Strategy for a future Chemicals Policy

Expectations of the European Chemical Industry:

Workability and Competitiveness

cefic

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Background

The European chemical industry supports the political objectives of the White Paper on Future Chemicals Policy. The existing legislation needs to be simplified and updated to ensure both a high level of protection for human health and the environment and the promoting of a consistent and transparent framework for business. The industry maintains that the objectives set out in the White Paper, including protection of human health and the environment, ensuring the competitiveness of the European chemical industry, and prevention of fragmentation of the Internal Market, should be equally met.

The industry has been working actively to help clarify and refine the concepts of the White Paper, so that a workable, consistent and balanced chemical regulatory framework can be created and implemented successfully, making the best use of available resources.

To this end, the industry initiated a pilot trial of its “Thought Starter”, which sets out a practical way of implementing REACH (Registration, Evaluation and Authorisation of Chemicals) procedure. REACH is a central component of the White Paper, which proposes a mechanism for registration, evaluation and controlling the use of chemicals.

The aim of the trial - which involves real chemicals and real supply chains - was to identify and resolve any practical problems in applying the Thought Starter’s approach. The report on the trial project produced by the independent consultant RPA confirmed that Cefic’s tiered, risk-based, and substance-tailored information provision regime appears to provide a good basis for implementing REACH in a cost-efficient manner.

Executive summary

The European chemical industry supports the political objectives of the White Paper, aimed at ensuring the protection of human health and environment, as well as the competitiveness of the industry.

There are two key messages of the industry regarding the on-going review of the policy.

The first key message stresses the need to create a workable system:
We must focus on science-based risk assessment, which is in line with the conclusions of the World Summit on Sustainable Development in Johannesburg, in order to establish a workable system. Sound scientific risk assessment of chemicals, a fundamental principle that has long governed chemicals regulation, must be maintained and targeted to deliver real results on areas of most concern in the shortest possible time.

The second key message focuses on competitiveness:
As the European chemical industry is a genuine success story which contributes significantly to the economy, technological innovation and welfare of society, it needs a legislative framework that still enables it to remain competitive on the global stage.

1- Workability:

"To deliver safe use of chemicals as fast as possible, we must focus on science-based risk assessment, and establish a workable system"

Sound scientific risk assessment of chemicals, a fundamental principle that has long governed chemicals regulation, must be maintained and targeted to deliver real results on areas of most concern in the shortest possible time. The pursuit of information in an intelligent way is key in avoiding an unwieldy and overburdened system. Industry is seeking a practicable framework that helps enhance customer and consumer confidence through the safe and environmentally responsible use of chemicals.

Testing, registration and evaluation

It is essential to keep the REACH procedure workable and manageable. Consequently, its scope should be limited to non-polymeric substances that are placed on the EU market in quantities greater than 1 tonne per year. Polymers generally have non-hazardous properties. Intermediates, which are only used within the chemicals industry, should be exempted from registration and related requirements. Humans and the environment are not generally exposed to intermediates, because they are fully consumed in chemical processes under controlled conditions. Potential exposure of workers is controlled by other legislation.

Polymers and intermediates are therefore of low risk to humans and the environment and should be of low regulatory priority. The number of intermediates and polymers exceeds by far the number of other substances. Treating intermediates and polymers with the same priority as other substances does not lead to the best use of resources, but would result in an unmanageable system, without enhancing human and environmental protection.

We promote a risk-based and tiered approach to the generation and provision of hazard data. Only those tests should be carried out which are necessary to ensure that a substance can be used without posing unacceptable risks. The move from one tier of testing requirements to the next should be based on the risk criteria and risk management in place. This approach should also be tailored, which means that the testing requirements for a substance should be based on the actual exposure from use and applications of that substance.

We welcome the initiative by the European Commission to encourage the formation of consortia for joint registration, which could be implemented by having a pre-registration step (PREACH). This would give the manufacturers, importers, formulators, and downstream users a possibility to co-operate, if they so wish.

The deadlines to complete registration and further testing must be based on a realistic assessment of the information required and resources available. The tight deadlines in the White Paper are not achievable.

Risk assessment

We support a transparent, flexible and practical approach to risk assessment and management. The cornerstone of this approach is that, depending on the degree of hazard and exposure, different information requirements are needed to demonstrate safe and responsible production and use. The risk of a given chemical depends on how and where it is used and not just on its intrinsic properties.

Risk management and authorisation

We believe that the Authorisation process in the REACH system is unnecessary as most, if not all, of the substances to be included are controlled by existing legislation. If Authorisation is introduced, it should be confined to the uses of substances of very high concern, namely category 1 and 2 carcinogens, mutagens, reproductive toxicants (CMRs), and persistent organic pollutants (POPs).

A clear distinction should be made between the authorisation procedure and the accelerated risk management/ restriction procedure. Only substances with a pre-established hazard profile should be subject to authorisation. Accelerated risk management is triggered by the identification of a risk related to a specific use of a substance, and not only from intrinsic properties of a substance. The accelerated risk management/restriction procedure shall provide for adequate risk management, including, if necessary, restriction or prohibition measures.

Classification and labelling

We support the implementation of the Globally Harmonised System for classification and labelling of chemicals (GHS). This should lead to convergence of the existing global systems, and the EU and other competent authorities should not seek to perpetuate divergence of systems. We agree with the White Paper that the "substance inventory" (Industry List), which will contain comprehensive information about the classification and labelling of all dangerous substances, should be limited to substances that are placed on the market.

Information through the supply chain

We support the concept that information on the hazardous characteristics and exposure related to intended uses of substances should be widely accessible. Safety Data Sheets should be the main tool of communication for down-stream users (industrial and professional), while labels should inform the consumer. Mechanisms must be set up to safeguard the legitimate interests of suppliers in intellectual property rights, and commercially sensitive information.

A central substance database should be created, managed by a central agency in charge of the administration of the REACH system. Such a central database could facilitate the circulation of health, safety and environmental information through the supply chain, help to improve the quality of the information, and thus ensure consistency and transparency. It would also provide access to non-protected data on substances for downstream users and the public. It is therefore important that accessible information reflects the latest status. There must not be a delay between updating information on the central database and accessibility of that information.

Substances of "very high concern"

Exposure to substances posing a very high concern should be investigated with priority. Prioritisation should be based on both exposure potential and hazard level. The evaluation of the degree of exposure in "exposure categories" can be based on the use pattern to protect human health, and the release pattern and physico-chemical properties to protect the environment. The hazard level can be characterised by the existing information contained e.g. in the Globally Harmonised System for classification and labelling of chemicals (GHS), which is the preferred option to identify hazard linked to category 1 and 2 CMRs.

Endocrine disrupting chemicals as a separate category should not be subjected to authorisation, since the CSTEE and other international bodies have stated that 'endocrine disruption' is not an adverse effect per se but rather a mechanism potentially leading to adverse effects. Any risk assessment and management should be carried out within the framework of the normal risk assessment, focusing on the induced specific adverse effects. The chemical industry devotes very substantial resources to develop screening methodologies under the auspices of the OECD.

Chemicals with sensitising potential do not generally give rise to major concern. Regarding occupational safety, respiratory and skin sensitisers are adequately controlled by existing regulations.

Substances in Articles

REACH should apply only to those substances which are marketed as substances or as constituents of preparations. Articles should be exempted from the REACH requirements. However, when substances may be released in significant amounts from articles during normal handling, use, and disposal and consequently cause exposure to humans and the environment, these released substances should be covered by REACH.

2- Competitiveness:
"Help a successful European industry remain competitive on the global stage"

Our industry is a genuine European success story contributing significantly to the economy, technological innovation and welfare of society. European legislative reform should help support our efforts to grow in a competitive and sustainable way in Europe as well as globally. The reforms must deliver a cost-effective, new system that is consistent with the EU's international commitments. An unintentional development of "fortress Europe" must be avoided.

The White Paper puts the European production base at risk

The EU chemicals legislation is already the most stringent in the world. The White Paper will increase regulatory compliance costs and bureaucracy. Its effects will not be limited to the chemical industry, but will extend to the entire production chain, from raw materials to finished products. Increased production costs will lead to loss of market share in the EU and in the global markets. In particular, the downstream users are unlikely to be able to pass on the higher production costs to their customers, as the existing WTO rules allow the import of cheaper products and articles manufactured outside the EU with chemical substances that have not been subjected to a REACH-type system.

The increased costs will significantly reduce the competitiveness of the EU companies, probably forcing them to relocate certain production lines outside the EU. Such a development would have a very negative impact on employment.

The cost

The estimated cost of the proposed REACH system to industry varies from 2.2 to 7 billion Euros, depending on the scope and scenario chosen for testing. This cost does not include the administrative and compliance costs, which may run into several more billions of Euros.

SMEs will be hardest hit. Many of the smaller speciality SMEs have indicated that the likely cost burden will cause them to withdraw from the market, due to their inability to remain innovative and thus compete effectively. Also the large chemical companies will be forced to deselect from their product portfolios those substances that do not warrant the increased costs, even if they do not raise health and environmental concerns, thus depriving the market of the benefits of those products.

Trade and investment

Increases in cost faced by manufacturers and importers will lead to higher product prices. Consequently, EU chemical trade with third countries as well as the trade surplus will decrease. Furthermore, many aspects of the ongoing policy review have generated a climate of legal uncertainty, which is holding investors back from making long-term investments in the EU, and causing them to redirect those investments to the US and Asia instead.

Innovation

Innovation is of key importance for a high technology sector like the chemical industry. The White Paper assumes that innovation will be driven by the search for safe substitutes for hazardous substances. Whilst this may happen to some degree, another result will be that many chemicals will not be defended, because companies will not be prepared to pay the testing costs for their product range. Instead, they will withdraw products from the market, thus narrowing the base for the development of new products. In addition, reduced profits will restrict the finances available for reinvestment in innovation and scientific expertise, already a scarce resource in Europe. These funds will be directed instead towards management of the regulatory process.

Already today, bringing a new chemical to the EU market takes 3 times longer and costs ten times as much as in the US. Substance innovation with new chemicals is therefore mainly taking place outside the EU. The situation is clearly inconsistent with the commitment made by the March 2000 Lisbon European Council, towards the goal of making the EU the most competitive and dynamic knowledge-driven economy in the world by 2010.

About Cefic

Cefic, the European Chemical Industry Council, is the forum and the voice of the European chemical industry. Cefic represents about 40,000 large, medium and small chemical companies which employ about two million people and account for more than 30% of world chemical production. Cefic is made up of the national chemical industry federations of 25 countries in Europe along with large international "corporate members" and a vast number of "business members". As an umbrella organisation, Cefic has also recognised about 100 sector groups and affiliated associations. Cefic's objective is twofold: to provide a mechanism for the structured discussion of issues affecting chemical companies operating in Europe; and to represent the industry's position on these issues in order to contribute to the legislative decision-taking process.

Cefic - The European Chemical Industry Council

Chemistry making a world of difference

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