



New EU Chemicals Policy

KEY ELEMENTS OF THE NEW LEGISLATION

The view of Environmental NGOs

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Introduction

EU chemical legislation has been operational for decades, but it is clear to everyone that it has not delivered adequate protection of human health and the environment. In particular, it has not generated sufficient knowledge and public information about chemicals in use, and it is ineffective in controlling dangerous chemicals.

After pressure from many Governments, the European Commission and many environmental organisations, the EU is entering a major and overdue reform of a flawed system.

Based on the REACH Concept (**R**egistration, **E**valuation and **A**uthorisation of **C**hemicals) in the Commission's White Paper (February 2001), the Council Conclusion (June 2001), the Parliament Resolution (October 2001) and the outcome of the Commission's Working Groups (February 2002), the Commission has announced that it will release draft legislation in autumn 2002 - representing the first step in putting REACH into practice.

Environmental NGOs have been contributing intensively to the discussions of the policy reform in the EU institutions, and have presented some common position papers together with animal protection groups¹.

In addition to this, environmental NGOs also invested considerable resources in contributing to the Commission's technical working groups on the White Paper during winter 2001/2002.

This paper outlines the Commission's proposals, followed by the eight key elements that environmental NGOs consider must be in the new EU legislation in order to ensure a high level of protection for human health and the environment..

Background

The REACH concept presented in the Commission's White Paper of February 2001, seeks to bring about fundamental change in order to:

- shift regulatory pressure from substances being placed on the market for the first time to those substances which have been on the market for decades (95% of the current market)
- shift workload and the burden of proof from Member State authorities to industry;
- make industry responsible for ensuring safety in the design and use of chemicals;
- prevent the production and use of chemicals of very high concern, (unless such uses are authorised); and
- motivate innovation towards safer products and processes.

The Commission's White Paper proposes the following key features:

- All chemical substances > 1 t/a produced or imported must be registered and risk assessed within 10 years, with the producers and the commercial users having the responsibility to provide this information. The burden to collect information and to produce a risk characterisation will be shifted from state authorities to industry. Within industry, producers and users of chemicals at different stages in the supply chain will be made collectively responsible for prevention of risks throughout the whole life cycle.

¹ "Transparency demands for a new EU chemicals policy" in April 2002; "A new EU chemicals policy - some key arguments" in August 2001; and the Copenhagen Charter launched in October 2000 in Copenhagen and signed by more than 100 organisations

- For chemicals of very high concern the burden of proof will be reversed, with the chemical being taken off the market unless the producer/user can prove the need for the product (through a socio-economic analysis) and/or prove negligible risk. This is predicted to affect about 5 to 10% of the industrial chemical substances² on the market.
- Animal testing will be avoided where the information requirement can be met by other means (e.g. sharing existing data, limiting the use to low exposure applications, using in vitro-testing and QSARs).
- Independent evaluation of the registration dossier will be incorporated into the system. For all chemicals > 100 t/a the authorities will carry out the evaluation. Chemicals of < 100 t/a will also be evaluated by the authorities if there is a concern.
- Improved communication up and down the supply chain in order to link hazard information to exposure information.
- More hazard and risk related information should be made publicly available.

Effective implementation of REACH will need both an investment of resources and a change in behaviour:

- A study commissioned by DG Enterprise estimated that the costs of implementing REACH would be between 1 and 7 billion EURO over 10 years. This is much lower than earlier industry estimates of 20-30 billion. 85% of the total costs are due to a lack of information about the properties of chemicals, in spite of the fact that these chemicals have been in use for more than one generation. This demonstrates the need for the industry to deal with its burden of past avoidance of responsibility.
- More intensive communication and co-operation in the supply chain will need changes in the attitudes and management styles of companies.
- Increasing the amount and quality of publicly available information will in turn need clear rules on which information can be claimed confidential and in which way trade and industry should provide justification for such claims. It will also be necessary to create a system to avoid free riders, by providing some form of intellectual property protection.
- Shifting the responsibility to industry will still require an increase in scientific and administrative capacity for regulatory authorities, in order to review and monitor the industry. It is also essential to ensure that the new system is properly enforced and that there are adequate checks on industry performance – without adequate enforcement, industry responsibility will fail.
- Setting up a new regulatory system in Europe should have a positive impact on the global trade of goods containing chemicals, ensuring that chemicals of high concern are no longer used. However, the Commission and Member States will need to promote the new system internationally to ensure that it is properly understood around the world. In addition, effective systems of import controls need to be set up.

² Based on the estimates in the White Paper, about 30.000 substances > 1 t/a may be subject to registration and 1350 of these may be carcinogenic [C], mutagenic [M] or toxic to reproduction [R]. Including other substances of very high concern, e.g. persistent organic pollutants [POPs], persistent, bioaccumulative and toxic substances [PBTs], very persistent and very bioaccumulative substances [vPvB], endocrine disrupters [not already classified as CMR], potent skin sensitisers, respiratory sensitisers and substances with a high chronic toxicity to humans, the number of targeted substances would possibly grow to about 2000. This estimate is based on screening of available databases, carried out by the White Paper Working Groups in winter 2001/2002.

Eight Key Elements for a New Chemicals Legislation

In the Copenhagen Charter³, signed in October 2000, over 100 organisations summarised their expectations on what must be achieved in the review of EU chemicals policy.

The following are eight key elements that environmental NGOs believe must be in the new legislative proposal:

1. BASIC DUTIES OF PRODUCERS, IMPORTERS AND USERS TO BE RE-DEFINED.

In the new legislation, industry obligations should be laid down as a basis for information requirements and as guidance for allocation of liability:

- Producers and importers must keep themselves, their customers and the public informed about the hazards of the substances they produce or import. They should monitor the post-market usage of the chemicals through the whole life cycle and assess the associated risks. They should instruct their customers what type and conditions of use generate no unacceptable risk during the life cycle
- Companies using chemicals must make themselves aware of the intended use of any chemical they handle and the measures needed to prevent, reduce or manage relevant risks. Substances or uses of substances for which there is no appropriate risk assessment must be forbidden
- Companies must make themselves aware whether less hazardous chemicals, safer techniques or processes are available. There should be a general requirement to use the safest available chemicals, techniques or processes⁴, applying the substitution principle.
- Companies selling chemicals to consumers – whether as a component in chemical products or as a component of articles - have the duty to inform consumers about the associated risks during use and disposal and make available relevant data, including but not limited to, data from existing animal tests, human exposure data and health effects data. There should be a duty that such information must follow the flow of the substance through the supply chain.
- In order to avoid animal testing and to reduce financial burdens, producers and users holding information on the inherent properties of chemicals must share this information with other producers or importers of the same substance. Compensation of costs must be ensured and duplication of animal testing must be prohibited.

³ Copenhagen Charter:

1. A full right to know, including what chemicals are present in products.
2. A deadline by which all chemicals on the market must have had their safety independently assessed. All uses of a chemical should be approved and should be demonstrated to be safe beyond reasonable doubt.
3. A phase out of persistent or bioaccumulative chemicals.
4. A requirement to substitute less safe chemicals with safer alternatives.
5. A commitment to stop all releases to the environment of hazardous substances by 2020.

⁴ Taking into account any possible shift from toxic risks to other types of environmental impacts.

2. SANCTION FOR NON-COMPLIANCE – NO DATA NO MARKET

If the producer, importer or user of a substance fails to fulfil his duty within a certain time frame, and no other company provides the obligatory information, the substance and/or certain uses must be regarded as “non existent” and hence production import and/or use should be automatically forbidden. This sanction must be in the new legislation.

3. PUBLIC RIGHT TO KNOW

In addition to the regulatory framework created by the new system, safer chemicals and safer use of chemicals also requires market “drivers”, through the provision of publicly available risk information. In addition, an open and transparent system is essential to assist in the adequate oversight of the system.

Publicly available risk information should include:

- results of hazard assessments with their quality statement (including peer review, good laboratory practice, all test data, relevant human exposure data, and a reference number which will allow access to the full dossier);
- detailed information on intended uses and emission scenarios. Broad use classifications such as industrial, professional and consumer use are not sufficient;
- a list of producers and importers;
- substance volumes on the EU market, subdivided by categories of intended use, including an indication of the production volume not covered by the intended uses listed; and
- the safety data sheet and any risk assessments.
- the results of any risk assessments that downstream users have performed on uses not covered by the producer/importer risk assessment, and including information on the volume used in this application.

Producers and retailers should have the duty to i) label preparations and articles containing dangerous substances and ii) provide further hazard and safety information to consumers, on request. In addition, industry should have a general duty to provide information on request on the presence or absence of hazardous substances in articles or preparations, including substances for which there is a potential hazard based on scientific evidence.

All articles containing substances of very high concern must be labelled with a clear simple warning, which includes a contact address (e.g. a web site) to enable access to further information.

If substances of very high concern are used in any production sites, the company must be obliged to actively publish this information to inform workers, the local community and other interested parties.

The current confidentiality with regard to accumulated market volumes and use patterns must be lifted.

4. BASIC INFORMATION REQUIREMENT TO BE FULFILLED BY INDUSTRY

The new legislation should define a default basic information requirement for all substances. Waiving certain information requirements (and hence cost savings or minimising animal testing) may be possible based on justification by the registrant, however this waiver should only be allowed if the registrant can provide sufficiently robust information

evidence to justify this, in the judgement of the regulatory authorities. A waiver should only be possible down to a minimum information requirement to be defined in the legislation. In the case of waivers based on expected exposure, industry should be required to undertake follow up monitoring to ensure this expected exposure is accurate.

The current EU legislation on new substances⁵ defines a base set of information to be available for all substances (annex VIIa to Directive 67/548) placed on the market. This base set should be maintained and enhanced as the obligatory information requirement applied to all substances currently on the market either as a substance, or in mixtures or articles (including marketed intermediates).

The registration of **non-marketed intermediates** is necessary as on-site exposure of workers and emissions to air and water may occur, in particular in batch production or if there is an accident or malfunction. Waiving information requirements for onsite closed-system intermediates may be acceptable if the registration data set includes robust information on expected and monitored exposure, including i) the amount of emission via waste water and air (based on information to be generated under the IPPC Directive) and ii) the number of workers exposed to the substance and the level of exposure (based on information to be generated under the Chemicals Agent Directive).

5. SIMPLIFIED REGISTRATION FOR CHEMICALS BELOW 1 TONNE

Current EU legislation requires new chemicals to be registered once their import or production occurs at above 10 kg/per manufacturer or producer and year. In a substantial de-regulatory move, the White Paper proposes that registration would only start at 1tpa per producer or importer.

It is important that the new legislation does not weaken the protection of the environment and human health, particularly in the workplace. We consider that the new system should require a simplified registration of all chemicals, except for those produced exclusively for research and development. This simplified registration should include the identity of the substance, the intended use and the volumes. Nevertheless, anyone handling these substances should be obliged to provide the minimum information requirement if the a regulator requests.

6. INDEPENDENT EVALUATION OF PRODUCER RISK ASSESSMENTS

It is vital that producers' and importers' risk assessments are of good quality. This will require:

- Clear guidance to industry as to what data should be included in the risk assessment, including a requirement to seek out and use the 'worst case' toxicity and exposure data.
- An independent peer review (audit) of all risk assessments produced by industry.
- An independent evaluation by regulatory authorities for all substances produced and imported at more than 100 tpa, and for substances of concern that are produced and imported at less than this tonnage. Such evaluation should ensure that the risk assessments undertaken by industry are rigorously checked – and hence will need to be considerably more than just a “plausibility check”, as has been suggested by some parties.

⁵ Placed on the market after 1981

7. AUTHORISATION TO BE REQUIRED BASED ON INTRINSIC PROPERTIES OF SUBSTANCES

Substances of very high concern, which include those that have the inherent property to cause irreversible harm at very low or unpredictable concentration or where the effects may become only visible a long time after use, should only be used in exceptional cases. The use of substances of very high concern should only be authorised if industry proves that there is an overriding societal need and that there is no safer alternative available, and this authorisation should be time limited.

The Annex lists the intrinsic properties that environmental NGOs consider are of very high concern and so subject to authorisation. In particular, environmental NGOs consider that chemicals of very high concern include those that are very persistent and very bioaccumulative, those with endocrine disrupting properties and those that give rise to a similar level of concern.

Many of these substances of very high concern have already been identified, particularly in the case of CMRs and some PBTs and vPvBs. The authorisation mechanism as proposed in REACH should be applied in parallel to registration, from the time when the new legislation enters into force, thus enabling rapid controls on chemicals of very high concern which have already been identified.

The criteria by which a substance should be identified to be of very high concern are listed in the annex. In particular, environmental NGOs consider that chemicals of very high concern include those that are very persistent and very bioaccumulative, those with endocrine disrupting properties and those that give rise to a similar level of concern.

8. SUBSTANCES IN IMPORTED ARTICLES MUST BE INCLUDED IN THE SYSTEM

Finished products, (e.g. textiles, cars, electronic articles, furniture, toys and building material) are a significant source of exposure to chemical substances. Losses of dangerous components into the natural environment and into the consumer's environment may be as high as 20% to 30% during the service life of the product. The REACH system must apply to chemicals in articles both made within Europe, and imported into Europe.

Environmental NGOs understand the need for prioritisation of this system, and propose that the Commission's legislative proposal should initially prioritise the chemical components of articles imported in very large quantities, e.g. textiles, cars, electronic articles, furniture, toys and building material. However, the Commission, Parliament and Member States should work out a strategy for future inclusion in the system of substances in all imported articles. This strategy should be developed in parallel with the legislative process.

Innovation triggered by REACH

Environmental NGOs consider that the new system will provide a boost to innovation in the EU chemical industry and within downstream users:

- REACH will trigger more intensive communication up and down the supply chain. Producers of chemicals will learn more about their customers and their needs. This is part of the basis for innovation in customer-driven markets.
- REACH will provide a common system of rules for all chemical substances, regardless of when they have been placed or will be placed on the market for the first time. The competitive advantage of old chemicals (chemicals on the market before 1981) will be eliminated, thus encouraging the innovative development of new substances.
- Innovative and pro-active companies often face the problem that potential customers are not sufficiently motivated to buy the “better” product. The authorisation regime for substances of very high concern will give a clear and convincing signal to the market to look for better alternatives. This is an incentive for innovation, giving the first to react a competitive advantage.
- The information generated in the REACH System will contribute to the development of safer products and processes with regard to both health and environment. This will make companies less vulnerable to loss of reputation, whether in financial markets, or public opinion. The same applies to the vulnerability to liability claims, in particular in the US market.
- REACH should create a market for good quality, risk-related information. This market on its own may create new business.
- REACH will reduce the testing costs for new substances < 1 t/a. This means that around 50% of all new substances (on the basis of current figures) would have testing costs substantially reduced, thus lowering the costs of placing a new chemical onto the market.
- The public has lost confidence in chemicals and the chemical industry. This loss of confidence also applies to many of the professional users of chemicals. REACH should increase the public availability of good quality risk information and ensure that chemicals of very high concern are removed from the market. A strong regulatory system will be the basis for regaining trust in chemicals.

The implementation costs of REACH are an investment in a future market!

Annex – Substances of very high concern (SVHC)

CMRs In class 1+2	Substances fulfilling the criteria Directive 67/548 to be classified as carcinogenic, mutagenic or toxic to reproduction. Sufficient evidence for causal relationship or strong presumption that human exposure results (may result) in adverse effects.
CM and R In class 3	Substances fulfilling the criteria under Directive 67/548 to be classified as carcinogenic, mutagenic or toxic to reproduction. Concern, but not sufficient evidence that human exposure may result in adverse effects. C 3 after case by case assessment.
Endocrine Disrupters	Substances with endocrine disrupting properties, including those which effect non-mammals.
Respiratory Sensitisers	Substances that may cause sensitisation by inhalation according to the criteria under 67/548; evidence usually based on human experience;
Potent skin sensitisers	Substances that may cause sensitisation by skin contact according to the criteria under 67/548 and which have a high potency (indicated e.g. by low classification limit in the preparations directive)
Toxic at prolonged exposure	Substances likely to cause serious (functional or morphological) damage after repeated or prolonged exposure according to criteria under 67/548;
POPs	Persistent organic pollutants according to criteria in the Stockholm Convention
PBT	Substances that are persistent and bioaccumulative and toxic, according to the criteria laid down in Draft EU Technical Guidance Document on Risk Assessment 2002 (for the marine compartment)
VPvB	Substances that are very persistent and very bioaccumulative according to the TGD criteria
Other Substances	Substances causing an equal level of concern with regard to long term effects and/or effects for which no safe dose can be established.