AeroSpace and Defence Industries Association of Europe

REACH REFIT 2017 position paper

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Overview

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1. Authorisation

Authorisation of chemicals in existing use is a new concept; it is unsurprising that this is an area where significant improvement is needed.

1.1. Authorisation dossiers

In the absence of example 'template dossiers' that fully meet legal requirements, industry has had to guess the precise level of data required. Discussions in early years and the first real applications for authorisation have shown that there are many different interpretations on how to approach the dossier, resulting in a number of issues.

Key problems

- There is still lack of clarity and/or agreement among stakeholders (ECHA, committee members, industry and NGOs) in how far to break up or separate different (but similar) use cases; how far to go with analysis of alternatives; and how much measured data is necessary to support a model.
- Effectively managing communication of often sensitive information amongst supply chain actors is very challenging, as this requires very extensive work and coordination between companies who have in many cases no contractual relationship.
- Technical language can be very different from one sector to another, which often leads to difficulties for industries and RAC and SEAC representatives to understand each other's main messages. Concepts communicated by industry in authorisation dossiers may not be fully understood, due to differences in background and experience.
- Due to the technical and industry-specific nature of information, there may be misunderstandings between the different stakeholders, such as the difference between real world use cases and the conservative assumptions often used in authorisation dossiers – in

particular the exposure assumed in a socio-economic analysis will typically be very pessimistic.

Proposals

- **The Authorisation dossier content** should be very much **simplified.**
- **Some currently expected dossier requirements should either not be mandatory, or further standardised.** For example, the monetisation of health impacts should not be mandated, or a method should be officially described and mandated by ECHA to remove any interpretation or liability on the choice of method and results of the calculation.
- **RAC and SEAC rapporteurs and experts should eyewitness related example industrial processes** concerned by the application, with on-site visits prior to the final assessment of a given Authorisation dossier, wherever there is a significant difference of understanding.
- **For Authorisation renewals**: the dossier should be extremely **simplified**. Only monitoring data collected during the initial Authorisation period and significant changes to the initial dossiers (e.g. alternatives and/or socio-economic analysis) should be mandatory.
- Credit should be given in Authorisation dossiers for existing professional workplace risk controls and training.

1.2. Supply-chain coverage of Authorisation

It is generally accepted that upstream applications for authorisation are necessary for a range of reasons, including support of SMEs, flexibility of supply chains, and effective use of industry and committee resources. In order to be able to cover the whole supply chain, authorisation applications need to be made by substance manufacturers, importers or formulators. However, upstream applications in complex supply chains lead to a number of additional challenges.

Key problems

- SMEs and/or companies with complex supply chains (for whom upstream applications are the only workable solution) are currently at a disadvantage since upstream authorisation applications tend to get shorter review periods than downstream user applications, resulting in a distortion of Authorisation processes.
- There appears to be the unrealistic expectation that upstream suppliers of commodity chemicals used in complex supply chains should know every user, expecting applicants to have close to full data regarding use conditions and users. This unrealistic expectation gives rise to a perception of poor dossier quality and results in shorter review periods.
- The economic interest of different actors in a supply chain can vary widely. An upstream chemical supplier may only have interest in the profit margin of one relatively low cost chemical, whilst the downstream users may face loss of their entire business. It is therefore possible that upstream applicants may refuse to renew authorisations at the end of a review period, while downstream customers could still need it. The sensible option in such a case - a replacement upstream application – would, however, be unnecessarily difficult if it means starting from scratch with a new applicant.

Proposals

- The facts associated with **real supply chains and the distortion resulting from erroneous expectations** should be recognised by the authorities, who should ensure a level-playing field between all forms (downstream and upstream) of applications for authorisation.
- The evaluation bodies of a dossier submitted under a consortium should consider **aggregated data as the standard practice** (not requesting specific data for each and every individual applicant or user covered by the application).
- Where replacement upstream authorisations are necessary, such authorisations should be transferable **to allow new applicants to take over the original dossier on a review basis** to avoid re-starting a full dossier from scratch.

1.3. Authorisation process effectiveness and scheduling

There is a substantial imbalance between the durations for dossier formation, for opinion forming and decision, and for the implementation of any requirements resulting from the decision.

Key problems

- ECHA recommendations for inclusion into Annex XIV currently allow for 18 to 27 months for industry to develop authorisation dossiers until the latest application date is reached, which does not reflect the complexity of consortium formation for complex supply chains and widely used commodity chemicals. The time needed to develop a consortium application for authorisation has in some cases been over 3 years. The challenge of managing authorisation in complex supply chains where broad-usage chemicals are concerned appears to be underestimated.
- In contrast, the Committee opinion (ECHA) and decision (Commission) processes can take up to 2 years from the point of dossier submission. The decision is very often made close to the sunset date or in some cases afterward, and any conditions of authorisation may need to be applied instantly. This decision process timescale appears to be excessive from an industry planning and uncertainty perspective.
- From an SME perspective, ECHA opinion documents appear to be complex and difficult to understand.

Proposals

- **Committee processes should be simplified** to radically reduce the decision making time to less than 12 months. A particular focus should be on the time intervals between meetings. This would allow an application (made before the latest application date), to benefit from at least 6 months of supply chain communication and implementation time before the sunset date. Simplified processes could reduce the committee workload and even lead to reduced application fees.
- Any conditions laid down by the authorisation as pre-requisite for continued use of the substance should account for **reasonable transition periods** to allow for communication down the supply chain, and for putting any necessary equipment or monitoring in place.

- **Widely used chemicals need significantly longer time** (3 years) from Annex XIV entry to the latest application date due to the time required for consortium formation, supply chain mapping and data gathering.
- **A simple but exhaustive summary of ECHA opinions** for SME use would be very helpful so that they understand the proposed conditions of use under an authorisation.

2. Visibility and predictability in the evolving lists of substances

Sectors with very long product development and use lives struggle to plan ahead for REACH Candidate and authorisation list changes. Aerospace and Defence industry products typically have product life cycles of 20-30 years, and sometimes in excess of 50 years.

Key problems

- The way in which REACH develops is generally not compatible with aerospace and defence sector's product timeframe since research and development of alternatives generally takes many years, during which time many additional substances may have been added to the candidate or authorisation lists.
- In some cases, investments are made into alternatives which are then included in Annex XIV a few years later. In other cases, because of lack of visibility and predictability, some promising potential alternatives are not explored in further detail due to the pending risk that they become subject to Authorisation or Restriction a few years later.
- In addition, there appear to be different views between member states regarding the purpose of the candidate list – in particular whether all substances will be eventually included into Annex XIV or not. This may cause confusion and does not help companies to focus limited resources on the most critical research and development areas.

Proposals

- **More clarity should be given on the prioritisation of substances** already on the Candidate List before being included in Annex XIV.
- More **structured milestones** should be proposed. For example, if it has been agreed that a Candidate List substance is to be included in Annex XIV eventually, there should be a minimum time period between entry on the Candidate List and consideration for Annex XIV, perhaps 5 to 10 years. This will allow substitution in advance of Annex XIV entry for quicker product cycle industries.
- **The objectives of the Candidate List should be clarified and agreed across all member states**.

3. Recovery from unintended non-compliance situations

A downstream user can find out too late that an upstream authorisation did not cover his use, either as a result of the applicant not covering it, or as a result of committee decisions. Equally, downstream user may find out too late that a substance was not registered in the supply chain as

expected, or not registered for the necessary use. In both cases, the time needed for dossier development and committee decision processes means that such a user will find out far too late to react. This can put such a user out of business, impacting downstream markets. With respect to authorization, it is therefore crucial that committee opinions (RAC/SEAC and REACH Committee) do not attempt to change the scope of authorisation coverage from what was originally applied for through review processes.

Key Problem

- Because REACH puts the responsibility and costs for substance registration or authorisation on industry, downstream businesses can find themselves in a situation where a substance is not registered or a use is unauthorised due to the actions of upstream businesses with which they have no direct relationship.

Proposal

- **A fast-track recovery process in case of unintended non-compliance** should be made available through agreement with national enforcement authorities.

4. Supply Chain Communication

Whilst we fully recognise the greater need for product responsibility, there has been a tendency toward excessive detail in supply chain communication and notification requirements, beyond what is needed for human health and environment protection, and beyond what many small companies can cope with.

Key problems

- The CJEU ruling on 'once an Article, always an Article' relating to Article 7(2) and 33 reporting (case C-106/14) has a great potential to create an information requirement which is excessive and not proportionate to what is necessary to ensure the safe use, especially for complex assemblies and for SMEs, unless care is taken in the updated guidance document.
- The structured system developed for exposure scenarios, appended to extended safety data sheets (eSDS) has created a highly complex information and compliance requirement (reference Articles 37 to 39), for which many businesses struggle to access the relevant skills and competences to understand. Most companies do, however, understand the basic safety data sheet.

Proposals

- For Article 33 and Article 7 compliance, individual articles within complex assemblies should not need to be specifically identified, unless required for safety of use. Where such identification is not necessary for safe use, aggregated information at a practical level of sub-assembly should be sufficient, given that tracing back to individual component article level is still possible on an exceptional basis if needed.

- A radical review – from the perspective of SME downstream users – of the detail required in exposure scenarios is strongly recommended, with the objective to remove detail that confuses or does not help human health or the environment.

5. RMOA and consistency between chemical regulations

Whilst REACH has reduced the EU chemicals management framework into fewer legislative instruments, there remains a number of outstanding issues to resolve. In 2013, the SVHC roadmap sought to consider alternative possible regulatory routes for risk reduction through the risk management options analysis (RMOA).

Key problems

- REACH is increasingly regulating workplace Health and Safety aspects, in a way that is sometimes inconsistent with the SCOEL* approach and with national regulations. The legitimacy of ECHA in setting OELs is regularly challenged, for instance in the recommendations of authorisation dossiers that list additional workplace constraints. (**The Scientific Committee on Occupational Exposure Limit Values (SCOEL) was set up in 1995 with the mandate to advise the European Commission on occupational exposure limits for chemicals in the workplace.*)
- In some cases, industry needs to choose between two incompatible regulations. For example, some alternatives to CMRs could increase VOC emissions, creating priority challenges. That is a problem especially when the regulations come from different bodies which do not seem to have a consistent approach.
- The Risk Management Options analysis approach is a very promising and helpful instrument. Unfortunately, it is inconsistently applied among member states and is non-binding only.

Proposals

- **RMOA should be applied wherever possible** as it helps focusing REACH efforts. In this aim, the RMOA should be improved to be **conducted in a more harmonized and predictable manner**, according to defined processes and criteria.
    - Before concluding on candidate listing and Annex XIV as a 'blanket' risk management instrument, there should be a general assessment of the sectors affected; expected market responses in case of candidate list inclusion; and availability of alternatives for critical uses.
    - To this end, sector (downstream) stakeholders should be invited to provide relevant input, which is normally not included in the registration dossier.
    - Non-REACH measures should be explored, such as the sufficiency of EU OSH legislation.
    - The status of an SVHC substance or its precursor as a Critical Raw Material (CRM) according to the related EC CRM policy should be considered when deciding on the appropriate Risk Management Option (e.g. beryllium, borates, cobalt).
- **The Roles and responsibilities of ECHA vs SCOEL should be clarified** to avoid different exposure limits/reference values derived by different methods.

- **The European Commission should ensure consistency** between European policies on substances.
- **Authorisation decisions** should specify an obligation of outcome (e.g. exposure limits), but should avoid mandating the means of protection and operational conditions – because industrial settings can vary significantly in context.
- If the risk is primarily a workplace risk, the Occupational Exposure Limits route (e.g. via the Carcinogens and Mutagens Directive) should be the prime route in some cases, as long as the OELs are practically achievable by users.

6. Mutual recognition of defence exemptions

REACH allows member states to adopt defence-related exemptions for certain substances in specific cases. Despite the adoption of an EDA Code of Conduct, the lack of a formal requirement on member states to recognize exemptions granted by other member states puts a heavy burden on industry.

Key problem

- The current situation where member states are not required to acknowloedge defence exemptions granted by other states leads to major challenges in multi-national partnership programs and creates difficulties with use of specialist chemical products containing Annex XIV substances where specification, formulation, and end-use take place in different member states. Defence technology sharing cannot be trusted without a binding common framework for inter-state recognition of exemptions that goes beyond the current (non-binding) EDA Code of Conduct.

Proposal

- Within the limits of EU law, a maximum level of flexibility is desirable and the defence industry would benefit from automatic **recognition of defence exemptions** by EEA member states where granted by other EEA member states. The acceptance of these exemptions in other member states would support and enhance cross-border trade in the sector and lessen the burden for both industry and member states.

As signed by Jan Pie, ASD Secretary-General, 24th January 2017