REACH

Approach of the European Chemical Industry to an Effective New Chemicals Policy for Europe

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Suggestions of the European chemical industry to improve REACH

The chemical industry supports the political objectives of the White Paper. However, implementation of REACH in its current form will create a bureaucratic, costly and inefficient system. Successful implementation of REACH depends upon resolving crucial workability issues.

A REACH process is needed in which every step is efficient and value-adding.

Decisions under REACH must be based on risk. Neither volume, nor hazard as such determines whether a substance poses a risk. Risk can exist only if there is both hazard and exposure combined, i.e. depending both on the intrinsic properties of a substance and on the way it is used. Therefore, decisions made under REACH must be based on risk, in line with sound scientific principles and taking into account the actual use and exposure of substances, instead of being based on volume and hazard.

The REACH process must be based on risk, i.e. taking into account the actual use and exposure of substances, not only on volume and hazard.

A workable REACH system must include prioritisation based on risk. The efficient way to manage the testing and registering of more than 30,000 existing substances is to prioritise these substances by first identifying the substances of real concern, i.e. substances for which risks for human health and the environment might reasonably be expected. Annual volume alone is not a suitable criterion. Resources have to be allocated properly to address those concerns. Imposing a bureaucratic regime on more than 30,000 chemicals without risk-based prioritisation would actually dilute efforts to control the chemicals of concern by diverting resources.

Substances of highest concern need to be assessed first. Risk, not the annual volume, is the suitable parameter for identifying substances of high concern.

Additional substances should not be added to the list of substances of very high concern unless sound scientific criteria exist as a basis for inclusion. The proposed Regulation makes it possible to subject substances to authorisation without sound scientific criteria. A simple suspicion that substances and groups of substances generate effects similar to those of CMR, PBT or vPvB substances should not be sufficient to include such substances in the authorisation procedure.

Sound scientific criteria must exist before additional substances can be included in the authorisation.

A link is needed between the provisions for authorisation and restrictions. Insufficient co-ordination may otherwise result in inconsistent decisions and duplication of work. For reasons of workability and proportionality, generally applicable restrictions must be the preferred option for risk management, including for substances subject to authorisation.

Restrictions, not authorisation, must be the preferred option for risk management to ensure workability of the system.

The European Chemicals Agency must have full responsibility for all aspects of prioritisation, decision-making, setting up of processes and management of the system. Central management is the key success factor for a speedy and efficient REACH process; it will ensure uniform implementation and interpretation of legislation throughout the EU, and the homogeneity and compatibility of data.

The Commission's proposal only centralises the registration process with the Agency, but evaluation – and thereby the main responsibility for compliance with the data requirements – is left with the Member States. In addition to causing non-harmonised implementation of legislation, this would also create unjustified bureaucracy and means documentation being shuffled back and forth between different authorities.

The European Chemicals Agency must be given the power to ensure harmonised implementation. A non-centralised system would create distortions of the internal market and competition.

Find out more at
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Existing European chemicals legislation is complex and unclear. This has been recognised for a long time by both politicians and industry. On the one hand, concerns exist about a perceived lack of information; on the other hand, research and innovation are clearly constrained by existing laws. Consequently, the Environment Council decided in 1998 that the set of existing legislation should be reviewed.

Following this request, the European Commission adopted its White Paper "Strategy for a future Chemicals Policy" in February 2001. The main objectives of the new strategy are to:

- ensure a high level of protection for human health and the environment;
- ensure the efficient functioning of the internal market;
- stimulate innovation as well as competitiveness of the chemical industry.

In May 2003, the European Commission presented the first draft of a new comprehensive chemicals Regulation with the goal of streamlining and updating the current regulatory framework. After a public internet consultation, the Commission modified its proposal and adopted it on 29 October 2003. This proposal has now been passed on to the European Parliament and the Council.

The European chemical industry fully supports the goals of the White Paper and wants to contribute to the process of designing an effective regulation.

WHAT IS AT STAKE

The European chemical industry is a major EU asset and one of the driving forces of the European economy, employing around 1.7 million people directly. It is one of the top three industries in most of the EU Member States.

The European chemical industry operates on a global scale. Its success must not be taken for granted, though. Its position as the biggest producer in the world has been slowly eroding. The EU 15's share of global output has declined from 32% a decade ago to 28% today.

In order to maintain or improve its position in the face of fierce global competition, our industry needs a framework within which it can flourish and strive for leadership in innovation, business excellence and sustainable development.

The purpose of this brochure is to clarify the background and the basics of REACH, and to explain the key suggestions of the European chemical industry to make the new system workable and cost-efficient.

As the chemical industry supplies most other industry sectors, any negative impact it suffers will cascade down the supply chains and affect the entire European economy. There are serious risks of unintended consequences if the details of REACH are not properly thought through.

Existing high standards in the European chemical industry ensure the protection of human health and the environment. Only a workable chemicals management system can maintain or even enhance this situation. Costly and bureaucratic measures divert limited resources from where they are needed. Such measures may also result in increased levels of imports of finished goods, which may contain unwanted and untested chemical substances.

Only a workable and efficient European chemicals management system can ensure a high level of protection of human health and the environment without compromising the competitiveness of the European Industry.

WHAT IS REACH?

REACH is the acronym for **R**egistration, **E**valuation and **A**uthorisation of **CH**emicals. The REACH proposal requires industry to register all existing and future new substances with a new European Chemicals Agency.

Existing substances (about 30,000) have to be registered within the first 11 years, the so-called phase-in period. The Commission's proposal basically prioritises these substances based on produced or imported annual volume.

All substances will have to go through one or more stages of the REACH process as described below.

Registration
For all substances produced or imported in quantities of 1 ton or more per year, manufacturers and importers must prepare a registration dossier to be submitted to the European Chemicals Agency. It is industry's task to gather and assess the required information (requirements mainly based on volume, comprises data on physicochemical, toxicological and eco-toxicological properties). In addition to these data on the substance, individual identified uses of downstream users throughout the supply chain as well as assessments of the associated risks and safety measures derived from these must be specified. If further testing needs to be undertaken a test plan is required as well.

For substances with annual volumes of more than 10 tons, the assessment of the safe handling (Chemical Safety Assessment) must be documented in a Chemical Safety Report.

Evaluation
Dossier evaluation: The Member States authorities can check the compliance of any registration dossier with the requirements of REACH, and examine and endorse the testing proposals provided by the industry.

Substance evaluation: The Member State authorities are allowed to examine registration dossiers in order to evaluate whether a substance presents a risk to human health or the environment, and to determine the need for possible authorisation or restriction of marketing and use.

Authorisation
Authorisation will be required for each use of a substance belonging to specific groups, i.e. substances of very high concern - CMRs category 1 and 2 (carcinogenic, mutagenic or toxic to reproduction), PBTs (persistent, bio-accumulative and toxic), vPvBs (very persistent and very bio-accumulative) and other substances identified as causing serious and irreversible effects on humans and the environment.

Authorisation will be granted for these uses if the manufacturer or importer is able to demonstrate that risks can be adequately controlled. If such evidence cannot be provided, authorisation can only be granted if an analysis shows that the socio-economic advantages of the specific use are predominant.

Restriction
If a risk is identified as not being adequately controlled, a proposal to restrict marketing and use of a substance can be made by the Commission or a Member State. The decisions on restriction are taken by the Commission in consultation with the Member States.

The new European Chemicals Agency will be established to facilitate the registration tasks (including establishing and maintaining the necessary databases). The Member States still have the responsibility for evaluation and authorisation phases. The final decision on authorisation will be taken by the Commission, in consultation with the Member States.

BETTER REGULATION

In line with the principle of better regulation as outlined in the Interinstitutional Agreement on better law-making (Council document 12175/03), the cost-efficiency and workability of REACH must be properly assessed. This should be done by means of an extended business impact assessment and pilot trials.

a) Need for an extended business impact assessment

The Commission estimates that the overall costs of testing and administration of REACH will be up to EUR 2-3 billion, which according to the industry is largely underestimated. Moreover, the bulk of the costs will be borne by the fine and specialty chemical sector that consists mainly of SMEs.

Cefic and UNICE have agreed on a Memorandum of Understanding with the Commission regarding a multi-stakeholder project to undertake further work on impact assessment, the impact of REACH on business throughout the supply chain, innovation, and accession countries.

In line with the principle of better Regulation and with the Lisbon process of "making the EU the most competitive and dynamic knowledge-based economy in the world" by 2010, it is fundamentally important to understand the impact of REACH on the entire value chain.

b) Pilot trial to test the workability of REACH

REACH can only achieve the goals of the White Paper if it is implemented properly. Only a workable regulation can be successful.

SPORT is a comprehensive European-wide pilot trial with the Commission, Member States and industry as equal partners to:

- test workability of REACH including alternative approaches leading to the same regulatory outcome;
- identify needs for methodologies, tools and guidance;
- gather information about effort and subsequent business decisions (e.g. de-selection, substitution).

The pilot trial should examine real life examples and cover a number of diverse supply chains. It builds on the multi-partite pilot study completed in the German state of North Rhine-Westphalia in early 2004.

Better regulation is the key

This sector accounts for just 20% of the total chemical industry manufacturing output but will have to bear over 80% of the costs. Due to its low production volumes, this sector will not be able to carry the extra burden. In addition to the direct costs, indirect and induced costs several times higher will occur which have not been properly assessed yet at the European level.

The Commission's Interim Strategy for the practical preparation for working under REACH includes so-called 'strategic partnerships' with stakeholders. Cefic has proposed a Strategic Partnership on REACH Testing (SPORT).

The Interim Period provides an opportunity to identify workability problems and to develop cost-efficient solutions.

CONCLUSION

The aim of the White Paper is to create a strategy for a more workable and efficient chemicals management. Replacing the existing unworkable system with another inefficient and unworkable system would not benefit anyone. We need a workable chemicals management system based on the principle of sustainable development.

The chemical industry reiterates its willingness to make all its expertise and resources available, and to co-operate constructively with the stakeholders to ensure an effective, workable and cost-efficient system.

A sustainable chemicals management system is the only viable solution. Environmental, social and economic goals must be balanced for the benefit of everyone.

Cefic - The European Chemical Industry Council

Chemistry making a world of difference

Cefic is the Brussels-based organisation representing national chemical federations and chemical companies in Europe. Cefic represents, directly or indirectly, around 29,000 large, medium and small companies in Europe, which employ about 2 million people and account for more than one third of world chemicals production.

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