Streamlining and simplifying the REACH authorisation for applications concerning uses of substances in low volume and legacy parts

AmCham EU urges the Commission to refine the REACH authorisation process so that it becomes an example of better regulation

Executive summary

The REACH authorisation process was designed to deal with large volumes of chemicals with the assumption that alternatives could be found in a relatively short period of time. It is a lengthy, bureaucratic and expensive process. "Upstream" may be proportionate and "fit for purpose", but at or near the end of the "downstream" and for "legacy parts" it is a disproportionate burden. So disproportionate in fact that it is endangering the competitiveness of manufacturing in the EU and risks forcing the premature obsolescence of products. One size definitely does not fit all, and we fully support the objective of building a simpler, proportionate procedure.

AmCham EU believes that authorisation procedures can be simplified so that they focus on pragmatic chemical risk management - not on trying to impose an unwieldy and unsuitable administrative burden on downstream users. In this paper we have outlined the type of products and processes that should qualify for simplified authorisation, together with possible simplified solutions.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2014 and directly supports more than 4.3 million jobs in Europe.

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CONSULTATION RESPONSE

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Introduction

AmCham EU welcomes the Commission's public consultation on streamlining and simplifying the REACH authorisation application procedure for applications concerning uses of substances in low volume and on a one-time extension of transitional arrangements for uses of substances in legacy spare parts.

The consultation is welcome as it addresses the much-debated issue of how best to apply chemical safety policy to products that do not pose a risk for consumers or the environment during their use, but may do so during their production and their maintenance, repair and overhaul. These products in REACH terms are the ultimate stage of the "downstream" - separated by a long and complex supply chain from the chemical producers.

We welcome the Commission's move on this matter as it does recognise that the authorisation procedure as currently formatted places a disproportionate burden on both the authorities and industry in certain cases. A simpler and much more proportionate process has to be found. It is important that such products and processes are tightly defined and meet stringent qualifying criteria, but once this is done, we think that simpler, less costly procedures should be put into place, for example, in compliance with EU Occupational Safety and Health laws.

This issue is contentious due to the economic and competitiveness implications for the EU of disproportionately applying chemical safety legislation to such products. There are grave concerns that specialty chemicals used in low volumes will not be made available for manufacturers in the EU due to the cost and complexity of the authorisation procedure for each chemical substance for specified uses. This will disrupt supply chains - leading at best to increased manufacturing costs and at worse to a delocalisation of manufacturing within the EU, with no benefit to human health or the environment which REACH rightly aims to solve, nor for the good functioning of the internal market as foreseen by Article 55 of Regulation 1907/2006. For manufacturers – from the Original Equipment Manufacturers (OEMs) to SMEs in their supply chains – REACH authorisation will be a disproportionally costly and complex charge for large companies and a potentially impossible task for smaller companies.

Thus, AmCham EU believes it is vital that the Commission and Member States take steps to refine the REACH authorisation process so it can be applied in a proportionate manner and be an example of 'better regulation' and even more importantly send a clear signal to the market-place that speciality chemicals can be supplied to manufacturers in the EU market.

Central to achieving this outcome will be:

1) Closely defining what type of products and manufacturing and maintenance processes should be concerned by such a refinement of the authorisation procedure in order to give both clarity and prevent abuse;
2) Deciding and defining appropriate administrative and working environment measures to ensure that risks to human health and the environment are fully addressed;

3) Deciding how to best deal with continued use of legacy spare parts – but this needs to include transitional arrangements for parts and processes being used in legacy and on-going production, not just "spare parts".
4) Gathering data on the use of SVHCs used in the manufacture of finished products..
5) Significantly reducing the costs, in man hours and money related to the authorisation procedure

1. DEFINITION OF PRODUCTS USING IN SUBSTANCES IN LOW VOLUMES

We agree with the Commission that products using substances in relatively low volumes should benefit from a simplified authorisation procedure for substances of very high concern (SVHCs) featuring in Annex XIV provided they:-

1) Have no intended release during use;
2) Are typically used in low volumes;
3) Are often qualified, certified or type-approved to meet safety and performance standards set by safety authorities, which effectively "fix" both product design and manufacturing process limiting design changes in long-lasting final products like: automotive vehicles; aerospace products; space technologies, energy generation equipment; medical equipment; locomotives; and defence products;
4) Are often used in anti-corrosion and other high-performance requirements where substitutes are very limited – often being restricted to similar chemical families that also present similar chemical risks;
5) Are used as process chemicals;
6) Are used in low volumes to prepare products that are mainly used in R&D and professional laboratory workplaces in scientific research and development (SRD) settings; and
7) Are used as essential trace elements (i.e. in biological fermentation processes) such as cobalt dichloride and boric acid.

This list of "essential characteristics" could be developed into a set of criteria that would have to be met in order to qualify for simplified or streamlined authorisation procedures.

2. APPROPRIATE AUTHORISATION PROCEDURES

We agree that authorisation be granted to legal entities for their "own use". Some consideration could also be given to applying the low volume threshold per individual use of a substance per legal entity.

In this context "authorisation" procedures may not be the only approach to ensuring safe use of SVHCs listed in Annex XIV and a more appropriate approach could be to focus on chemical risk controls, e.g. the use of worker protection legislation that addresses the specific risks of SVHCs of such products, that is during their production and maintenance, repair and overhaul phases. In this case, proving that worker safety rules are obeyed could be the criteria to granting and complying with an authorisation.

It is often the case that performance criteria for products - including materials, designs and processes for products- are mandated by regulatory agencies or OEMs, allowing little to no flexibility within the immediate supply chain to make independent changes, that is to search for alternative substances and technologies with potential to be certified or qualified to replace an Annex XIV substance. A simplified authorisation request should not include this requirement in such cases.

An assessment of alternatives could be done in a review process involving the relevant competent authorities (e.g. the European Safety Agency, the European Medicines Agency), the European Chemical Agency and the companies who have to comply with Agency requirements; and/or with reference to a classic authorisation dossier performed by upstream users. Such an approach may also help with the problem of a lack of "visibility" of upstream users compiling dossiers that may not cover all the speciality uses of their substances.

The procedure for a simplified authorisation request should be designed so that a company can be reasonably confident that it can be granted in a timely manner without excessive cost, e.g. the need for external consultants. The current process, which can take 5 years to complete and incurs significant costs in internal man-hours and external consultants, is clearly disproportionate.

We take note of the Commission's proposal to define the scope via the establishment of volume limits, but we do not believe this is a suitable approach. The volumes used are indeed relatively low, but this should not be the sole defining criteria. Primarily, because low volume per se is not relevant to controlling the chemical safety risks posed by these products. Potential exposure to SVHCs listed in Annex XIV to consumers, workers and the environment should be the prime determinant.

To illustrate the limitations of setting volume limits:-

- A substance used in surface treatment for example could be used by a legal entity in small volumes (less than 10kg per year) and be present in the final product at a concentration less than 0.1 per cent by weight;
- A substance or mixture used in a metal treatment bath could be used in quantities of over 1,000kg per year, but then either be present in the final product at a concentration less than 0.1 per cent by weight, or not at all, e.g. chrome tri-oxide used in a treatment bath, but not present on the final product;
- A substance used as a process chemical catalyst or in low volumes (less than 100 kg per year/per legal entity) to prepare products used in R&D but are not present in the final product;
- A substance could be used as an essential part of a production process to produce a product in which the SVHC listed in Annex XIV is not present in the final product
- Substances could be used as solvents for pharmaceutical production during chemical synthesis, but are not present in the final formulation. In this case pharmaceutical products are strictly regulated by the EU via Directive 2001/83/EC. This includes testing the final product for the absence of residual solvents (limits specifically set by the ICH guideline Q3C (R5) on impurities / European Medicines Agency).

Chemical risk controls could also cover eventualities such as when a specific process or use in a product has not been identified and specifically covered in authorisation requests developed by

consortia for large volumes - as it may be the case that all the uses by downstream users may not have been identified, particularly in these types of products where there are a multitude of niche, specialist and indeed confidential (often the case in military and space products) processes and products.

We agree with the Commission that regular review of authorisations be held in order that a "disconnect" between regulators and industry does not develop and that there is a continued focus on chemical risk management and the aims of REACH. For the products illustrated above, many are long-lasting from an average of 12-15 years in automotive to 30-40 years in aerospace. The questionnaire posits seven years as suitable regulatory period but the periods should be adjusted given the typical life-times of different product groups.

3. LEGACY PARTS AND PROCESSES

We support the extension of transitional periods for legacy spare parts and agree this is an important first step. However, defining the scope to only include spare parts for out of production would severely limit the potential benefit to most industries .The concern is not just for spare parts for discontinued production, but also for the production and processes of legacy and current products where both the designs and the maintenance, repair and overhaul are effectively "fixed" and substitutes are either prevented by regulations/certification or not practicable.
Indeed the Commission in its explanatory note for the questionnaire gives an example of using small amounts of paint for repairing small scratches in aircraft – stating that this process would not clearly be covered by a "legacy spare parts category". We think that deleting "spare" is a necessary clarification for both the reality of production of such "final" products and their legal status under any measures taken to deal with the question of "legacy" parts and processes. We also agree that the extension of transitional arrangement should also include use of substances in the repair and maintenance of articles.

We agree with the suggestion in the explanatory note that one way to deal with legacy parts and processes is to bring them under the ambit of measures to simplify and streamline the authorisation procedure. But given the time sensitivity, with application and sunset dates imminent, a solution needs to be found rapidly. We think that the simplest method here would be longer sunset dates for substances in Annex XIV that are used in processes and parts meeting the criteria for both legacy parts and "low volume use" and consequently they could be subsumed into the regular review suggested in the section above.

Within the automotive industry, spare parts must meet the performance demands of the original part and function identically with associated systems and components to make sure that the function and safety of the vehicle is not adversely affected. This issue has been addressed in the End of life Vehicle 2000/53/EC. Subsequently, all new material restrictions in the ELV Directive have a "repair as produced" exemption for spare parts that were not originally designed to be compliant with the new material restriction. To ensure the continued supply of spare parts of the necessary quality and functionality, spare parts that are no longer in current mass production (legacy parts) be exempted from the provisions of REACH, Article 56, when they contain substances that have been listed in REACH Annex XIV. This is a clear example of how legacy parts could be treated under REACH authorisation.

Our industries have long and complex supply chains including many SMEs, based in many countries in Europe and outside Europe. The burden of managing authorisation together with the complexity of the requirements and the supply chains must be considered when constructing an effective solution for legacy parts. In order to achieve a maximum on planning certainty and to **avoid the outsourcing of capacities to outside Europe**, any solution for such legacy parts must be easily and quickly integrated in the context of the REACH regulation.

4. GATHERING RELEVANT DATA

The Commission is correctly asking for data on legacy spare parts from industry describing their use of substances in Annex XIV, the volumes involved and the time periods where the spare parts are likely to be needed. We repeat our view that to make sense, this data needs to cover legacy parts and processes, not just "spare parts".

Industry will no doubt gather this data, but we would like to point out some reservations, as we may have misinterpreted the purpose of the data request as presented in the questionnaire:-

The annual volumes – as explained above, there is not always a direct correlation between volumes used for production and specific parts – e.g. substances or mixtures in a metal treatment bath do not necessarily result in their presence in the final part. It may make more sense to differentiate between volumes needed for coating a substrate, those needed in parts and those in the final product;

Experience in the working of consortia has found it very difficult to estimate volume by use across all legal entities. It has been possible to define the main generic uses of substances, but not for every specific use. If the Commission is asking for all specific uses we are afraid that this will not only be extensive, but also still not exhaustive;

Such data on the 31 SVHCs currently listed in Annex XIV will necessarily only give a "snapshot" of the present situation, but the Annex combined with the "candidate list" presents industry with a moving target. In other words, the current list presents severe problems, but we see further problems if the annex is added to. For example, in some cases potential substitutes for the 31 substances in Annex XIV are on or may be added to the candidate list. We hope that the Commission intends to take this dynamic into account when analysing and presenting the results of the data gathering exercise.

Besides the authorisation requirements for substances used in the production of spare parts there are further burdens which are seen as a risk to the availability of spare parts. Under Article 33 of REACH there is no effective date for its applicability set out and therefore communication of the Candidate List substances appears to apply to spare parts that were produced before and after REACH came into force. The information to be provided under Articles 33.1 and 33.2 should be limited to that which was legally required under EU regulations at time of production of the part. Furthermore for re-manufactured parts, the re-used content should be excluded from Article 33 obligations and only the new parts which, have been fitted to remanufacture the product (article) shall be subject to the communication obligations of Article 33 if that were produced after REACH came into force. We do want to ensure that the Commission receives relevant data for its assessment of legacy parts and processes, but we would welcome further clarification of its intentions so we can ensure the relevant data is prepared and submitted.