EU chemicals legislation under scrutiny

On 18 November 1998, the Commission adopted a Report on the operation of the four key EU laws on the classification, packaging and labelling of dangerous substances and preparations, the evaluation and control of the risks of existing substances and restrictions on the marketing and use of certain dangerous substances and preparations[1].

The four legal instruments were assessed on how they were achieving their objectives of protecting human health and the environment in the context of the Internal Market.

The Commission's Report was in response to public concern about chemicals in use in the Internal Market and the discussions of the April 1998 Informal Environment Ministers Council in Chester.

The report identifies a series of issues that need to be addressed to improve their operation. Generally, the findings stress the need to use the instruments more efficiently and to implement as well as enforce them more rigorously and consistently. They need to be streamlined and updated to take account of new emerging problems, such as endocrine disruptors.

The findings recognise the important role of sound science, but highlight the need to meet more fully the concerns of the outside world by giving full consideration to the *precautionary principle*.

At Chester, the Commission proposed that the stock-taking exercise should include a public brain-storming with all stakeholders - Member States, industry, consumers, NGOs, scientists, the European institutions - to focus on remedies for the future in the light of the review's findings.

This brainstorming exercise under the auspices of the heads of DG III and DG XI (Commissioners Bangemann and Bjerregaard) was held on 24 and 25 February 1999.
It was structured into three parallel sessions, entitled "Burden of the past", "Hazard vs. Risk" and "Challenge for the Future". The main speakers in each session (alternating between industry, the competent authorities and an NGO) put their cases around the following key questions:

Burden of the past
- What has been achieved so far and what remains to be done?
- How good is our current understanding of the issue?
- Why is a review needed?

Hazard vs. Risk
- What are the pros and cons of hazard and risk assessment?
- How can hazard assessment, risk assessment and other approaches be used for risk management?
- How should cost-benefit assessments be included in the process?

Challenge for the Future
- What should be the responsibilities of the different stakeholders?
- Where should the emphasis lie?
- What mechanisms can be used to accelerate the process?
- How can the efficacy of risk management be improved?

There was a measure of agreement between participants that the EU had some useful instruments, but opinions differed widely as to whether they are used efficiently, how they can be improved, what other kinds of instruments should be developed, and who should foot most of the bill for risk assessments, for example.

The main points discussed were:
- Existing provision for hazard identification, risk assessment and risk management is quite complicated and not especially useful for dealing with existing substances let alone new problems like endocrine disruption or phthalate migration in soft PVC toys.
- The existing legal instruments focus more on cure than prevention, when the opposite is required.
- One major concern is the number of chemicals which constitute the "burden of the past", and for which little data is

[1] Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances, Directive 88/379/EEC on the classification, packaging and labelling of dangerous preparations, Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances, Directive 76/769/EEC on the restrictions on the marketing and use of certain dangerous substances and preparations.

available, especially on eco-toxicity and bio-accumulation.

- There is no consensus about the scale of the problem - how big is the burden? Is it the 100,000-plus chemicals suggested by some, or EU industry's lower estimate of 1200?
- For how many of these chemicals have the hazardous properties been identified? According to the US Environmental Defense Fund, the "minimal" toxicity data required by the OECD is not publicly available for about 75% of the 3,000 chemicals in large-scale use.
- Of the 110 priority chemicals selected for risk assessment since 1993, the technical work has only been completed on 19 to date.
- The time from selecting a priority chemical to an agreed risk assessment report can be as long as four years. How can the process be speeded up?
- Are the risk assessment requirements an obstacle to the process?
- Should substances be grouped by chemical properties and / or use?
- Should "targeted" rather than "complete" risk assessments be used more often?
- What about chemicals which are known to cause cancer, or which are mutagenic, or toxic to reproduction? Does their risk assessment need to be supplemented by a cost-benefit analysis prior to managing the risk?
- Should a lack of sound scientific evidence stand in the way of action when faced with problems like carcinogenicity etc.?
- How can the commitment of Member States, the Commission and industry be secured (implementation and compliance are handled differently in the different Member States)? How can the necessary financial and human resources be made available? How can the efficiency and effectiveness of the legal instruments be improved?
- An integrated and coherent approach to the EU's future chemicals policy must be developed which adequately reflects both the precautionary and sustainability principles.
- What are and should be the responsibilities of the different stakeholders and on whom should the onus of proof lie?

Based on the conclusions of the review of the four major legal instruments, and taking the discussion and different viewpoints of this brainstorming exercise into account, the Commission will prepare a Communication to the Council and the European Parliament on the way forward for chemicals legislation in the EU. The Communication should set out the strategy for the future, including any legislative options.

How the Commission will reconcile the differing interests of the various DGs involved in chemical policy-making remains to be seen. Even more important is how the different interest groups like consumers, environmental groups and trade unions will overcome their overt or concealed rivalries. Nobody will seriously claim that we can or are willing to live without chemicals, so a balance needs to be struck between real or imagined diverging interests, and not just in Europe. ■

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SLIMming down Directive 67/548/EEC

One of the cornerstones of EU chemicals legislation, Council Directive 67/548/EEC on classification, packaging and labelling of dangerous substances[1], is currently under review. Since January 1999, it has been a target of the so-called SLIM exercise (Simpler Legislation for the Internal Market), launched by the Commission in May 1996 to identify ways of simplifying Single Market legislation[2].

"Simplification" in this context means that internal market legislation must "be made more accessible and easier to understand, in particular by improving the quality of that legislation through consolidation and by more consistent and comprehensible texts"[3].

But: "the objective of simplification must preserve the acquis communautaire and the pursuit of Community harmonisation in the sectors concerned where necessary and in particular the requirements of health protection, safety, fair trading, environmental protection, worker protection and consumer protection contained in those rules"[4].

The first phase of SLIM covered Intrastat (the system for collecting intra-Community trade statistics), construction products, the recognition of diplomas, and ornamental plants. This was followed by VAT obligations, the Combined Nomenclature for External Trade, fertilisers, and banking legislation.

The current fourth phase of SLIM covers company law, pre-packaging and dangerous substances, as announced at the Internal Market Council of May 1998 and proposed by ECOSOC and the European Parliament in their reports on the previous phases of the Commission initiative.

The SLIM team

Under the SLIM procedure, small groups of experts - four or five representatives each of national governments and users - are called together for each topic. They are chaired by a nominee of the Commissioner responsible for the legislation concerned. Other Directorate Generals directly or indirectly concerned by the topic can send observers.

The teams are set a fairly short deadline (6 months or less) in which to come up with recommendations to simplify the legislation.

The group dealing with Dangerous Substances Directive 67/458/EEC started work on 22 January 1999 and completed its task at the end of May. The Member States represented are Denmark, France, Portugal, The Netherlands and the United Kingdom. The user side comprised representatives of industry and trade union associations as well as environmental and consumer groups.

What is Directive 67/548/EEC about?

The Directive was adopted in 1967 and has been amended 8 times and adapted to technical progress 25 times since then. It lays down common provisions on classification and labelling and basic requirements for the packaging of dangerous substances.

Substances are considered dangerous if they meet one or more of the fifteen criteria[5] established so far, describing the type and severity of adverse effects the substance may cause ("intrinsic hazardous properties").

"Existing" substances[6] must be classified and labelled in line with these criteria by the competent authorities[7], whereas "new" substances have to undergo a notification

procedure and risk assessment before they can be placed on the market.

The Directive also sets specific requirements for specific groups of substances[8] and a streamlined notification procedure for substances placed on the market in small quantities[9].

Nine annexes set out:
- the substances classified as dangerous (Annex I);
- the testing methods to determine the dangerous properties of substances (Annex V);
- the danger symbols or the wording of standard phrases on the nature of special risks (R-phrases) or safety precaution phrases (S-phrases) relating to the handling and use of dangerous substances used for the labels (Annex II to IV); or
- detailed criteria for the proper choice of the class of danger and how to assign the danger symbols, R- and S-phrases to a tested substance (Annex VI);
- Annexes VII and VIII relate not to the classification or labelling of substances, but to the notification of "new" substances; and
- Annex IX includes provisions on childproof fastenings and tactile warning devices as special packaging and labelling elements.

Impacts on other fields of legislation

There are links between this Directive and other areas of European legislation like:
- the export and import of certain dangerous chemicals;
- worker protection (e.g. lead, asbestos, carcinogens, or chemical agents as such);
- biocidal products;
- pesticides;
- pharmaceutical products;
- cosmetic products;
- the restriction of marketing and use of certain dangerous substances and preparations;
- animal testing; or
- the risk assessment of existing substances.

In a broader setting, the Directive's provisions are discussed in international fora which deal world wide with the harmonisation of existing national systems for the classification and labelling of dangerous substances.

Why review Directive 67/548/EEC?

Council Directive 67/548/EEC is not the only piece of legislation currently under review. On 18 November 1998, the Commission adopted a report of findings on the operation of the four key EU laws on the classification, packaging and labelling of dangerous substances and preparations, the evaluation and control of the risks of existing substances and the restrictions on the marketing and use of certain dangerous substances and preparations (see previous article).

The report identified for each legal instrument a number of issues that need to be addressed with a view to improving its operation. Failings criticised in Directive 67/548/EEC include:
- the time-consuming procedure for reaching harmonised agreement on the classification and labelling of dangerous substances and publishing them in Annex I to the Directive;
- the complex system of R(isk)- and S(afety)-phrases;
- under-enforcement of the classification and labelling provisions;
- the difficulty of tracing chemicals not classified as dangerous under the Directive;
- holding back innovation and competitiveness in the chemical industry, especially in the fields of polymers and intermediates, and difficulties gaining exemptions for research and development;
- the time taken to circulate notification dossiers and other information among the national Competent Authorities;
- the massive cost in staff and time needed to carry out a proper risk assessment;
- the complicated structure of the Directive as it has evolved over more than thirty years;
- the failure to produce an official consolidated version.

The group's recommendations will be presented to the Internal Market Council in June 1999. ■

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[1] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[2] On the simplification process see also Molitor Group: deregulation assault on health and safety, TUTB *Newsletter*, N° 1, October 1995, pp. 2-3. For French translation: "Le groupe Molitor: la santé et la sécurité au centre d'une tentative de dérégulation".

[3] Council Resolution of 8 July 1996 on legislative and administrative simplification in the field of the internal market (96/C 224/03).

[4] *Ibid.*

[5] such as "explosive", "very toxic", "carcinogenic" or "dangerous for the environment".

[6] Existing chemicals are those which were placed on the Community market before 18 September 1981 and are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). "New" chemical substances are those which are not in EINECS.

[7] And provisionally by the manufacturers, distributors and importers.

[8] e.g. polymers or substances used for research and development.

[9] Less than one tonne per annum per manufacturer.