POSITION PAPER

BUSINESSEUROPE

27 November 2013

Competitiveness Check: the Approach to SVHC under REACH

KEY MESSAGES

1 Proper implementation of REACH should deliver a balanced approach through the protection of human health and the environment while enhancing the competitiveness of the EU chemicals industry.

2 Industry is committed to REACH and supports its objectives while being actively engaged in its implementation.

3 However, the approach to substances of very high concern (SVHC) should be reconsidered. Industry would like to see a better focus on the competitiveness aspects of the Authorisation process and the implications for the global level playing field.

WHAT DOES BUSINESSEUROPE AIM FOR?

- *A new methodological approach for SVHC which incorporates engagement with industry thus ensuring the safe use of chemical substances and maintaining the competitiveness of EU industry in the long term.*
- *Intervention to help alleviate regulatory burdens and in turn contribute to protecting the competitiveness of EU manufacturing.*
- *Greater certainty on the approach to SVHC to enable European industry to plan for the future.*

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Competitiveness Check: the Approach to SVHC under REACH

European industry supports the objectives of REACH and remains committed to engaging with its implementation. Yet as REACH becomes fully operational, threats to competitiveness are becoming evident. The identification of Substances of Very High Concern (SVHC), their inclusion on the Candidate List and the Authorisation process is of particular concern. While the principle of identifying SVHC so that they may be properly assessed and authorised is justified, Authorisation may not necessarily be the most appropriate measure to control the risks posed by a particular substance.

This is particularly relevant when dealing with chemicals that have significant socio-economic benefits. When used under tightly controlled conditions, there are compelling examples of substances on the Candidate List which can enhance product safety and durability with significant resource efficiency benefits – reduced waste, reduced emissions and with associated reduced upstream and downstream environmental impacts.

The current process also presents competitive risks to industry, and in particular SMEs who are especially exposed because of the costs and complexity associated with the process. This paper outlines in more detail three key areas where competitive risks are heightened: through the adoption of SVHC targets; the authorisation process and the lack of a global playing field.

The SVHC roadmap proposed by the European Commission, European Chemicals Agency (ECHA) and the EU Member States offers constructive options for ensuring analysis of the appropriate Risk Management Options (RMO) when selecting substances for the Candidate List in future. This is a significant and welcome step, with the potential to remove a significant source of unnecessary regulatory burden by targeting regulatory action where it is genuinely needed.

The Current Approach

Article 55 of the REACH Regulation states:

> "The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable."

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Despite this emphasis on ensuring the good functioning of the internal market, it is clear that thus far the process has mostly been driven by the substitution objective and followed an approach based on considerations of the substance hazard characteristics rather than on risks associated with its use.

- Target Based Approach to the identification of SVHC

A target-based approach to adding substances to the Candidate List is inherently arbitrary and may not necessarily lead regulators to adopt the best regulatory approach. The focus of action must be to put in place the most effective mechanism to control risks.

- The Authorisation process

While companies have the ability to apply for Authorisation (a time-limited approval from the European Commission to continue to use substances subject to authorisation whilst R&D activity to find an alternative is underway) it is recognised that the process is expensive, potentially complex and, above all, highly uncertain. To date it is not clear how applications for authorisation will be judged.

Also, the process of completing the Authorisation dossier requires large amounts of information and it is the applicant's responsibility to carry out the socio-economic analysis, as well as the analysis of the alternatives. Therefore, in addition to the cost imposed by the fee, there is also a great amount of administrative cost in preparing the dossier. SMEs, especially those not in the chemical industry sector, often have to pay for expertise by engaging expensive consultants. In the case of some substances it is apparent that the costs of applying for Authorisation and uncertainty about the length of time for using a substance according to a granted authorisation could lead to the disappearance of these substances from the market, rendering them unavailable for use in production in the EU. The availability of economically and technically viable alternative substances or technologies then becomes irrelevant. Even if the time span for which the authorisation is granted is known, a period of 7 to 12 years would be much too short. Investments in production sites for substances for which no alternatives exist would not be profitable.

Companies operating in industrial sectors such as aviation, automotive engineering, food contact materials or mining find the authorisation process particularly problematic as they must comply with additional safety-critical material verification procedures in addition to REACH. These procedures, which are put in place for safety or quality reasons, are prescribed in the relevant legislation that must be complied with. These procedures are lengthy and in some cases it is already apparent that no economic and technically viable alternatives, as stated in Article 55, are available. The timeframes for these verification procedures can be protracted and sit uncomfortably with the time-limited nature of Authorisation application.

- Lack of a Global Level Playing Field

Global competitiveness is a particular concern under Authorisation as it does not apply to imported finished goods. This means that EU based manufacturers will be operating in a distorted global market competing with manufacturers outside the EU who can continue to use SVHCs in manufacturing articles and supply those to the EU market. The risk is that under these circumstances "REACH leakage" could occur, for example if substances are withdrawn from the EU market but are needed for applications with no known alternatives and remain available outside Europe.

Furthermore, by its very nature, the Authorisation application process forces businesses to consider a scenario where the process cannot be done in the EU and assess where it can be done and what the associated costs are. This is particularly the case for global businesses based in the EU but which operate in territories where manufacturing costs are lower.

This places European manufacturers at a great disadvantage without yielding any net benefit for human health and the environment on a world scale, and is an incentive for businesses to externalise activity outside of the EU.

The Way Forward

EU article manufacturers and downstream users of chemicals are already reporting that they are at a major disadvantage as a result of the authorisation requirements and the Candidate List. This disadvantage must be addressed through careful selection of instruments for substance regulation through the RMO analysis process. Targeted intervention could help alleviate regulatory burdens and in turn contribute to protecting the competitiveness of EU manufacturing.

A new methodological approach which incorporates engagement with industry would ensure the safe use of chemical substances and maintain the competitiveness of EU article manufacturers in the long term. European industry is prepared to cooperate in every respect, but for this to occur, industry representatives must be included in the processes of analysing RMO from an early stage to improve the efficiency, effectiveness and quality of the ultimate decision making process. Early communication of the considered substances is essential for an efficient, correct and smooth process. The incorporation of industry expertise should be required in order to ensure that the conditions for all substances are equal regardless which Member State Competent Authority (MSCA) is responsible.

- Risk Management Options (RMO)

An ECHA guidance document, or framework, on conducting RMO analysis processes would help increase the importance given to the RMO. This assessment of the RMO should always take place before any initiative, regulatory or communication of intention is started to ensure that the appropriate route is followed for all substances. It must

precede any inclusion on the Candidate List and should be applied immediately to the process of prioritising the 144 candidate substances already identified. An effective analysis of RMO should be based on sound science and take the following aspects into account:

- Practical experience of the industrial sectors involved in the manufacture and use of substances as well as existing sector specific legislation
- Conflicts of objectives between substance regulation and other political goals such as the transition to sustainable energy, climate change mitigation, resource efficiency, promotion of innovation
- Maintenance and strengthening of the competitiveness and productivity of European industry on the global market
- Effectiveness of the instrument to control the risk associated with the use of SVHC
- Expansion of EU companies' ability to develop and deploy key technologies, both now and in the future, including the necessary long-term planning certainty
- Avoidance of negative impacts on safety-critical applications (e.g. in aeronautical and aerospace engineering, automotive engineering and mining)

BUSINESSEUROPE is calling for:

- The incorporation of EU wide industry expertise along the entire supply chain in the process of analysing RMO
- The proper balancing, from the outset, of socio-economic impacts against health and environment protection
- The scrapping of arbitrary targets for SVHC in the Candidate List
- A decision about the RMO that is transparent, effective and proportionate before a substance is included in the Candidate List
- A retrospective analysis of RMO for substances already on the candidate list.
- For the substance or its applications, consideration should be given to whether risk management measures are necessary and if they are, the most appropriate measure should be selected in close cooperation with industrial stakeholders
- Individual decisions for each substance, taking account its uses, the nature of any hazards, exposure routes and any legally binding control measures
- Greater certainty for industry to allow adequate long term planning
- In the case of substances already covered under other legislation, consideration of whether an additional regulatory measure under REACH is necessary in order to avoid double regulation

Annex of Examples

The following examples present some key areas of industrial manufacturing where EU article manufacturers will inevitably be severely disadvantaged if the relative SVHCs contained or used during their manufacturing become subject to authorisation. The consequences will be serious for both innovation and for environmental targets and will have a major impact on the EU as an industrial location.

- Hard chrome plating: Prohibition of use without Authorisation for the hard chrome plating process, with serious impacts on the production and maintenance of hydraulic cylinders, work rollers and print rollers, and automotive and aeronautical components (e.g. chromium trioxide). In most cases, this will also result in lower performance of the articles manufactured using viable technical alternatives or substances.
- Energy storage: Restriction of the options for manufacturing decentralised energy storage systems for renewable energies (e.g. lead compounds) and major restriction of the options for manufacturing electricity storage devices (already regulated in the Battery Directive and the End-of-Life Vehicles Directive) (e.g. lead, cadmium and their compounds)
- High-temperature processes: Significant increase in energy use (respectively increase of CO2-emissions) in industrial high-temperature processes, e.g. the manufacture of metals, glass and ceramics (e.g. aluminium silicate fibres)
- Glass fibres, technical ceramics, optoelectronic components: Major disadvantage in the manufacture of glass fibres, high-performance glass, technical ceramics and optoelectronic components, i.e. for high-speed internet in Europe (e.g. borates and lead compounds)
- Packaging steel, in particular Tin Free Steel (TFS, also called ECCS): loss to non-EU actors of major export and internal markets for their EU manufacturers if they are forcedly driven to implement non cost-effective alternatives; Chromium trioxide use is essential in its manufacture and not contained in the end-product.
- Synthetic fibres: Major disadvantage for EU manufacturers of synthetic fibres, such as polyacrylonitrile, elastane and aramid fibres. Dimethylacetamide (DMAC) and dimethylformamide (DMF) are essential in the manufacture of these fibres and in textile coating (polyurethane coating).