

# Addendum to: Brief on ASD Concern Regarding Upstream Applications in the REACH Authorisation System

For the aerospace and defence industries, substitution of hazardous chemicals for which alternatives are available is a key priority as it allows reduction of risks to human health and the environment, while ensuring supply chain continuity and minimising business uncertainty. However, in case of chemical applications for which fit-for-purpose alternatives have yet to be found, the REACH Authorisation process is critical. In such cases we strive for effective control of risk, including in accordance with conditions of Authorisation. ASD remains committed to continue helping all stakeholders to improve the effectiveness of the REACH Authorisation system.

This comment is an addendum to our paper of 26<sup>th</sup> February 2016 ('ASD concern regarding upstream applications in the REACH Authorisation system') and aims to share the aerospace and defence industry lessons learned in participating in such upstream applications for authorisation in complex supply chains, and to clarify some possible misunderstandings.

Upstream applications are necessary for a number of reasons: to cover the full supply chain and avoid disruption; to anticipate lack of REACH know-how and resources in many SMEs down the supply chain; and to use everyone's resources – industry, ECHA, European Commission, experts – efficiently.

The main issues when preparing an upstream authorisation application are to address uses which may be broad and cross-sectoral, as well as to manage the difficulties with gathering data on all users and uses of a chemical, as illustrated by the example of the CTAC Authorisation dossier. From that experience, possible suggestions for future improvements are made.

## Issues with measured data in Upstream Authorisation Applications

Through consortia, upstream applicants (substance manufacturers) aim to involve downstream users to gather data related to various downstream uses, alternatives and economic impact, as well as to share the cost of dossier development. A consortium will be formed from those companies that are aware of the need for authorisation and have the time and resources to support it. Not every company that benefits from an upstream application will be a consortium member or be represented by one.

### Data from the supply chain (consortium and non-consortium members)

A manufacturer of a commodity chemical product (whether a substance or mixture) mainly sells his product through distributors. The manufacturer does not know the actual users of his product, nor how his product is used or under which specific conditions, other than the uses defined in the corresponding Safety Data Sheets, and those advised against. The complexity of commodity chemical supply chains that may cause a lack of ultimate end-user knowledge can be compared by analogy with a farmer not

#### About ASD

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knowing every bakery and cake shop who uses flour from his wheat (recognising that wheat is non-hazardous).<sup>1</sup>

Downstream Original Equipment Manufacturers (OEMs), such as aircraft or engine manufacturers, join consortia to support and provide data for CSR (e.g. conditions of use, exposure and risk assessments), Analysis of Alternatives (e.g. analysis of substance functions, sector specific approval processes, suitability and availability) and Socio-Economic Impact Assessment for their specific industry segments they are belonging to. It cannot be assumed that the participating OEMs are representative of all users (not even for their own industry segment); OEMs will usually only know their first tier suppliers and some of their second tiers such as processing facilities.

The majority of end-users (including many component article manufacturers, platers, and formulators) covered by upstream authorisation applications for commodity chemicals will not be members of consortia and will usually not have any direct contractual/supply relationship with consortium members. While mapping the supply chain is evidently key in AfAs, the complexity of the supply chain for industry sectors such as aerospace and defence has presented enormous challenges in terms of identification, uses, data and alternatives.

Because of this, technical consortium consultants need to reach out to uninvolved downstream users via their suppliers, using letters of introduction and non-disclosure agreements to help get access to information.

However, companies may still be unable or unwilling to provide data for a range of reasons:

- Many of the users will be SMEs with poor awareness of REACH and few resources. Using the previous analogy, how would a baker respond if a farmer or his representative asked how much flour is inhaled by his workers?
- Lack of a clear requirement in the Regulation or guidance to provide such data to support an upstream authorisation application.
- Potential liability concerns (worker/community exposure and publicity), and whether companies could be linked to specific data.
- Uncertainty relating to how the data would be interpreted or used.
- Concerns relating to competitor use of information.
- Challenges also exist in some regulatory regimes with regard to personal monitoring data, where approval has to be given by the individuals affected.

### Consortia in Upstream Authorisation Applications

Companies joining a consortium have in common the same type of use (for instance, surface finishing with chromates), have a good knowledge of such processes and are able to describe them, in order to provide a mapping of the conditions of use of the substance, even if no official standards are available on the matter. The benefit of contributing to the activities of the consortium is to exchange between users on the conditions of use and to develop the relevant best practices, which, thanks to the

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<sup>1</sup> ASD fully understands the trend towards extended producer responsibility and similar principles, and that wheat and flour are not substances of very high concern. This analogy is simply to use a familiar scenario to aid understanding of real supply chains.

authorization mechanism, will be integrated in the SDS. Therefore, even if conditions of use and other data have not been provided by all users, the authorization dossier established in such consortia is representative of best practices and will be applicable to all users.<sup>2</sup>

Where there is a wide number of industries with very similar uses of a substance, the resulting authorisation applications can cover a variety of articles and end-products, and there may be significant variation in functional requirements of the substance as well as in the ability to substitute.

### Breadth of authorisation application use case

Such current upstream authorisation applications for broad use chemicals may appear as ‘too broad’. However, when a chemical is used in many different end-product sectors with overlapping supply chains, it is difficult to separate use cases in terms of the types of articles produced. For example, a supplier’s galvanic plating system may serve many different product types. This was the context that prompted a meeting with the Commission in March 2012 and subsequently the work leading up to the ECHA-EASA paper<sup>3</sup> in 2014. ECHA encouraged industry to focus on similarities between use cases rather than differences in the nature of end articles or products produced.

Feedback from SEAC and RAC committees suggests some current upstream applications are being viewed as ‘too broad’, and ECHA has expressed hope that they will be improved at the time of a potential renewal at the end of the review period. However, in order for improvement to be possible, consideration should urgently be given as to whether applicants will be expected to restructure those applications, whether such a case would be treated as a new application or an update, and whether the review period is long enough for such changes in the most complex cases.

In addition, the possible side-effect of narrowing the scope of an authorisation application by distinguishing more different uses should be discussed: since the economic interests of different supply chain actors are different, it may be that existing upstream applicants decide not to cooperate with a substantially increased range of uses (and associated costs) and stop supplying, despite the impact on downstream markets.

### A developing system where all parties are learning: the example of CTAC

Many parties are watching the precedent case of the CTAC authorisation with interest, because it is the first major test case of a broad-use commodity chemical in an upstream authorisation application. It is a process in which all parties are learning. Authorisation as a new regulatory system is still developing, the implications of which are still not fully understood by any party.

Given the difficulties described above, the CTAC consortium adopted a modelled approach backed up by data from consortium members and corroborated with data from other sources. This was then subjected to sensitivity analysis and application of conservative assumptions. In light of the ECHA guidance, this was understood to be a valid approach.

Activities to form the CTAC consortium commenced in late 2011, 3.5 years before dossier submission and 1.5 years before the submission of any application for authorisation. Key structural work and much

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<sup>2</sup> In particular because these best practices will be the reference for enforcement authorities.

<sup>3</sup> ECHA-EASA : An elaboration of key aspects of REACH Authorisation process, ISBN 978-92-9244-490-7, April 2014, at <https://www.easa.europa.eu/document-library/technical-publications/echa-easa-elaboration-key-aspects-authorisation-process>.

dossier development therefore took place well before the RAC and SEAC committees had developed their working procedures. At consortium formation there was very little clarity regarding how to approach the REACH Authorisation process, especially in complex supply chains, which is why the ECHA-EASA study addressed such questions as to who applicants should be and how to describe a use.<sup>4</sup>

As noted in previous papers, the CTAC consortium had to choose the upstream authorisation application approach to cover the full supply chain and avoid disruption; to anticipate lack of REACH know-how and resources in many SMEs down the supply chain; and to use everyone's resources efficiently. The total spend of the CTAC consortium was considerable - consultancy fees, legal costs, meeting costs and authorisation application fees totalled about €4M, not including benefit in kind hours of work and travel costs by consortium members.

## Possible Suggestions for the Future

ASD remains committed to making the REACH Authorisation system workable and practical for all parties, and we offer our continuing support to the various authorities to help provide context and understanding with regard to supply chain dynamics and complexity. Process development is needed to help resolve the possible misunderstandings and issues currently evident.

ASD would like to suggest the following areas for continued cooperation:

**Clear and practical expectations** in formal guidance and an example dossier in order to reduce fear or objection from end-users when they are asked to provide data to other companies and to set a clear benchmark expectation between industry, RAC and SEAC. The recently proposed practical guidance document is a good start in this direction, though at this time still needs strengthening from the perspective of upstream authorisation applications.

**For purposes of improved data in the review report** it has become clear that companies are far more willing to release data to member state enforcement authorities than to other companies or independent third parties, irrespective of non-disclosure procedures and communication campaigns. Member state enforcement authorities could in turn provide aggregated data to ECHA. This approach would ensure clarity in roles and responsibilities with regards to enforcement and could also help standardise the information content. Such data should be made available to replacement applicants where necessary in preparation for new authorisations if existing applicants choose not to submit a review report. In this regard, ASD would be most willing to contribute on the following questions:

- How personal biomonitoring data is treated, with regard to data protection law;
- How competition law concerns are managed to prevent companies accessing market data that could be used for competitive benefit, market limitation or pricing strategies;
- How any data set can be assessed as complete or representative of the user base;
- How ECHA or the Commission might use or interpret the data, particularly with regard to Article 61(3) where an existing authorisation can be cancelled at any point;
- Whether replacement upstream applicants could access the downstream user data in cases where existing applicants choose not to submit a review report;
- How 'freedom of information' requests are handled if data is held by authorities.

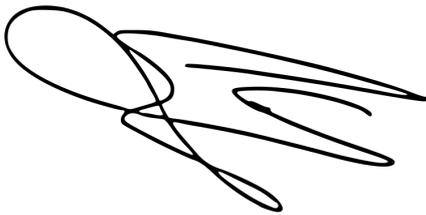
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<sup>4</sup> ECHA-EASA : An elaboration of key aspects of REACH Authorisation process, ISBN 978-92-9244-490-7, April 2014.

For **Analysis of Alternatives** information, regarding what uses are covered by an Authorisation application, the 'functional grid' as suggested by ChemSec<sup>5</sup> could be very useful in identifying the scope of the application. This would avoid excessive article/sector level of detail in the analysis, and help minimise confidentiality concerns with regard to sharing detailed AoA information.

### In summary

ASD hopes the above helps to understand the context of upstream applications for authorisation for broad-use commodity chemicals. Please be assured that substitution is our first priority where alternatives are available. Where unavailable, ASD remains committed to find practical solutions to make REACH Authorisation work for all stakeholders.



As signed by Jan Pie, ASD Secretary General, 30<sup>th</sup> January 2017

## ASD Concern Regarding Upstream Applications in the REACH Authorisation System

*This paper summarises the reason why upstream Authorisation applications<sup>1</sup> are necessary to make the Authorisation system as specified in the REACH Regulation workable for chemicals used in a variety of sectors and complex supply chains. Applicants for Authorisation in this context must not be penalised with short review periods; review periods should be driven primarily by the availability of alternatives.*

### Impact of Non-Authorisation

Safety is the primary concern of the Aerospace and Defence industry.

The Aerospace and Defence sector are minority users of a number of chemicals subject to REACH Authorisation. Due to stringent airworthiness, safety requirements and the longevity of the final products; the technical requirements of the industry are demanding and consequently involve long term test programs to allow confident replacement by alternatives.

In many cases alternatives cannot be implemented before the sunset date in all new, current and legacy products, and consequently successful REACH Authorisation is “mission-critical” for our industry, our many customers, workers and stakeholders. Impact areas include: the space industry and its ability to provide and launch satellites and scientific space missions; civil aviation, including the operational viability of existing and new aircraft and impacts on cargo, business and leisure travel, and military uses with potential operational impacts and national security concerns.

ASD wishes to ensure the gravity of the matter of upstream authorisation is fully understood.

### Different Authorisation Contexts

It is evident that the Authorisation process is in development, notably in some supply chain contexts, and in particular for very complex supply chains of widely used industrial chemicals.

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<sup>1</sup> *An application for Authorisation submitted by manufacturers, importers or formulators of chemical products that covers downstream users of those chemical products in accordance with REACH Article 56 (2), and by implication supports any article and product manufacturers served by those downstream users.*

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It is recognised that supply chains with different characteristics exist, which inevitably create different cases for Applications for Authorisation. We can distinguish at least three types:

- **Downstream user** applications are naturally limited in scope by the definition of the downstream use case. There is only one downstream user, the applicant, who can easily justify the nature of the socio-economic case, availability of alternatives and the risk controls implemented. An example of this is DEHP in fan-blade manufacture.
- **Narrow upstream** applications have very well-defined use cases, where the applicant has direct communication with its user -base, and there are a very limited number of downstream users. This is therefore not confused by complexity such as formulation of mixtures, wide distribution channels, or many supply sources. The application for use of Trichloroethylene in vapour degreasing systems is a good example of such a case.
- **Broad upstream** applications can cover many different industries, many different end-product types and include use in a variety of formulations as well as a pure substance. A well-defined use case or user base does not exist. An example of this type of context is the use of chromates in functional chrome plating or surface protection.

### Challenges with Broad Upstream Applications for Authorisation

In broad upstream applications:

- 1) The use in industry is broad, with many use cases, product sectors, industrial contexts and supply chains affected. This is compounded by use in mixtures (paints and specialist coatings), the impact on thousands of companies including SME's using such chemicals, and the many different product sectors such companies serve.
- 2) The many layers of the supply chain between the applicant and the ultimate equipment manufacturer means that the applicant cannot have reasonable knowledge of all users, conditions of use, and exposure levels. Under competition law, it is not appropriate for the applicant to enquire who his customers' customers are. Note the ultimate equipment manufacturer may be a user of the chemical himself, or may be two or more supply chain tiers further downstream of the end-user.

Consequently, only upstream applications make any logical sense, as foreseen in the REACH regulation., Such applications involve considerable resources to build collective dossiers, overcoming competition and Industrial Property issues as well as diverging business interests. This type of application summarises the known and intended use conditions, control measures, exposure data, availability of alternatives and socio-economic impact assessments.

ASD has been concerned for many years about the challenges regarding supply chain complexity and REACH<sup>2</sup>.

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<sup>2</sup> For additional information please refer to the document [AN ELABORATION OF KEY ASPECTS OF THE AUTHORISATION PROCESS IN THE CONTEXT OF AVIATION INDUSTRY](#)

## The Need for Upstream Applications

Upstream applications for broadly used chemicals cannot be avoided because:

- Many users of such chemicals are SMEs, who lack the key skills, technical know-how, materials knowledge or financial capacity to assemble complex Authorisation application dossiers as downstream users.
- Customers of these suppliers cannot apply on behalf of their suppliers for uses in the upstream supply chain; since supplier coverage by a downstream user application is limited to supply of the substance.
- Penalising upstream applications would inhibit changes to the supplier network, which is normally needed to address issues such as cost, quality and the changing needs of the market place. This is because any new supply source would require up to 2 years and considerable resource and expense to gain Authorisation before use can start.

Due to the nature and complexity of the supply chain, an application for Authorisation in any other format than an upstream application would therefore have extremely limited benefit in the described broad upstream cases, result in an unacceptably high risk of supply-chain disruption, and put unbearable limitations on enterprise and trade.

Broad upstream applications for Authorisation cannot be avoided for many chemicals; they are driven by the nature of the chemical, the supply chain context and the range of uses across European industry. The need to summarise resulting from these contexts is simply a fact of life, which the Authorisation process will need to cope with.

## Resolving Issues with Upstream Applications

Given that summarisation in Authorisation dossiers relating to broad-use chemicals is inevitable as a result of the supply chain context, it follows that the applicants should not be penalised with short Authorisation review cycles.

Despite decades of intensive research no alternative is available today for some uses. Alternatives, if and when available, will need to be implemented across a vast and complex supply chain.

If Authorisations are granted for a too short time, new Applications for Authorisation will have to be prepared since alternatives will not be available on time. A short review period would therefore not bring any additional elements to the existing dossier regarding the availability of alternatives, which should determine the length of the review period.

While a shorter review time may be seen as an accelerator to stimulate research, the realities of the industrial sectors must be recognised. Research has been underway for many years in any case, and short review periods would not help increase the pace of innovation, but may take resource away from it through redirection onto updated dossiers.

There is also a high risk that chemical suppliers' support for re-applying for Authorisation in order to cover the whole supply chain might be lost, and that the substances and chemical product containing them become unavailable on the EU market.

Short review cycles are damaging to business certainty affecting business decisions, such as whether to invest, or where to invest. This point is crucial for chemicals where alternatives cannot be substituted in

all applications for the foreseeable future. The length of the review period should be driven by the availability of alternatives, and not be a penalty for the difficulties of data gathering which arise from the complex downstream supply chain.

Instead, Exposure Scenarios in the chemical safety report, combined with the downstream user obligations in REACH Articles 37(5) and 66, is therefore the primary, and most effective, control for chemical safety under an Authorisation.

## Conclusions

- 1. Upstream applications are necessary to make the Authorisation system as specified in the REACH Regulation workable for the requirements of chemicals used in a variety of sectors and complex supply chains.**
- 2. Applicants for Authorisation in this context must not be penalised with short review periods; review periods should be driven primarily by the availability of alternatives.**
- 3. Exposure scenarios in the chemical safety report, combined with downstream user obligations in REACH Articles 37(5) and 66 are the primary and most effective controls for chemical safety under upstream Authorisations.**

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Signed by Jan Pie, ASD Secretary General, on 26 February 2016