

# elni

## REVIEW

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### Articles with focus on environmental law networks

- The Importance of International Environmental Enforcement Networks: INECE as an example
- European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL)
- NEEL: the Network of EU Environment Lawyers
- The Nordic Environmental Law Network (NELN)
- Networking in the Nordic Countries
- The Avosetta Group

### Articles with focus on other topics

- Towards an integrated approach for sustainability labelling and certification
- REACH: How far will the chemicals legislation reach to protect human health and the environment from hazardous chemicals?
- Rethinking the Role of Information in Chemicals Policy: Implications for TSCA and REACH

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## REACH - How far will the new chemicals legislation reach to protect human health and the environment from hazardous chemicals? A comparison of the positions of the European Parliament and Council

Axel Singhofen

### 1 Introduction

Chemicals legislation was initiated in 1967 when it was recognised that provisions relating to classification, packaging and labelling of substances on the market, in particular dangerous chemicals, should be harmonised throughout the Community in order to eliminate barriers to trade by national provisions<sup>15</sup>. It was only in 1979 that the environmental protection requirement was introduced into the existing legislation<sup>16</sup>. However, this was limited to new substances - testing requirements were only established for substances that were put on the market after 1981. There was no requirement to scrutinize existing substances. It took another twelve years for the institutions to start tackling existing substances. But these represent almost all of the chemicals put on the market. According to Regulation (EEC) 793/93, a risk assessment was to be done for some chemicals amongst the "high-production volume chemicals (>1000 tonnes/year and manufacturer) - the so-called "priority substances"<sup>17</sup>. For the other high-production volume chemicals, industry only had to provide available data.

It took until 1998 that Member States recognised that the current system does not deliver to adequately protect human health and the environment. At the Informal Environment Council in April 1998, the UK Presidency concluded that *"a wider review was necessary of the system as a whole"* and *"welcomed the idea of the European Commission to take stock of existing legislative instruments dealing with chemicals, in particular the regulation on existing chemicals"*<sup>18</sup>.

In November 1998, the Commission presented a report on the operation of the four legislative in-

struments governing chemicals<sup>19</sup>. It contained the following key conclusion:

*"Since the notification procedure has only been in place since 1981, all chemicals marketed prior to that date have never been scrutinised according to this procedure. Thus, for the majority of these chemicals few data are available. The immediate concern is therefore that man and the environment are potentially exposed to a large number of chemical substances for which the hazardous properties have not been identified and/or the risks have not been assessed."*

In June 1999, the Environment Council under the German Presidency stated the following on the Commission report<sup>20</sup>: *"as risk assessments have only been drafted for a very small number of existing substances pursuant to the EC legislation on existing substances, ..., maintaining the current approach is unlikely to tackle the problem of existing substances with the view to achieving an appropriate limitation of all the significant risks posed by these substances to man and the environment"*

In very concrete terms, in 1999, of the 100.00 existing chemicals, only 110 had been subjected to a risk assessment, only four of them had been finished, and not a single measure had been adopted. The fundamental problem of the current legislation was that the lack of knowledge led to a lack of restrictive measures - ignorance about chemicals was rewarded with non-action. With an average of about two risk assessments per year, it would have taken more than 1000 years to assess nothing but the high-production volume chemicals. So the Council called upon the Commission to submit a policy document outlining a new chemicals strategy by the end of 2000.

In 2001, the Commission presented the White Paper on a Strategy for a future Chemicals Policy<sup>21</sup>. Council adopted its conclusions on the White Paper in June 2001; the European Parliament adopted a resolution on it in November 2001. Both institutions welcomed the strategy and asked for it to be strengthened in various aspects. In May 2003, the

<sup>15</sup> Commission Working Document SEC(1998) 1986 on the Operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) 793/93 and Directive 76/769/EEC.

<sup>16</sup> Council Directive 79/831/EEC of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 259, 15.10.1979 p. 10.

<sup>17</sup> OJ L 84, 5.4.1993, p.1.

<sup>18</sup> Presidency Conclusions, Informal Environment Council Discussion on Chemicals, 25 April 1998.

<sup>19</sup> See note 1.

<sup>20</sup> Council Conclusions on Community Policy for Chemical Products, Environment Council, 24/25 June 1999.

<sup>21</sup> COM(2001) 88 final.

Commission submitted a draft proposal for internet consultation. As a result of strong industry pressure, the proposal was watered down significantly before its formal adoption in October 2003<sup>22</sup>. Council started the legislative work in January 2004. Due to the change in legislature, the European Parliament started the legislative work only at the end of 2004 and voted in November 2005<sup>23</sup>. This allowed the Council under the UK Presidency to come to a political agreement at an extraordinary meeting of the Competitiveness Council in December 2005<sup>24</sup>.

## 2 Positions of Council and Parliament in five different key areas

### 2.1 Duty of Care

The European Parliament adopted amendments to oblige manufacturers, importers and downstream users to ensure that their substances do not adversely affect human health/the environment. This so-called "Duty of Care" would apply for all chemicals irrespective of tonnage. This would entail the following obligations for industry: to take every effort to prevent, limit or remedy adverse effects, ensure adequate communication and information to prevent, limit, and remedy adverse effects, to describe, document and notify the risks, and to select substances on the basis of safest substance available.

The Council did not modify the Commission proposal, which only foresees a "principle" that manufacturers, importers and downstream users should ensure that their substances do not adversely affect human health and the environment.

In summary, whereas Parliament wants to translate the Duty of Care into legal obligations, the Council only agrees to it as an aspiration.

### 2.2 Scope

Numerous changes were made by both institutions to reduce the scope of REACH. Parliament adopted a number of complete exemptions as well as exemptions from many or some parts of REACH. Most notable are the complete exemptions for waste and for substances in batteries, the almost complete exemption for medical devices, and the exemption from registration for minerals, ores, concentrates and other materials derived by mineralogical and physical transformation processes.

Council introduced *inter alia* the possibility for Member States for complete exemptions of substances as such, in preparations or in articles in the interest of defence. It furthermore adopted partial exemptions for waste and cement klinker, *inter alia* from registration.

In summary, many new exemptions were introduced, and more so by Parliament than by Council. The exemptions clearly reflect the impact by the various industrial interests.

### 2.3 Registration

Registration represents the very basis for REACH. Requirements differ in time and data provisions according to the intrinsic properties of the substances, their tonnage and their use. The controversy centred in particular on the data requirements for low-volume chemicals (those between 1 and 10 tonnes), as these represent 20 000 out of 30 000 substances that fall under REACH, but account for only about 1 % of the total tonnage.

A clear majority in Parliament voted to significantly reduce the data requirements for low volume substances: a minimal data set (Annex V plus two tests) would only be required for new substances or for substances meeting certain screening criteria, for all the remaining substances, only available information would be required within 11 years. For substances above 10 tonnes, three key tests were omitted or made optional, and extensive possibilities to waive certain tests on the basis of exposure categories and/or risk management and/or adequate control were adopted. Moreover, very extensive exemptions were adopted for Research and Development activities, allowing such activities even with the general public. On the other hand, the requirement for a chemical safety report (CSR), which includes the actual hazard and subsequent exposure assessment, was strengthened: the threshold of 10 tonnes to trigger a CSR would not apply for substances that are carcinogenic, mutagenic or toxic to reproduction (CMR), persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB), or even not at all (CSR to be done for all substances). Finally, another group of substances, classified as R50/53 (i.e. very toxic to aquatic organisms) would have to be registered earlier (>100 tonnes: within three years; above >1 tonne: within six years).

Council took the same approach, but not going as far as Parliament. The requirements for low-volume substances are largely similar to those of Parliament, but with potentially more comprehensive screening criteria, so that more substances would have to provide a minimal data set, which includes one test more than requested by Parliament (Annex V plus three tests). The exact number of chemicals

<sup>22</sup> COM(2003) 644 final.

<sup>23</sup> European Parliament legislative resolution, 17 November 2005, P6\_TA-2005-0434.

<sup>24</sup> Council document 15921/05.

that would be captured by the screening criteria is subject to an ongoing controversy and the figures put forward range from 10 to 50%. As far as the testing requirements for substances above 10 tonnes are concerned, Council omitted one test. Council did not change the provisions on chemical safety report as suggested by the Commission (for all substances as of 10 tonnes). However, it also added the group of R50/53 substances when above 100 tonnes to the first phase of registration.

In summary, both institutions - and in particular the European Parliament - want to see a significant weakening of the Commission proposal on data requirements, especially for low-volume chemicals. While only Parliament calls for more chemical safety reports, both Parliament and Council agree to add a further group of substances to the first phase of registration.

## 2.4 Authorisation

After registration, authorisation has been the most controversial issue. Authorisation applies to substances of very high concern (i.e. CMR, PBT, vPvB, or equivalent concern). The conflict focussed on the role of substitution within authorisation.

Parliament called for a clear candidate list of substances that fall under authorisation and mandatory assessment of alternatives. It wants to see mandatory substitution of substances of very high concern - in other words, an authorisation should only be granted for a limited period of time (with a possibility of renewal), if no safer alternatives are available, if the socio-economic advantages outweigh the risks, and if the risk is adequately controlled.

Council also introduced a candidate list as well as mandatory assessment of alternatives as part of the application for an authorisation. However, the assessment of alternatives would have no influence on the granting of authorisation for substances which are deemed to be "adequately controlled" (i.e. CMR substances or substances of equivalent concern for which a threshold may be developed). The Commission would be *obliged* to grant an authorisation for these chemicals, even when safer alternatives were available. The availability of safer alternatives would only be decisive for PBT, vPvB and non-threshold CMR substances, substances of equivalent concern, or all those substances of very high concern that are not adequately controlled. For these, an authorisation *may* be granted if no safer alternatives are available and if the socio-economic advantages outweigh the risks, with time-limits on a case-by-case basis.

In summary, both institutions want to strengthen the authorisation provisions, but Parliament takes a far stronger approach.

## 2.5 Consumer information and confidentiality

A key antagonism consists between the information provisions to consumers versus business confidentiality. Consumer trust into REACH will be an important element for its success. This requires that business confidentiality is limited to those areas where it is justified.

Parliament adopted amendments that would oblige producers and importers to give to consumers full details on safety and use info on all substances in articles upon request. On the other hand, Parliament potentially undermined the non-confidentiality of the information about the properties of a substance by foreseeing a paradoxical opt-out clause from the compulsory sharing of this information from the provisions on "One-Substance One-Registration" (OSOR) due to business confidentiality. Finally, it wants to allow industry to claim the trade name to be confidential, if it can justify it (the Commission had proposed that the trade name would always be non-confidential).

Council also wanted to improve consumer information, but only for substances of very high concern that are present in articles. On the other hand, it also undermined the non-confidentiality of substance information by opt-out possibilities from OSOR. Finally, Council wants to allow industry to claim key information as confidential due to commercial interests, with due justification (to be justified): parts of the safety data sheet, study summaries of the toxicological properties, tonnage band, as well as impurities with dangerous substances. The Commission had proposed this to be always non-confidential.

In summary, both institutions want to improve consumer access to information about substances in articles (in particular the Parliament), while some information - previously meant to be non-confidential - can be claimed to be confidential (in particular so in Council), or risks to be undermined by an OSOR opt-out clause.

## 3 Evaluation of the positions of Parliament and Council

With only one exception (confidentiality), Parliament is more "extreme" than Council. This reflects the bigger impact by the different lobby interests in Parliament as compared to Council.

Importantly, the trend always goes in the same direction in both institutions: while both want to maintain or strengthen the provisions of REACH concerning Duty of Care, additional substances in the first phase of registration, CSR, authorisation, and consumer information, they also both want to weaken the provisions on scope, data requirements

under registration and increase confidentiality. This increases the likelihood of a second reading agreement.

While Parliament needs only a simple majority in first reading to adopt amendments (50% + one member of all members present), it needs an absolute majority in second reading (50% + one member of the constituent members). As far as the strengthening of REACH is concerned, in first reading, Parliament had an absolute majority on the base provision of a Duty of Care, the addition of a group of substances to the first and second phase of registration, and on requesting CSR for CMR/PBT/vPvB as of 1 tonne. As far as the weakening of REACH is concerned, it had an absolute majority for less data requirements under registration.

It is safe to assume that registration and authorisation will dominate the debate in second reading.

#### **4 Will REACH provide the framework to adequately protect human health and the environment against dangerous chemicals?**

To answer this question, it is important to first look at the current system. The current regulatory regime can be characterised by the following key deficiencies:

- lack of knowledge and lack of restrictive action,
- complex and unsystematic patchwork of 40 legal texts,
- disincentive for innovation (stronger rules for new substances)
- burden of proof on authorities,
- lack of knowledge in the supply chain.

In theory, REACH would eliminate these deficiencies by providing for:

- the knowledge basis needed for restrictive action to protect human health and the environment,
- one coherent legislative framework,
- an incentive for innovation towards safer substances,
- a level playing field new and existing substances,
- authorisation of substances of very high concern,
- a shift of the burden of proof on industry,
- adequate knowledge in the supply chain.

But a closer look at the reality gives a much differentiated picture. Clearly, REACH would provide a number of improvements:

- inventory of substances above 1 tonne,
- better info on some substances 1-10 tonnes and for all substances > 10 tonnes,
- more information in the supply chain,
- stronger control system for substances of very high concern,
- burden of proof partially shifted to industry.

However, firstly, this needs to be balanced against several concessions that were included in the concept of REACH from the outset as compared to the current system:

- less data for new substances,
- longer exemptions for R&D,
- Parliament is excluded from all further decisions (no more co-decision) - and Parliament has a clear track record of strengthening the provisions suggested by the Commission to restrict chemicals.

Secondly, one needs to consider remaining problems as well as new problems created:

- the legislation is very complex - indeed the legislator have made it even more complex by accommodating various corporate interests in the form of many exemptions and opt-outs,
- the unequal treatment between new and existing substances continues for most substances
- a potentially unequal treatment between substances in articles manufactured in the EU vs. those articles imported from outside the EU is introduced
- confidentiality on substance information is increased compared to current system
- the role of Member States is reduced

#### **5 The "One-million-Euro question"**

As we have seen in the beginning, the most fundamental deficiency of the current system is the lack of information on chemicals resulting in a lack of restrictive measures.

So will REACH provide sufficient data and adequate structures to restrict and/or control chemical substances - so as to achieve a high level of protection of human health and the environment from hazardous chemicals?

##### **5.1 Sufficient data?**

For low volume substances, the answer is clearly no. For most of these substances, we will only get "available" information on their intrinsic properties - and only within 11 years. The main problem with this is not so much the risk to not identify potentially problematic substances, but to miss out on the chance to identify safer alternatives. Substitution can only work properly when good information is available for the alternatives. As such, the lack of a uniform minimal data base is likely to create a significant obstacle to the substitution of substances of

very high concern. Exposure information on substances of low volume risks being very limited - to very broad categories only, and possibly with no exposure assessment at all.

It is very difficult to answer the question for substances above 10 tonnes, not least because there is still significant difference in the positions of Parliament and Council. In addition to the very problematic issue of the validity of animal test data for humans, it will depend on the provisions on waiving of data under registration, the effectiveness of evaluation to identify problematic substances after registration, and the time of data delivery under evaluation.

## 5.2 Adequate structures to take action?

Despite all the commitment to workability, the legislation and its decision-making procedures will be very complex, all of which is further compounded by many exemptions and opt-outs. There

is a serious risk of agency overload, as its tasks have been increased significantly, while adequate resources are not all guaranteed, rather to the contrary. Cynical minds might consider the shift of more and more tasks to the agency without any corresponding budget commitments as a deliberate "recipe for disaster". The many possibilities for industry to appeal risk to paralyse the system, and the crucial authorisation risks to remain undermined by the deficient concept of "adequate control".

Last but not least, the Commission's Directorate General for Enterprise and Industry, will be responsible for authorisation and restriction - and experience so far has shown that DG Enterprise is not a frontrunner when it comes to restricting the marketing and use of chemicals.

In conclusion, there is good reason to doubt that REACH will deliver what it would need to deliver to ensure a high level of protection of human health and the environment against dangerous chemicals.

The Öko-Institut (Institut für angewandte Ökologie - Institute for Applied Ecology, a registered non-profit-association) was founded in 1977. Its founding was closely connected to the conflict over the building of the nuclear power plant in Wyhl (on the Rhine near the city of Freiburg, the seat of the Institute). The objective of the Institute was and is environmental research independent of government and industry, for the benefit of society. The results of our research are made available of the public.

The institute's mission is to analyse and evaluate current and future environmental problems, to point out risks, and to develop and implement problem-solving strategies and measures. In doing so, the Öko-Institut follows the guiding principle of sustainable development.

The institute's activities are organized in Divisions - Chemistry, Energy & Climate Protection, Genetic Engineering, Sustainable Products & Material Flows, Nuclear Engineering & Plant Safety, and Environmental Law.

#### **The Environmental Law Division of the Öko-Institut:**

The Environmental Law Division covers a broad spectrum of environmental law elaborating scientific studies for public and private clients, consulting governments and public authorities, participating in law drafting processes and mediating stakeholder dialogues. Lawyers of the Division work on international, EU and national environmental law, concentrating on waste management, emission control, energy and climate protection, nuclear, aviation and planning law.

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The University of Applied Sciences in Bingen was founded in 1897. It is a practiceorientated academic institution and runs courses in electrical engineering, computer science for engineering, mechanical engineering, business management for engineering, process engineering, biotechnology, agriculture, international agricultural trade and in environmental engineering.

The *Institute for Environmental Studies and Applied Research* (I.E.S.A.R.) was founded in 2003 as an integrated institution of the University of Applied Sciences of Bingen. I.E.S.A.R. carries out applied research projects and advisory services mainly in the areas of environmental law and economy, environmental management and international cooperation for development at the University of Applied Sciences and presents itself as an interdisciplinary institution.

The Institute fulfils its assignments particularly by:

- Undertaking projects in developing countries
- Realization of seminars in the areas of environment and development
- Research for European Institutions
- Advisory service for companies and know-how-transfer

Main areas of research:

- **European environmental policy**
  - Research on implementation of European law
  - Effectiveness of legal and economic instruments
  - European governance
- **Environmental advice in developing countries**
  - Advice for legislation and institution development
  - Know-how-transfer
- **Companies and environment**
  - Environmental management
  - Risk management

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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.

The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.

The sofia team is multidisciplinary: Lawyers and economists are collaborating with engineers as well as social and natural scientists. The theoretical basis is the interdisciplinary behaviour model of *homo oeconomicus institutionalis*, considering the formal (e.g. laws and contracts) and informal (e.g. rules of fairness) institutional context of individual behaviour.

The areas of research cover

- Product policy/REACH
- Land use strategies
- Role of standardization bodies
- Biodiversity and nature conservation
- Water and energy management
- Electronic public participation
- Economic opportunities deriving from environmental legislation
- Self responsibility

sofia is working on behalf of the

- VolkswagenStiftung
- German Federal Ministry of Education and Research
- Hessian Ministry of Economics
- German Institute for Standardization (DIN)
- German Federal Environmental Agency (UBA)
- German Federal Agency for Nature Conservation (BfN)
- Federal Ministry of Consumer Protection, Food and Agriculture

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## elni

*In many countries lawyers are working on aspects of environmental law often with environmental initiatives and organisations or as legislators, but have limited contact with other lawyers abroad, although such contact and communication is vital for the successful and effective implementation of environmental law.*

*In 1990 a group of lawyers from various countries therefore decided to initiate the Environmental Law Network International (elni) to promote international communication and cooperation worldwide. Since then elni has grown to a network of about 350 individuals and organisations from throughout the world.*

*Since 2005 elni is a registered non-profit association under German Law.*

*elni coordinates a number of different activities:*

### **Coordinating Bureau**

The Coordinating Bureau was originally set up at and financed by the Öko-Institut in Darmstadt, Germany, a non-governmental, non-profit making research institute. The Bureau is currently hosted by the University of Applied Sciences in Bingen. The Bureau acts as an information centre where members can obtain information about others working in certain areas thus promoting the development of international projects and cooperation.

### **elni Review**

The elni Coordinating Bureau produces and sends to each member the elni Review twice a year containing members' reports on projects, legal cases and developments in environmental law. elni therefore encourages its members to submit such articles to be published in the Review in order to allow the exchange and sharing of experiences with other members.

### **elni Conferences and Fora**

elni conferences and Fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to bring together scientists, policy makers and young researchers, giving the opportunity to exchange views and information as well as developing new perspectives.

### **Publication Series**

The elni publications series contains 12 volumes on different topics of environmental law.

- Environmental Law and Policy at the Turn to the 21st Century, Liber amicorum, Betty Gebers, Ormond/Führ/Barth (eds.) Lexxion 2006.
- Access to Justice in Environmental Matters and the Role of NGOs, de

Sadeleer/Roller/Dross, Europa Law Publishing 2005.

- Environmental Law Principles in Practice, Sheridan/Lavrysen (eds.), Bruylant 2002.
- Voluntary Agreements - The Role of Environmental Agreements, elni (ed.), Cameron May Ltd., London 1998.
- Environmental Impact Assessment - European and Comparative; Law and Practical Experience, elni (ed.), Cameron May Ltd. London 1997.
- Environmental Rights: Law, Litigation and Access to Justice, Deimann / Dyssli (eds.), Cameron May Ltd. London 1995.
- Environmental Control of Products and Substances: Legal Concepts in Europe and the United States, Gebers/Jendroska (eds.), Peter Lang, 1994.
- Dynamic International Regimes: Institutions of International Environmental Governance, Thomas Gehring; Peter Lang, 1994.
- Environmentally Sound Waste Management? Current Legal Situation and Practical Experience in Europe, Sander/ Küppers (eds.), P. Lang, 1993
- Licensing Procedures for Industrial Plants and the Influence of EC Directives, Gebers/Robensin (eds.), P. Lang, 1993.
- Civil Liability for Waste, v. Wil-mowsky/Roller, P. Lang 1992.
- Participation and Litigation Rights of Environmental Associations in Europe, Führ/ Roller (eds.), P. Lang, 1991.

### **elni Website: elni.org**

The elni website at <http://www.elni.org> contains news about the network and an index of elni articles, gives an overview of elni activities, and informs about elni publications. Internships for young lawyers/law students at the Öko-Instituts environmental law division are also offered on the web.