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SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Improving REACH in 2018 and beyond – Restrictions

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Introduction: Restrictions in theory

In many instances, industry finds that restrictions are the most proportionate forms of chemical risk management. Restrictions allow for a targeted approach, enabling both efficient control of all identified risks and a straightforward implementation. The application of restrictions, stemming from a combination of hazard, risk and socio-economic assessment, results in a balanced management of chemicals. In most cases, restrictions send a clear message to the market, and helps prioritize actions for substitution and market deselection in a set timeframe.

Unfortunately, reality has shown that due to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) restriction process placing the burden of proof on the Member States, it has been used less than the Authorisation process and other Risk Management Measures (RMMs). This was especially the case before Risk Management Option Analyses (RMOAs) became more widely used.

Until recently, restrictions focused on targeted uses, ie, those responsible for the identified risk. In the last couple of years however, there have been trends towards broader restrictions. While it is understandable that this might help optimise Member State Competent Authority (MSCA) and European Chemicals Agency (ECHA) resources, this has created uncertainty and distorted legal clarity in the implementation.

ECHA and the Commission's reflections on how to improve the use of restrictions going forward is indeed very timely. It needs to be stressed however, that recent trends in the use of REACH restrictions should not be used as a model in the future. This is especially true in cases where the restrictions' scope, definition of uses, detection limits and substance scopes are unclear or too broadly applied. These types of restrictions, and those based on endpoints instead of individual substances, lose all the benefits of restriction in regard to ease of implementation, enforcement and adequate risk management.

1. The strengths of REACH restrictions in practice

Many of the first REACH restrictions started with a clear scope. They were based on traditional substances, with existing Chemical Abstracts Service (CAS) numbers, and their purpose was to reduce specific risks triggered in specific uses. Restrictions that are based on this model send the most effective market signals.

REACH restrictions also include a thorough risk assessment. They identify from the outset the risk and exposure routes of a given substance, and assess what an acceptable or unacceptable level of risk for society would be. The fact that this risk assessment is also coupled with a thorough socio-economic assessment on the basis of Annex XVI is a strong asset of the procedure. Restrictions should continue to be based on an understanding of the different uses of chemicals to be restricted, and whether substitution is possible and of the cost/benefit implications of phasing out a chemical in specific uses. Such an approach is a guarantee that the impact of a restriction is assessed before the restriction enters into force, and that such a restriction's impact on innovation, trade and competitiveness is understood and limited.

Finally, traditional REACH restrictions are transparent. The steps in the process are clear, and the public consultation is an essential part of the opinion forming procedure. The openness of exchange during these consultation periods should be emulated in other REACH processes. An example of this constructive risk management process is the restriction procedure on diisocyanates, where some Member States are open to another Risk Monitoring and Management (RMM) tool to address identified concerns rather than a ban. In this case, a proposal has been made for placing the burden on industry to develop a training and certification scheme for workers as a risk management measure to better address the specific concern of occupational asthma.

2. Recent trends

The REACH restriction process has however been criticized for creating inefficiency by going into unnecessary level of details, and recent restrictions have tried to make the process evolve to be less resource intensive and tackle multiple substances in one dossier. Many of these innovations have however led to restrictions, which are more opaque and open to interpretation and are therefore difficult, if not impossible, to implement and enforce.

For AmCham EU members, who will in many cases have to implement REACH restrictions, the developments below have been of concern:

Scope restrictions which are open to interpretation

Recent restrictions such as polycyclic aromatic hydrocarbons (PAHs) in consumer goods[1] and nickel compounds[2] have introduced creative concepts into restrictions' scope definitions. Concepts such as 'foreseeable conditions of use', 'direct and prolonged contact with the skin' or 'short-term repetitive contact with human skin or the oral cavity' are fundamentally open to interpretation. Although the intent to focus on specific areas of risk is appreciated, these concepts, if not further substantiated are too broad to clearly define what product category may or may not be concerned by the restrictions.

This raises implementation questions as well as enforcement questions. If industry cannot understand whether the scope of a restriction applies to its own products, the odds that other market actors including governmental agencies will also not properly enforce is quite high.

Restricting a risk, not substances

This trend is obviously taken to the extreme with precautionary restrictions which aim to tackle an environmental or human health risk which goes far beyond a single substance. The work on two current restrictions are evocative here: microplastics and tattoo inks. Restrictions on end points without an understanding of the exposure conditions and substances concerned, are not only a difficult exercise for the authorities, but raise questions about how far the liability of chemical manufacturers can stretch. Their efficiency is further limited by the lack of widely accepted unambiguous and reliable testing methods.

This trend already raises serious questions when applied to more 'severe' endpoints, e.g. carcinogenic, mutagenic or toxic for reproduction (CMR) substances in consumer products, or aspiration hazard for lamp oils. However, the recent intent to restrict textile and leather articles containing skin sensitizing, irritative and/or corrosive substances is a worrying precedent. For example, corrosive and sensitising substances have differing levels of severity, and should not be part of a same risk assessment analysis. In addition, some substances that are corrosive (or an irritant) as such, could be neutralised when in mixtures – and this, should be recognised in a more granular risk assessment specific to a substance and its uses.

[1] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:328:0069:0071:EN:PDF

[2] https://echa.europa.eu/documents/10162/7851171d-53e9-455a-8bb8-7ca22e89ad87

Scopes based on endpoints are unclear and a major source of confusion. Companies may well be able to provide some data (existing or to be generated), but calls for evidence which are so openly worded make it difficult to identify the appropriate data to support a meaningful discussion.

Impossible detection limits

We have also noticed that the final stages of restriction proposals can become political, which can lead to unfortunate compromises that might complicate the enforcement of the restriction. Acceptable limits, when set politically, have little to do with thorough calculations of what the acceptable risk is, and more about precautionary drives towards zero risk. This unfortunately leads to hazard considerations entering the world of REACH restrictions, which should be the most risk based of all the REACH procedures. Beyond issues related to whether this extra level of caution is justified, or if its impact has been assed, it is concerning to see restriction limits being set at levels which are barely at, or below, detection limits. This, by definition, means the creation of REACH restrictions cannot be enforced, which harms the credibility of the entire process.

Enforceability of restrictions is essential, not only for the competitiveness of the European market, but also for the circular economy. A restriction with an unmeasurable detection limit will lead to recycled products which cannot be sold since it will not meet the set chemical content requirements, as recyclers will not have the appropriate testing methods to test their feedstock.

Certainly, science and detections methods evolve. However, REACH has experience adjusting restriction to these new realities by amending restrictions. This is a proven approach. Trying to reverse the process will therefore only be counterproductive.

3. Future trends as outlined in the REACH Review

The REACH Review conclusions present a few solutions to address some of the shortcomings of the restriction processes. Drawing from their experience of the REACH processes – including the recent trends detailed above – AmCham EU would like to share its thoughts and reactions below.

Restrictions must in any and all circumstances meet certain requirements: (i) be the result of a risk management option analysis that concluded a restriction was the most appropriate course of action, and (ii) have a scope defined based on the assessment of unacceptable risk and a socio-economic analysis carried out as part of a full Annex XV dossier. These requirements are essential to ensure that restrictions retain all the benefits of an implementable and easily enforceable risk management measure.

Restrictions as a tool to complement an authorisation, ie, prevent the introduction in the EU market of articles containing substances on the authorisation list

Article 69(2) specifies that ECHA must consider the risks from authorised substances (after their sunset date) and should prepare an Annex XV dossier 'only if the risk of their use in articles is not adequately controlled'. This provision would have no effect if the future REACH practice was to apply a restriction before the Authorisation process is completed. We believe that the possibility of parallel restriction and authorisation, as embedded in Article 58(6), should only be used in exceptional circumstances to avoid the duplication of efforts, legal uncertainty and confusion in the supply chain.

The Commission must elaborate clear rules to explain the circumstances under which it would be most appropriate for these parallel risk management measures to be applied. Each such case would need to be accompanied by a justification as to why a restriction must be adopted on articles containing Annex XIV listed substances that cannot wait for the completion of the Authorisation process, and how that approach addresses the management of an identified unacceptable risk.

Restriction using Article 68(2)

The definition of 'consumer use' should not be sufficient to trigger a justification for a restriction, ie, should not be identified as synonymous to 'risk'. Instead, legislators should consider guidance on the application of Article 68(2), in particular clarification on cases where it is justified. There is strong support for restrictions as a way of controlling otherwise 'unacceptable risks'. This means that restrictions should only be applied insofar as an 'unacceptable risk' has been properly identified and defined. The concept of 'consumer use' alone does not equate to such a risk.

Waiving risk assessment

Risk assessment prior to the definition of the scope of restrictions, and as a key element, is an essential requirement for effective restrictions. The waiving of risk assessments is presented as a means to gain efficiency in compiling restriction dossiers. However, the absence of a proper and full Annex XV dossier in the preparation phase of a restriction will result in a poorly defined restriction scope or even unreachable detection limits. This would have direct consequences on the implementation, enforcement and overall effectiveness of REACH restrictions as a risk management tool.

The definition of the 'unacceptable risk'[3] is necessary – in particular in the case of 'qualitative endpoints' where authorities generally consider that a quantitative risk assessment is not reliable. In such circumstances, the concept of 'unacceptable risk' is the only way to define the scope of the restriction. There is a growing tendency to consider a substance's presence in the environment as sufficient ground to justify a restriction. This is done regardless of the actual levels measured, and therefore negates the definition of risk, which is hazard multiplied by exposure, as a valid definition for what is 'unacceptable risk'. Taken to the extreme, this trend will lead to a situation where risk is only considered sufficiently controlled under a 'zero emission' policy, and this simply cannot be implemented.

ECHA to do more restrictions to help MSCA lack of resources

One of the barriers to using restrictions in all cases where it would be the best risk management option, is closely linked to the lack of Member State resources in time and funding. However, the REACH Review report states that ECHA is currently the author of most Annex XV dossiers, due to the requests of the Commission.

Restrictions are an essential component of the risk management tools available in REACH. It is only logical that in cases where a restriction is identified as the ideal way forward, it receives the dedication necessary to be a successful risk management measure. AmCham EU supports ECHA as a strong provider of scientific and socio-economic analysis, and welcome its role in the early phases of the restriction process, insofar as it is seen as a way to maintain a strong restriction process, with adequate time and resources spent on a thorough risk assessment and overall strong Annex XV dossier.

AmCham EU thoughts and recommendations for better restrictions:

- Always start with an RMOA, clearly outlining the risk and concern being addressed.
- Definition/ scope comes first. A restriction's scope illustrates its risk assessment. If we do away with the foundation of 'unacceptable risk' as a concept, it becomes impossible to clearly define a restriction's scope.
- An open scope – even in the early stages of calls for evidence – makes the information gathering infinitely difficult. In case of scopes defined outside of those substances directly registered under REACH, or of substances with no CAS numbers, it means that no substance registrant can come to the fore to support the data gathering.[4]
- The product/use scope should be clear and explicit, ie, not open to interpretation. Concepts such as 'consumer use', 'foreseeable conditions of use' and 'repeated contact', may be appropriate and useful in the context of guidance, if well explained, but are ineffective in the restriction text. Thus leaving too much to the interpretation of customs and enforcement authorities. REACH restrictions will only be as effective as their enforcement.
- Detection limits should be set scientifically, not politically. A restriction limit below, or at detection limit, by definition cannot be enforced, and therefore will be ineffective. A measurement method should be specified at the time the detection limit is set.
- A guidance on the use of Article 68(2) is needed to clarify when and how it should be used. At the very least, we believe that 'consumer use' is not sufficient to justify an imminent risk in the meaning of 68(2).