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AN EU INDUSTRY RECOMMENDATION TO IMPROVE THE EFFICIENCY AND WORKABILITY OF REACH

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1. EXECUTIVE SUMMARY AND OBJECTIVES OF THIS NOTE

Industry continues to support the political objectives of the proposed EU chemicals legislation, namely the protection of human health and the environment whilst ensuring the competitiveness of European industry.

While industry acknowledges that a number of improvements on the internet consultation document were made in the Commission's proposal of 29 October 2003 we remain strongly concerned about key elements of the draft proposal.

The proposed system is still unnecessarily complex and burdensome, with significant legal uncertainty.

HENCE, THE CENTRAL MESSAGE OF THIS DOCUMENT IS THAT:

- If the legislation is to meet its information-sharing, health, social and environmental objectives, while preserving and enhancing the global competitiveness of the European industry as a whole, some elements of the proposal have to be changed fundamentally to achieve a more proportionate and better balanced system;

- REACH should be focused on its core principles of risk assessment and evaluation of chemicals. This will ensure efficiency and avoid overlap with existing legislation.

This position is submitted by UNICE representing 38 national member federations which cover 32 European countries and 20 million companies. It has been prepared with a wide spectrum of sectoral organisations which examine problems from the angle of producers, importers or users of chemicals. Its main objective is to provide EU institutions with some guiding principles, new ideas and strategic guidelines, supported by a broad cross-section of industry, to improve the efficiency and workability of REACH.

Industry strongly requests that due consideration is given to these principles and to the recommendations that arise from them, to further stimulate multi-stakeholder discussion on a practical way to implement them in the REACH proposal. Hence, it may be necessary to revisit the recommendations given herein in the light of:

- the results from the ongoing multi-stakeholder process organised by the Commission on "Further Work on Impact Assessment"

- Strategic Partnerships under the Interim Strategy

- and the outcome of other work to improve the workability of REACH.

2. BACKGROUND

In October 2003, the EU Commission adopted its proposal COM (2003) 644 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (further referred to as REACH proposal).

Presently REACH is mainly written from the perspective of, and experience with, conventional chemical substances. In fact, as currently drafted, REACH covers other substances like metals, minerals, ores, wood fibres, concentrates, alloys, preparations, waste for recycling, etc., commonly referred to as materials. It is important to acknowledge the differences that exist between chemical substances and the broader "chemicals and materials" (e.g. chemical elements, preparations, raw materials and articles of organic or inorganic nature) to ensure that the requirements imposed by REACH apply in an equal and non-discriminatory way.

It is also important to take into account the impact of REACH on the customers of the chemical supplier, namely downstream users.

- Further improvements are needed to ensure that the REACH proposal provides a workable, effective and competitive framework for chemicals management. Moreover, the proposal should contain a substantive reference to, or recognition of, the Lisbon competitiveness agenda.
- Substantial resources will be needed within governments and industry to comply with the REACH system. The call on resources, both human and financial, is often disproportionate to the objectives of effective chemicals management. This will adversely affect the workability of the system and its ability to deliver cost-efficient health and environmental benefits.
- Substances, preparations and articles are produced, recycled, handled, traded and used globally. Therefore the related management programmes have to be globally consistent. The REACH system should recognise ongoing international efforts to promote international cooperation and coherence in the area of chemicals and materials and make reference to the Johannesburg Chemicals management declaration and the UN initiatives in this respect (like SAICM)[1].

If the legislation is to meet its information-sharing, health, social and environmental objectives, while preserving and enhancing the global competitiveness of the European industry as a whole, **some elements of the proposal have to be changed fundamentally** to achieve a more proportionate and better balanced system. The resultant proposal would provide an effective level of chemicals management within a Sustainable Development concept.

[1] SAICM : Strategic Approach to International Chemicals Management is a UN initiative to cope with the IFCS Bahia declaration and the Johannesburg Chemicals management declaration.

3. FRAMEWORK FOR A NEW AND MORE SUSTAINABLE APPROACH FOR REACH

3.1 GENERIC GUIDING PRINCIPLES FOR A WORKABLE AND PROPORTIONATE CHEMICALS MANAGEMENT SYSTEM

Industry proposes the following generic principles upon which it solicits opinions. If agreed, these principles would guide a more structured review of the REACH proposal.

REACH SHOULD:

- **focus on the core objective of chemicals management** i.e. the risk assessment/evaluation of chemical substances, and provide risk management guidance. This has to be based on risk-driven, tiered (iterative) and targeted (focused) requirements, processes and decisions, rather than hazard-driven or unnecessarily exhaustive processes.
- apply the "Precautionary Principle" in a reasonable and balanced way in accordance with the recommendation of the Commission Communication (COM (2000)1 of 02.02.2000).
- avoid unnecessary overlap and conflicts with other existing EU environmental, health and safety legislation as well as with specific product legislation.
- ensure that all substances receive fair and consistent treatment throughout the REACH process.
- generate and promote consistent levels of chemicals management while protecting sensitive business information.
- apply the proportionality principle, in particular with regard to (1) the graduation of risk and (2) the use of scarce human resource capacities of governments, authorities and industry, through a focus on substances of highest concern and the application of objective prioritisation criteria, while ensuring full compatibility with WTO rules.
- preserve the competitiveness of the whole of EU industry in particular SMEs throughout the supply chain, within the framework of the Lisbon targets.
- in general, be aligned with the international target of the Johannesburg declaration to achieve sustainable chemicals management in 2020.
- ensure equal treatment and consistent, balanced application at all stages by clarifying the role of the Agency and strengthening its coordination functions.
- clearly assign responsibilities along the supply chain according to the different roles and competences of the various actors in the supply chain.

REACH should be focused on its core principles of risk assessment and evaluation of chemicals. This will ensure efficiency and avoid overlap with existing legislation. The application of REACH should be in accordance with the **general principles** listed above.

3.2 RECOMMENDATIONS FOR A WORKABLE AND PROPORTIONATE "CHEMICALS MANAGEMENT" APPROACH

In order to significantly improve the effectiveness and workability of REACH industry proposes the following key suggestions for fundamental changes:

TITLE II: REGISTRATION OF SUBSTANCES

SCOPE

Focus the scope of REACH on providing risk-based information on substances and risk management guidance and limiting duplication of existing legislation.

In addition to the exemptions already included in the COM proposal (including the Annexes II and III) REACH should also not cover:

- primary raw materials
- secondary raw materials for recycling and energy recovery
- waste
- R&D throughout the supply chain.

In order to reduce the administrative burden there is a case to exempt chemicals solely destined for export to non-EU countries, where local legislation already applies; but the possible re-importation through substances in articles and formulations must be considered.

REGISTRATION OF SUBSTANCES

Industry strongly suggests introducing priority-setting into the REACH system so as to achieve proportionality between the efforts / resources to be spent and the possible risk of substances.

This priority-setting would be risk-based and applied primarily in the registration step.

Putting emphasis on the substances of highest concern will ensure a workable and effective REACH system.

Volume alone is not a sufficient criterion to assess the potential impacts of a chemical on human health or the environment. Uniform comprehensive data requirements will lead to the generation of large amounts of superfluous information on the many harmless low-risk large-volume substances. It is necessary to determine early in the process a more proper targeting of problematic substances.

With a view to risk-based prioritisation, registrants should produce basic information on hazard, volume, main use/exposure categories and other available information on the substance. On the basis of this information the registrant will perform a risk estimation allowing for risk-based prioritisation for the next steps in the REACH process.

If there is no concern, no further action is required and the substance can be registered. Consequently, no evaluation would be necessary.

In cases where the information is not sufficient to enable safe use of substances, additional information will be generated. If this includes vertebrate animal testing, an inquiry has to be undertaken with the Agency.

This would direct the resources of both industry and Authorities to the substances and uses/exposure where there might be risks.

Timetables in REACH should be linked to the results of the prioritisation to ensure workability of the whole system for both governments and industry

Vertebrate animal studies should be shared by all registrants.

3.2 RECOMMENDATIONS FOR A WORKABLE AND PROPORTIONATE "CHEMICALS MANAGEMENT" APPROACH

TITLE II: REGISTRATION OF SUBSTANCES (CONTINUED)

SUBSTANCES IN ARTICLES

UNICE believes that at present, the requirements on substances in articles:

- Are not workable in practice in the absence of clear definitions, such as for article type, threshold values for minimum concentrations or substance release criteria, etc.;
- Overlap and/or are inconsistent with existing sector-specific product legislation;
- Overlap and/or are inconsistent with existing occupational health and safety legislation;
- Are not enforceable;
- Expose the EU producers of articles to unfair competition from producers of the same articles outside the EU.

The requirements should also be fully compliant with WTO rules.

For those industry sectors for which REACH overlaps with existing specific product-related and occupational health and safety legislation, the present requirements on substances in articles constitute unnecessary duplication and should be removed.

For other sectors for which such legislation would not ensure a level playing field, the potential negative effects on the competitiveness of EU producers of articles vis-à-vis their extra-EU competitors must also be limited. This could be the case through workable provisions for substances in articles, or alternatively a refocus and adequate scope of REACH.

USE AND EXPOSURE CATEGORIES

- UNICE advocates the registration to be built on clear, broad, simple and standardised use and exposure categories that cover the whole supply chain, taking into account the work of the ongoing REACH Implementation Projects.

- European IPR would be at stake if individual companies were required to reveal each individual use of a substance/preparation in their processes and products.

3.2 RECOMMENDATIONS FOR A WORKABLE AND PROPORTIONATE "CHEMICALS MANAGEMENT" APPROACH

TITLE III: DATA-SHARING AND AVOIDANCE OF UNNECESSARY TESTING

Data-sharing should be based on voluntary consortia and in line with competition compliance rules, to be set out in guidelines

Industry cannot accept schemes of compulsory data-sharing, beyond those concerning vertebrate animals test data. It would be contrary to confidentiality, competition law and IPR.

Mandatory data-sharing should only be applicable in the case of vertebrate animal tests and on the basis of financial compensation

Industry fully supports the idea of reducing the overall costs as well as the workload for the central Agency by allowing companies to jointly register substances but it should be managed on a voluntary basis. Industry cannot accept a system based on mandatory membership of consortia.

TITLE IV: INFORMATION IN THE SUPPLY CHAIN

- The communication of information through the supply chain may be simple in theory but it is much more difficult in practice. Reasons for this include different industrial sectors and levels of expertise of actors involved in the chain, confidentiality issues and the complexity of the actual supply chain. The complete supply chain may not be linear or direct, which means that every actor in the supply chain may not be fully aware of actors which do not directly precede or follow them in the supply chain. Rather, a supply "chain" may resemble a "net" or "matrix".
- UNICE therefore requests that Safety Data Sheets (SDS) be standardised internationally and become the exclusive document to communicate data on substances through the supply chain. There should be no additional information requirements in parallel (compare art. 30).
- The quality of information provided through Safety Data Sheets must be ensured so as to enable downstream users to handle substances appropriately and to fulfil their obligation under REACH and under their respective sectoral legislation.
- Any information annexed to the SDS must be easily accessible for downstream users and communicated in a standardised format (art. 29).
- All documents used for REACH should be standardised after discussions with and input from industry. It must be possible to transmit them electronically in a single standardised format.
- The use of clear, broad and simple use and exposure categories such as industrial, professional and consumer, would facilitate the flow of information up and down the supply chain. Such use categories would also meet downstream user business confidentiality requirements, while delivering the objectives of adequate and efficient communication through the supply chain.
- Downstream users should be responsible for implementing adequate risk management measures, not for registration or testing

3.2 RECOMMENDATIONS FOR A WORKABLE AND PROPORTIONATE "CHEMICALS MANAGEMENT" APPROACH

TITLE VII: AUTHORISATION AND TITLE VIII: RESTRICTION

UNICE believes that restriction, not authorisation, must be the preferred option for risk management in cases where the risks cannot be adequately managed by other means. Decisions must be based on sound science and, where relevant, sound economics. Fast-track restrictions would be more workable and effective than authorisation. They would better protect the integrity of the Internal Market and would minimise the amount of bureaucracy. From the start, authorisation and restriction decisions must properly consider and optimise the three pillars of Sustainable Development, in order to protect innovative capacity. A wide range of substances must remain available to EU industry.

- UNICE acknowledges the legitimacy of the concept of authorisation if it can be assured through the adequate control of risks, as in the present text. UNICE rejects a default obligation to substitute substances based purely on their intrinsic properties and irrespective of actual risks ("substitution principle"). This would require substantial re-engineering without improving the protection of health and the environment. The requirement to prepare a substitution plan should be deleted.

- UNICE calls for thorough socio-economic assessments in case adequate control cannot be assured. An authorisation "should" (Commission proposal: "may") be granted if the socio-economic benefits outweigh the risks.

- When conducting the socio-economic analysis and looking for the existence of "suitable alternative substances and technologies" (art. 57), suitability must be determined with reference also to costs and a risk assessment. Similarly, the present text demands that the holder of an authorisation shall ensure that the level of exposure is reduced to as low as is technically possible (art. 57) - again, considerations of costs and benefits must be made.

- If a substance is not granted an authorisation or is restricted for a certain use, sufficient time must be available to find alternative solutions without compromising the functionality of the final product. Finding a substitute can be difficult, even impossible, and re-engineering of the affected processes or products may be costly. During this period of seeking alternatives, the substance in question must remain available. It is therefore imperative that "sunset dates" for the ban of a use (art. 55) and "time limits" of authorisations (art. 57) take account of specific product cycles and lead-time needs. These vary greatly between sectors and applications.

- Detailed application-specific discussions and appropriate consultations must be allowed under REACH, meaning as -a minimum- that applicants must have sufficient time to comment (art. 61).

3.2 RECOMMENDATIONS FOR A WORKABLE AND PROPORTIONATE "CHEMICALS MANAGEMENT" APPROACH

TITLE VII: AUTHORISATION AND TITLE VIII: RESTRICTION (CONTINUED)

- UNICE place great importance on rights to a hearing and/or appeal, as well as sufficient protection of sensitive business information, including for the information published on the Agency's website.

- Substances should not be subject to authorisation and included in the relevant annexes until they have been officially classified as CMRs category 1 or 2 based on an agreed sound scientific assessment (see art. 54 f).

- R&D should be exempt from REACH, including authorisation.

- Substances used in articles should be exempted from prior authorisation if they are neither intended to be released nor can reasonably be expected to be released.

- Restrictions should be triggered when the risk of a substance at community level cannot be managed by more efficient means and taking the socio-economic benefits of the substance into account. Industry should be better involved in the process. In order to protect sensitive business information only summaries of the conforming dossiers should be published.

TITLE IX: AGENCY

The Chemicals Agency should ensure the workability, transparency, consistency and efficiency of the implementation of REACH and a level playing field for all substances.

The Agency should be responsible for the operation and monitoring of the registration system according to criteria set out in the Regulation.

The Agency should be responsible for the evaluation process, using the existing competences and resources of Member States.

The Agency should be responsible for the application of agreed risk-based prioritisation criteria for Registration and Evaluation.

WHAT IS UNICE?

UNICE is the voice of more than 20 million small, medium, and large companies.
Active in European affairs since 1958, UNICE's members are 38 central industrial and employers federations from 32 countries, working together to achieve growth and competitiveness in Europe

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