REACH Authorisation Procedure Review and Improvement Proposals

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Addressees:

- **Competent Authorities for REACH and CLP (CARACAL)**
- **European Commission: DG GROW and DG ENV**
- **European Chemicals Agency**

Context and Purpose

Several members of our industry associations have taken part in the REACH authorisation process for a specific substance directly or indirectly. This document intends to review this process and identify key issues and improvement proposals from the industry's perspective.

It is important to keep in mind that the aim of authorisation is to ensure the good functioning of the internal market while making sure 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. At the same time those objectives are overarched by the more general objectives of the REACH-regulation like the strengthening of the EU's economic and innovation power. Furthermore, when setting regulatory actions relevant are also more fundamental principles of the EU like the proportionality principle.

The first experiences with the authorisation of some substances have shown a need for improvements in order to achieve the aims of the authorisation process while ensuring the functioning of the internal market:

1. Period between the decision on the authorisation of use and the sunset date

In the current process, a company is having less than six months (in the best case) to prepare itself, the suppliers upstream and the customers downstream to adapt to the decision. In the worst case, a decision might be only obtained after the sunset date.

Before a decision regarding a REACH application for authorisation (AfA) is made, there is an uncertainty to businesses should they be affected by conditions of use added as a result of the decision process. The current timeframe, mentioned above, is not long enough for companies to

react without creating major business disruptions, when significant changes to the conditions of use are required as a result of the authorisation decision process.

Such a short timeframe makes it impossible for industries with long product cycles or long product life-times with the need for an uninterrupted spare-part-supply over a very long period of time. The same is also true for industries with strict product and process approval/control throughout the supply chain to manage. This creates a risk of production shifting from EU to other regions. This leads to negative impacts; through unemployment, damaging or moving businesses outside of the EU or affecting the European economy.

Objective for the Improvements:

- Achievement of predictability to industries in the whole Authorisation process by assuring minimum periods to adjust to Authorisation decisions.

Improvement Proposals:

a) In case new conditions of use are introduced in the authorisation decision, such as additional technical controls or monitoring requirements, the decision text should include a reasonable timescale to allow industry to communicate and take the necessary steps.
b) All necessary measures should be taken to provide predictability to industries in the whole Authorisation process.

2. Applications for authorisation covering multiple operators

Applications for authorisation (AfA) covering multiple operators, including upstream and multiple downstream users applications, which potentially cover different industry sectors, product types and use conditions encountered difficulties with RAC and SEAC Committees due to being "overly broad" or not having sufficient detail. The existence of "uncertainties" from the perspective of these committees leads to shorter review periods than for a single downstream user AfA for the same or similar use scenarios.

One example is the difficulty in determining the exact monetisation of risks to human health or the environment and socio-economic benefits for multiple operators. When data is lacking, estimations are necessary. These estimations are currently evaluated as "uncertainties", which are penalized with reduced review periods.

With the experience made with the Chromium Trioxide Application for Authorisation (AfA), it became clear that the level of detail expected by the ECHA Committees cannot be achieved by an upstream application such as CTAC Sub. This implies that a certain level of adjustment will be necessary in terms of the authorisation process in order to guarantee success to upstream applications.

The experience gathered in the supply chain is that it is not possible to have only individual applications in case of substances in complex supply chains and broad use such as Chromium

Trioxide. Applications for authorisation covering multiple operators are necessary to reduce administrative burden and costs for both applicants and ECHA. There are other reasons such as:

- Maintaining supply chain flexibility for the customers of end-users, since any supply chain shift would require a new (DU) AfA and a 2 year delay, if their supplier (the end-user) goes bankrupt or provides poor quality.
- Supporting SMEs who do not have the capability or capacity to pursue their own AfA.

Objectives for the Improvements:

Review rules for applications covering multiple operators with the objective to:

- Clarify the expected contribution of each type of supply chain actor in the development of an upstream applications for authorisation, multiple downstream users and of newly proposed two-level application strategy.
- Assure affected companies the same level of success in terms of review period given, as would be obtained in case of an individual downstream user application.
- Promote individual and joint efforts in finding alternatives for the different uses.

Improvement Proposals:

a) The review period should be only based on the availability of alternatives for specific uses and the complexity of the sector and its industrial cycle, respecting the assumed periods necessary to identify and integrate alternatives.

b) Review the procedure to monetise the risk to human health or the environment arising from the use of the substance, in order to demonstrate that the socio-economic benefits outweighs them. This evaluation should be performed on a contextual and qualitative basis giving it more flexibility.

c) Provide 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. This guidance should clarify expectations of what a good upstream, multiple downstream users and of newly proposed two-level application strategy AfA consists of so that it would have equal treatment as a single downstream user application when it comes to the review period. A complete set of criteria would be helpful.

d) Guidance would also explain how DUs obligations under articles 37(5) and 66 would ensure DUs compliance with conditions of use.

e) The proposed practical guidance document is a good start in this direction, though at this time still needs strengthening from the perspective of upstream, multiple downstream users and of newly proposed two-level application strategy AfAs. We consider the possibility that industry can contribute to this work as vital to ensure the workability.

f) European programmes for building up capacities and networks to develop and find alternatives would also be promoted having in consideration a risk prioritization.

3. SMEs are in a fragile position

Small and Medium Size Enterprises (SMEs) have a huge difficulty in preparing an AfA individually. As a result, this creates a high dependency on upstream applications.

Objective for the Improvements:

- Ensure sufficient support for SMEs affected by Authorisation procedures.

Improvement Proposals:

a) Provide improved guidance to upstream applications in order to enable them to successfully cover a broader group of companies including SMEs.
b) Simplified procedure for low volumes and exploring the possibility for regional AfAs without prejudice to the harmonized application of the REACH Regulation.
c) Clear rules how SME can in practice apply in a non-English language without any additional burden and costs to the applicants compared to English applications.
d) Provide direct links on ECHA's website to the Commission decision documents of the specific application for authorisation, in order to have all relevant information readily available for DUs.

4. Supporting committees in understanding AfA dossiers

AfAs cover a wide variety of industrial uses and supply chains contexts. Our members have experienced difficulties in conveying a common understanding of the issues involved in communication with RAC/SEAC committees and rapporteurs. This is in our view due to a lack of direct industry experience in RAC and SEAC committees.

Objective for the Improvements:

- Create the conditions that facilitate conveying a common understanding of the AfA dossiers.

Improvement Proposals:

a) RAC and SEAC committees should use independent technical advisors specialized on the industrial supply chains, industrial processes and technical aspects related to the AfA with the objective of supporting the evaluation of the applications and/or other initiatives that might facilitate that process.
b) Add more trialogues during the opinion development upon request from the applicant, the RAC/SEAC committees or even ECHA or EU Commission to help clarifying potential misunderstandings.
c) Potential providers of alternatives should submit more details on their alternatives, e.g. related risks, hazards, availability, regulatory risks, supply-risks and similar. This would improve the comparability and foster a sound analysis.^

5. Avoid non sustainable substitution

Substances or technologies that are chosen as alternatives to Annex XIV substances can themselves be subject to authorisation at a later stage. All substances that are evident alternatives but have the potential to be added to the Authorisation List should be flagged as clearly as possible, in order to avoid regrettable substitutions that cause a waste of resources.

Objective for the Improvements:

- Providing assurance that the alternative substances / processes that will be implemented have a minimum period of protection, to motivate companies to actively look for alternatives, unless there is evidence of overwhelming risk to human health or the environment.

Improvement Proposals:

a) Establish a mechanism of positive incentives (e.g. tax-reduction) that would encourage companies to invest in alternatives.
b) Establish a mechanism that provides assurance of a minimum period of protection for companies that invest in alternative processes to be able to use those alternatives and return investments.

6. Balance unfair competition by non-EU Companies

Products containing Annex-XIV-substances– in particular articles, but also some mixtures – may be imported without the burden that would be comparable to the burden that EU-producers of the same products face due to REACH-authorisation. This creates unfair competition that negatively discriminates EU-enterprises.

Objective for the Improvements:

- Explore mechanisms that balance the above effect to support EU companies negatively affected by REACH requirements, without threatening trade between EU and non-EU countries.

Improvement Proposals:

a) European program to support investments in new or upgrade of technologies, such as the Horizon 2020 - EU Framework Programme for Research and Innovation, which already considers substitution projects.
b) Member States should implement positive incentives (e.g. tax reductions, subsidies) for innovation activities driven by reduction of risks to human health and environment.
c) Support activities and enhance funds for research on alternatives.
d) Only impose further regulatory burden on EU's producers once a reasonable level-playing-field between non-EU and EU products is established.

7. Analyse the most suitable regulatory option

When it comes to Annex XIV substances used in processes, authorisation may prove not to be the most suitable regulatory option to address them. On the other hand, it may have the unwanted effect to push companies to move plants or choose to invest in new plants outside Europe. This is because applications for authorisation are burdensome for industry and give no long-term visibility for companies.

Objective for the Improvements:

- Improve effectiveness, efficiency and proportionality criteria on the selection of REACH Authorisation to address the identified risks.

Improvement Proposal:

a) All regulatory options should be thoroughly considered during the Risk Management Option Analysis phase to find the most effective, efficient and proportional way to address the identified risks, beyond REACH Authorisation.

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