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POSITION PAPER

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UNICE SUPPORTS A RISK-BASED APPROACH TO AUTHORISATION AND SUBSTITUTION WITHIN REACH

Introduction

UNICE supports:

- The Commission proposal on authorisation based on adequate risk management or socio-economic assessment.
- A risk-based approach to REACH from Registration to Authorisation which focuses on managing the risks to the environment and human health from substances of very high concern.
- Authorisation only to be applied to substances of very high concern classified as category 1 or 2 CMRs, PBT and vPvB. For other substances of high concern restriction should be the preferred control mechanism.
- Substitution assessments and timings on a case-by-case basis in consultation with suppliers and users, taking into account product lead times and re-testing and re-engineering requirements.

A risk-based approach to REACH is needed from registration through to authorisation, allowing industry to focus its resources on substances and uses of very high concern which may impact on the environment and human health. If a risk-based approach is not adopted, these resources will be diverted to deal with the consequences of substances lost from the market, with little or no benefit to the environment or health and safety.

Managing risks associated with substances needs both the hazard and the exposure to be considered in the context of Europe's sustainable development objectives. UNICE supports the fundamentals of the Commission proposal on Authorisation that an authorisation shall be granted based on evidence of adequate control through risk management and, if not, that an authorisation may still be granted on the basis of evidence of socio-economic aspects.

The (im)practicalities of substitution: Re-engineering and re-testing

Managing risks associated with the manufacture and use of hazardous substances costs money. Clearly this is already a driver for industry to substitute substances for less hazardous alternatives where possible, and indeed this is common practice in industry. In order for a substitute to be successful, the substitute must however be fit for purpose (in terms of physical, chemical and mechanical properties), available in the required amounts and at a comparable cost without creating an additional risk for the environment and human health. If these criteria are not met, it is unlikely that the substitute will be suitable.

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Testing the suitability of substitutes can be costly, but these costs appear small when the costs associated with substitution are magnified along the supply chain. Manufacturers of preparations and articles will need to re-engineer and retest their products as a result of substitutions. Contrary to innovation, this is expenditure to stand still. Practical experience of restrictions on the use of a limited number of substances under the End of Life Vehicle Directive 2000/53/EC, for example, underlines the difficulties and costs associated with the re-engineering and re-testing of products and processes in highly complex, global supply chains.

Considerations other than the health and safety and environmental impacts of the substance must also be taken into account. For example, changing the composition of vehicle tyres would have a serious effect on tyre properties such as dry and wet grip and durability, and would also affect the performance of the vehicle in terms of fuel consumption. This would require extensive short- and long-term testing in order to ensure that product safety, as well as environmental concerns are addressed. This highlights the importance of viewing substitutions within the wider context of sustainable development objectives and of minimising the withdrawal of substances for economic reasons, by making sure that the requirements of REACH are workable in practice.

The Commission's proposal for the authorisation process reflects these concerns by taking a risk-based approach through the consideration of adequate risk management or the socio-economic requirements for substance use.

Managing risks

The authorisation of substances of very high concern for uses that are adequately controlled is essential to prevent substances being lost from the supply chain without any benefit to human health or the environment. Industrial processes are already tightly controlled in terms of, health, safety and environmental impacts through regulatory regimes such as the health and safety at work regulations, Control of Major Accident Hazards (COMAH) Directive 96/82/EC and the Integrated Pollution Prevention and Control (IPPC) Directive 96/61/EC. For example, complex electronic components, such as semi-conductors, may need for their production minute quantities of classified CMR substances, which are used in closed and tightly controlled processes, in terms of both environment and health and safety, and which are not present in the final product. At end of life, any risks associated with recycling the article are controlled through the Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC.

The REACH proposal partly reflects current risk management processes in the way that intermediates are dealt with. If substances are not authorised for a use where the risks are adequately controlled there will be little or no environmental or health and safety benefit from the decision not to authorise.

Assessing substitutes

For certain non-professional uses of substances, it may not be possible to demonstrate adequate risk control. In these cases, where a substance of high concern whose use cannot be justified for socio-economic reasons and which cannot be adequately controlled, substitution should be considered. However, a 'one size fits all' approach to substitution is unlikely to be successful.

REACH will cover a wide range of substances, each with different properties and uses and the potential to find substitutes will vary as a result. For example, inorganic substances such as metals will have very limited options for substitution, as there are a finite number of metals in existence. Timescales for assessing and reviewing progress on substitutions will need to be agreed on a case-by-case basis. Product lead times and development cycles, which vary widely between applications, must also be considered. For example, product lead times in the aerospace sector can run into decades due to the exacting safety, durability and performance standards required.

Considering the costs and benefits

Substances which provide a socio-economic benefit but where the risks associated with the substance cannot be adequately controlled and there is no substitute readily available should be granted an authorisation where the benefits of their use can be demonstrated and outweigh the risk associated with the use.

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