public authorities or industry. After a first wave of studies (*cf.* note 5), a second series of sector impact studies took place;¹⁵ their results were published recently and analysed during a workshop of the Member States on 10-11 May in Luxembourg. They are already much less negative for industry than some earlier studies. Here again, the methodological difficulties seem too numerous for us to make progress on this question at our workshop. The participants have debated and can continue to debate these questions in other settings.

Accordingly, we preferred to have high-level European experts provide illumination about other aspects of the REACH proposal. These raise simultaneously questions of principle, substance and implementation. They may deal with the intermediate term—the REACH process through 2012—or the longer term—its integration in international initiatives or its effects on innovation.

While not excluding critical analysis of the proposal (Macrory), we stress the importance today of placing the debate from the outset as close as possible to reality and to proposals for improvement, to keeping it concrete. We are wagering that the negotiations underway will not substantially call into question either the logic of the system or the level of requirements of the various stakeholders.

At the same time, we will look farther ahead; we would like everyone involved to consider together the different scenarios that might help optimise the consideration of the challenges we face today. When we look past the closest horizon, we are more likely to find what we are looking for: ways to improve complementarity and cooperation between economic stakeholders, public authorities and citizens, as well as within the industrial world.

To reach that point, it is first necessary to find the best reasoned economic logic (or even the most reasonable!) that will allow States to commit the resources necessary to invest in the future, most especially in education and research (Guinot, Lattes).

VI. Articles in this Document

This collection brings together the texts of nine authors.

Nigel Haigh reviews the history and weaknesses of the legislative provisions that have progressively governed the use of chemicals in Europe.

Laurence Musset presents the work conducted by OECD on chemicals and the associations between this work and the REACH proposal. She also discusses relevant initiatives by other OECD countries.

Richard Macrory reports on important aspects of the 2003 report by the Royal Commission on Environmental Pollution (a standing committee of independent experts), entitled *Chemicals in Products: Safeguarding the Environment and Human Health*.

Ulrich Müller-Herold sheds light on the difficult question of the synergistic effects of chemicals with a simple model and examples from the recent scientific literature.

Sven Ove Hansson and Christina Rudén show that the information required by REACH is insufficient to characterise substances produced at low volumes. They propose a method for correcting the regulation's weakness for the very low volumes.

Eckard Rehbinder argues that the REACH proposal is an application of the precautionary principle and analyses the liability scheme introduced, the question of the burden of proof and its compatibility with the World Trade Organisation rules.

For Michael Warhurst, regulations, including REACH, are a key component in ensuring that the chemical industry contributes to sustainable development. It must nonetheless be completed by investments in sustainable chemistry and systems to provide technical assistance to companies.

François Guinot shows that the challenges facing European chemistry today, including the pursuit of sustainable development, can be met if both Member States and the European chemical industry place research and innovation firmly at the centre of their strategies to foster the emergence of a new chemistry.

Armand Lattes presents and comments the efforts made toward green chemistry and especially biotechnology by the large industrialised countries (France and the rest of Europe, in particular).

Finally, while the final bibliography proposed for readers at the end of this document is relatively modest, we strongly suggest they consult the references, often very rich, included in those works.

- 1) COM(2001)88 final.
- 2) In a letter dated 20 September 2003 to Romano Prodi, the President of the Commission, Prime Minister Tony Blair, President Jacques Chirac and Chancellor Gerhard Schröder expressed their concerns, especially in relation to competitiveness and jobs, but also about the bureaucratic character of the proposal, considered very difficult to implement.
- 3) More than 6000, cf. <http://europe.eu.int/comm/environment/chemicals/whitepaper.htm>
- 4) Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants, COM(2003) 644.
- 5) The Netherlands, during its presidency of the European Union, organised a workshop at the Hague to debate the principal impact studies, based on a summary document, which is available on the Internet: http://www.eu2004-reach.nl/downloads/Comprehensive_Overview-v2.pdf
- 6) A history of how the REACH proposal came into being and was prepared as well as reactions at various stages can be found at <http://www.panda.org/downloads/toxics/theonlyplanetguide.pdf>.
- 7) DDT use is tightly restricted as part of the Stockholm Convention, which came into effect in 2004 and has been ratified by more than 70 countries.
- 8) *Cancer, approche méthodologique du lien avec l'environnement. Une expertise collective de l'Inserm*, Inserm 2005, 101pp. <http://ist.inserm.fr/basisrapports/cancer2005.html>
- 9) This is the case in particular for Côte d'Ivoire, Ethiopia, Papua New Guinea and South Africa.
- 10) Report of Médecins Sans Frontières, 13 October 2001.
- 11) COM(2000)1.
- 12) See the proposal by the United Kingdom and Hungary entitled *One Substance, One Report* (the OSOR proposal).
- 13) Seminar of scientific perspectives and launching of the research program of the National Environmental Health Plan and the Workplace Health Plan,

Ministry of Research, 31 March and 1 April 2005.

14) Second parliamentary encounter *Environmental health*, National Assembly, 9 December 2004.

15) There were two studies. In particular, one commissioned by CEFIC and UNICE from KPMG, and the other commissioned by the European Commission from its Joint Research Centre and from the Institute for Prospective Technological Studies (IPTS), both made public on 27 April 2004.

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- (a) Müller-Herold U., *Beyond REACH. A Tutorial Approach to Toxic Effects of Chemical Mixtures at Individual No-Observed Effect Levels*, this volume, pp. 43-45.
- (b) Müller-Herold U., Morsini M, Schucht O., and Scheringer M., *Precautionary Pre-Selection of New Organic Chemicals – A Case Study on the Application of the Precautionary Principle in the European Union*, in O.Renn et al.: *The Application of the Precautionary Principle in the European Union*, Part E and Part G; <http://www.sussex.ac.uk/spru/environment/precaupripdfs.html>.
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A Brief History of EU Regulation of Chemicals

Nigel Haigh

Former Director, Institute for European Environmental Policy (IEEP), London, United Kingdom

EU chemicals legislation dominates national policies. It began in the 1970s and has evolved in four overlapping phases with REACH constituting the last phase. In the 1970s a framework was created for *ad hoc* restrictions on the marketing and use of any chemical found to be dangerous. This will continue under REACH. Beginning in the 1980s—the second phase—no new chemical could be placed on the market before it had been tested and the results notified. As a result useful information has been provided for safe use and some chemicals were not marketed which otherwise would have been. In the 1990s—the third phase—a programme was introduced for existing chemicals. Priority lists of existing chemicals needing evaluation were drawn up with the work of risk assessment being shared among the Member States. Although this is resulting in published risk reduction strategies, these are being produced so slowly that pressure has grown for a major reform of the existing regimes. This is the fourth phase, called REACH.

► READ PAPER PAGE 29

The OECD Chemicals Programme and some Features of the Proposal for a New EU Chemicals Policy

Laurence Musset

Organisation for Economic and Cooperation and Development (OCDE), Paris, France

The objective of the OECD Chemicals Programme is to assist member countries as effectively as possible in protecting human health and the environment from chemical risks. This is done through the harmonisation of high quality tools and policies for chemicals management, whereby duplication of work for member countries and industry can be avoided, and through work sharing. The evolution of the Programme reflects the progress in OECD countries, from risk management for a

few specific chemicals of high concern, followed by the development of instruments for the control of new chemicals and finally cooperative work on existing chemicals. For global efficiency, the OECD now works with selected non-member countries in order to promote convergence of chemical safety policies.

The OECD Test Guidelines and Good Laboratory Practices are the two keystones of the Mutual Acceptance of Data. The Programme provides guidance documents on risk (assessment and management). To reduce costs and animal use, it also works to facilitate regulatory acceptance of alternative test methods and computer-based data estimation methodologies. In many ways, including its work on harmonisation of classification and labelling criteria, the Programme contributes to the implementation of UN recommendations related to chemicals management.

Several elements of the proposal for REACH are new compared to the current EU legislation, but are already part of the chemicals policy of some EU and/or other OECD countries. This is the case in particular for the systematic examination of existing chemicals and for the high concern for persistence and bioaccumulation properties. On the other hand, industry responsibility for assessing chemical safety and the authorisation procedure for chemicals with very hazardous properties are new features. In many ways, the OECD Chemicals Programme will provide input to the new EU chemicals policy, and vice versa.

► READ PAPER PAGE 33

Chemicals in Products: Safeguarding the Environment and Human Health

Prof. Richard Macrory

University College London, London, United Kingdom

The Royal Commission on Environmental Pollution made 54 recommendations for action and change to chemicals regulation in its report to the UK Government, *Chemicals in Products: Safeguarding the Environment and Human Health*, which was published in 2003. The Royal Commission believe that REACH will take too long to clear the backlog of

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untested chemicals and proposes a system that would 'quick check' all 30 000 chemicals within three years, as opposed to subjecting each one of them to a much slower, more expensive and exhaustive analysis. The first step would be to compile a list of chemicals on the market, and the second step to assess them according to hazard with computer-based molecular modelling techniques and computerised methods for searching the scientific literature and databases. Restrictions would then be placed on their use according to the level of risk. The Royal Commission anticipates that most of the chemicals would emerge from this screening as being of no particular concern. However, some of the chemicals in the 'high concern' category might have to be immediately banned from production or importation. Several hundred, and perhaps more than a thousand, would probably be categorised as being of high, medium or low concern and then be subjected to more thorough risk assessment. The Royal Commission believe all of the chemicals of concern identified by the screening could have their risks fully evaluated by 2009. Although the Royal Commission do not believe that such a system would identify every chemical with adverse properties, it would be more effective than the REACH approach. The report also recommends that the government should also make more use of environmental monitoring in identifying chemicals of concern that require further action. The Royal Commission want to see a UK government strategy to achieve a steady, measurable reduction in the use of hazardous chemicals and substitution with safer alternatives. The report argues that giving the public far more information about chemicals on the market would drive producers and users of chemicals towards substituting for risky products others that are inherently safer, and those that are hazardous should be restricted to certain uses and subject to a charge.

► READ PAPER PAGE 38

Beyond REACH. A Tutorial Approach to Toxic Effects of Chemical Mixtures at Individual No-Observed-Effect Levels

Prof. Ulrich Müller-Herold

Swiss Federal Institute of Technology (ETH), Zurich, Switzerland

It is shown that the 'additivity of effect' rule as provided for by Appendix 1b of REACH systematically underestimates the risks of synergistically acting mixtures of chemicals. This is illustrated with a simple model and examples from the recent scientific literature.

► READ PAPER PAGE 43

Improving the Scientific Basis for Decisions in the REACH System

Prof. Sven Ove Hansson
and Christina Rudén

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A science-based risk assessment of potential or actual exposure is only possible when a reasonable amount of knowledge is available about the inherent properties of the substance in question. A major advantage of the REACH proposal is that it will extend our toxicological database for industrial substances and thereby improve the scientific basis of risk assessments. However, our analysis shows that this improvement, although substantial, will still leave large gaps in the data. For substances produced in quantities of less than 10 tonnes, REACH does not require the information necessary for application of any of the major criteria for science-based classifications according to (for example) acute or chronic toxicity or ecotoxicity. For substances produced in quantities of 100 tonnes or less the information required by REACH does not provide any of the information that determines whether or not the REACH authorisation process should be triggered, for example, whether the PBT (persistent, bioaccumulative, and toxic) or the vPvB (very persistent very bioaccumulative) criteria for potential ecotoxicity are applicable.

The tests included in REACH and other regulatory test systems are all carefully constructed according to scientific principles. This does not suffice, however, to make the test system as a whole science-based: the combination of the tests and the rules for how tests follow one another must also be based on scientific principles. We propose research aimed at developing test systems that are science-based on the systemic level.

Special efforts should be made to use physicochemical properties as the first tiers of these test systems. Such data can be obtained at relatively low cost and without extensive animal testing. We propose that a set of persistence and bioaccumulation data, enough to apply the PBT and vPvB criteria, should be requested for all substances regulated by REACH.

We also propose that substances for which basic scientific data is missing should be classified as insufficiently investigated and assigned a warning label, including a warning symbol, such as a question mark. This will provide companies with an incentive to perform voluntary testing of low-volume substances, in addition to the minimum requirements.

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Legal Issues of REACH

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The REACH proposal constitutes a change of paradigm in regulating chemicals that in principle is to be welcomed under the perspective of precaution but which raises questions of fundamental economic rights, proportionality and conformity with WTO rules.

The introduction of a registration procedure for existing substances associated with mere informational obligations can be justified by an 'initial suspicion' of hazard and risk that is based on our experience with chemical substances. While there may be good policy arguments that the full registration obligations should be triggered only by the results of risk screening in the preregistration phase, the more demanding solution of the REACH proposal evidently does not impose excessive burdens on producers or importers. The introduc-

tion of the authorisation procedure for ultra-hazardous substances is associated with more burdensome legal consequences but justified by the special nature of the hazards and risks that are to be addressed.

The imposition of a fundamental duty of care including risk assessment and risk management along the whole supply chain rests on firm precautionary grounds because it extends the information base for risk assessment and management. However, REACH's reliance on producer responsibility tends to blur the responsibility of public authorities. Therefore, much will depend on the incentives the actors along the supply chain have to live up to their responsibility.

The reversal of the burden of proof associated with the authorisation requirement is justified by the nature of the potential risks and the safeguards built into the system for addressing remaining uncertainties, especially the standard of adequate rather than absolute control of risk and the authority to consider socio-economic benefits.

Finally, REACH is justified under article XX (b), (g) and the chapeau of the GATT because the registration and authorisation procedure as such is necessary to protect health and the environment and does not constitute a disguised protectionist measure, and because burdensome interventions such as restrictions of substances and the denial of an authorisation must be based on a risk assessment.

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Achieving Sustainability: The Interplay between Green Chemistry, Regulation and Industry

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Achieving a sustainable society is a huge challenge for all of us. We must reduce consumption of material considerably, make a massive improvement in energy efficiency and reverse environmental pollution. As a major user of resources and energy and potential polluter as well as a producer of alternative solutions to these negative effects, the chemical industry is at the core of many of these issues.

ABSTRACTS

This paper examines the roles of regulation, green chemistry, government and industry itself in making the chemical industry focus on being part of the solution.

Innovation is the key to discovering new, more sustainable ways of doing things, but this innovation must also be channelled in the right direction by taking into account three drivers (willingness, opportunity, capacity) of innovation within industry.

Maximising the willingness for innovation within industry is a complex challenge, and substantial new regulations like REACH can have a role. As for opportunity, a regulation such as REACH can assist in generating positive innovation in number of ways, for example through discouraging or phasing out less sustainable technologies and thus creating a market demand for safer substitutes. It can also make it easier to create new technologies, as REACH does by reducing the regulatory requirements for new substances.

Although regulation creates a demand for change, this demand can only be fulfilled if alternatives can be found. This is a key role of green chemistry, discovering innovative new ways of doing things and creating the safer products that REACH will encourage.

Finally, capacity is a significant challenge for many companies, especially smaller ones. Ensuring an educated workforce, and encouraging companies to train their workers, will assist in generating more capacity. Many businesses will, however, have problems obtaining the necessary in-house or even hired expertise. In this case a technical assistance, like that proposed by the Toxics Use Reduction Institute (TURI), in Massachusetts, USA, might be considered.

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The Case for Sustainable Chemistry

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The development model followed until now, although it led one fifth of humanity to a prosperity and longevity never before known, is

called into question today because of the risks it has imposed on the human species. It is being rejected for another more balanced model that indissociably unites economic efficiency, human solidarity and ecological prudence.

Because chemistry was an important pillar of the old model, many think it logical to reject chemistry together with the model. This would however be a strategic error. Chemistry is essential to the success of the development model now being built. It is entirely capable of adaptation to this new model. If Europe, the birthplace of chemistry, applies the so-called Lisbon strategy, based on knowledge and innovation, it can become one of the most dynamic societies on the planet in terms of growth and jobs. It is essential for Europe to become aware that the emergence of a new chemistry at the service of this development model is a keystone of its future.

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Green Chemistry for Sustainable Development

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Chemistry today must respond to the diverse, even contradictory, expectations of society: continue to furnish new ever more effective products, contribute to economic growth and employment, and preserve the environment. We look at what the proposed European regulation REACH can contribute to the development of a new and sustainable chemistry. The crucial issue of reorienting chemical industry objectives to search for methods, processes and products that are safer, healthier, more efficient, and more environmentally-friendly is not receiving sufficient attention in Europe generally and in France in particular, especially compared with the United States. It requires efforts in terms of investments and professional training that have not yet been provided. We nonetheless see the beginning of mobilization for the biotechnology sector.

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