ORGALIME

Position Paper

Brussels, 18 December 2014

Orgalime comments on the Commission preliminary proposals to streamline and simplify the REACH authorisation process

Orgalime welcomes the commitment of the European Commission, ECHA and Member States to work on streamlining and simplifying the overall REACH authorisation process, and to consider a simplified one for specific cases. We recognise that the paper presented at the last CARACAL meeting is designed as an initial discussion paper with a view to substantiating many of its points in more detail as a next step. In this respect, we welcome the opportunity to comment and look forward to further discussing more details at upcoming meetings, such as the Commission and ECHA workshop announced for February 2015. At this stage, Orgalime would like to raise the following issues:

- ***The different facettes of how the issue affects us***

Orgalime represents a downstream user and article manufacturer industry that depends on the use of chemicals for its own manufacturing processes. At the same time, the industry is a key enabling sector that supplies its technologies to every other industrial sector, including chemical, automotive, aerospace or energy, and private consumers. In certain (though rather exceptional) cases, we may face authorisation obligations directly, in most of the cases we expect to be impacted by the authorisations granted or rejected in the value chain. Knock on effects can be expected to occur as soon as our suppliers face burden and costs.

Also, we are increasingly faced with policy conflicts stemming from the resource efficiency policy initiatives that promote the use of secondary raw materials (recovered materials) in our products, and substance policy, which strives to eliminate certain substances inevitably present in such materials (see Orgalime Position Paper on the Circular Economy Package of October 2014). Such conflicts become particularly evident in this debate on streamlining REACH authorisation, notably with respect to the relationship between REACH and recycling (end of waste criteria). “Authorisation light” (in combination with appropriate end of waste criteria) could in our view indeed be a tool and proper way forward for this specific case.

Finally, as article manufacturers we have to compete globally while REACH authorisation applies on processes in Europe “only”. The issue therefore has an immediate impact on our global competitiveness. The discussion paper acknowledges this and the Common Understanding Paper on the interface between RoHS and REACH is outlining solutions in this respect (see also separate entry on page 2). We recommend referring to it also in this debate and promoting its application in practice.

Considering all these cases, we appreciate the objective of reducing the burden on companies, and in particular SMEs, and to avoid a possible “REACH leakage” effect, and the relocation of companies or the outsourcing of certain industrial processes outside the EU in particular.

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- ***Focusing on improving the authorisation process is a sensible decision***

We welcome that the discussion paper explicitly states that the Commission will not, in the course of 2014, include further substances into Annex XIV, but focus its efforts on the improvements of the process as a whole. This should be supported in order to prove the credibility of the instrument and remedy to the extent possible the negative consequences stemming from authorisation requirements on industries operating in Europe in comparison to their global competitors.

- ***Substance prioritisation requires improvement - RMO-As are the first crucial step in the process***

Orgalime would like to reiterate that Risk Management Option Analyses (RMO-As) are essential in order to select the most appropriate risk management measure for a substance, including filling the REACH Candidate List and REACH authorisation where appropriate. RMO-As are therefore the first step well ahead of REACH authorisation process, including "authorisation light". Substances should not be added onto the Candidate List and subsequently included in the Annex XIV unless it is demonstrated that authorisation indeed represents the best management option.
The "general approach to prioritisation" falls short in taking into account socio economic criteria, different risk management options, or the implementation of Article 58(2) REACH. The stakeholder consultation on socio-economic impacts, which was launched in parallel with ECHA's draft 6th Recommendation of Priority Substances to be included in Annex XIV, is in our view a good step in the right direction. If data gathered during the consultation show that there would be a disproportionate economic impact for little health and environmental gains, those substances should not be included in the Annex XIV and other risk management measures should be selected. This would avoid forcing European companies into costly and burdensome authorisation procedures and discriminating against them in the face of their competitors producing outside the EU. We also request the Commission's support for ensuring a balanced application and implementation of REACH articles 58.2 and 56 REACH. So far, in ECHA's recommendations for the prioritisation of substances to be included in the Annex XIV, the application of these legally granted exemption mechanisms has in our view been too narrow.
Also with respect to RMO-As, it is essential that these properly implement the Common Understanding Paper on the interface of RoHS and REACH for our sector.

- ***Existing legislation and tools should be properly considered and used – the Common Understanding RoHS REACH needs to be properly implemented***

One should avoid that alternative processes are triggered to regulate issues that can be tackled through existing legislation.

For example, if there is a concern for a substance related to workers exposure and an indicative OEL is not deemed sufficient, a RMO should consider whether a binding OEL, rather than the authorisation of the substance, could be the most appropriate means of regulating workplace exposure. Moreover, in the framework of an application for authorisation, there should be the possibility to use existing risk assessment studies performed under other pieces of legislation to demonstrate adequate controls of risks. This could concern for example chemical risk assessment for workers at the workplace, but also risk assessment relevant to the local population and the environment performed according to Directive 2011/92/EU on 'the assessment of the effects of certain public and private projects on the environment'.

A proper implementation of the existing Common Understanding Paper concerning the interface of REACH and RoHS can solve many problems arising for our sector with respect to substance restrictions and REACH authorisation. We ask regulators to do so. This ties in with the statement of the discussion paper on the possibility "to explore whether an exemption to an annex XVII restriction due to the absence of risk or due to proper control of the risk could be equally qualify for an exemption under article 58(2)". For articles in the scope of the RoHS Directive and their spare parts, the issue should be solved through the application of article 58.2 REACH following the Common Understanding RoHS-REACH instead of REACH authorisation ("full" or "light").

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- ***Orgalime welcomes initiatives addressing the challenges faced by downstream users, such as improved socio economic assessments and a proper "definition of uses"***

Orgalime appreciates the efforts that the Commission and ECHA are taking to address the challenges faced by downstream users in the authorisation process. In this context, we would like to emphasise that more often than not downstream users, and especially SMEs, need to rely on an application submitted by suppliers, which may be several steps up their supply chain. SEAC assess socio economic impacts relevant for applicants; however, socio economic impacts on downstream users may vary considerably. Therefore, we suggest that the ECHA Socio-Economic Analysis Committee should not only consider the socio-economic elements, which are relevant to the applicants but also those related to downstream users using that substance. As mentioned above, gathering some socio-economic impacts during ECHA stakeholder consultations on its draft recommendations is a positive step.
The "definition of uses" covered by the authorisation will, as the discussion paper properly outlines, indeed be a key issue for downstream users, such as European engineering industries.
We support the Commission´s suggestions as outlined in the discussion paper, however suggest that this step is coupled with further simplification measures, such as reducing the burden stemming from reporting and measurement obligations. For example, if a socio economic analysis is undertaken for a number of SMEs and results are the same, it should be possible to consider the report for the entire branch.
We also support the suggestions made in the Commission´s discussion paper regarding the simplification of CSR documentations for downstream users in applications for authorisation. Downstream Users should indeed not have to develop a new CSR for documenting exposure to the substance in some specific cases but be able to submit the exposure information as documented in the exposure assessment for the use applied for included in the registration dossier.

- ***Strengthening ECHA's support to applicants is a welcome suggestion and should be supported***

Orgalime welcomes the intention to foster communication between ECHA and industry on what an "ideal" application for authorisation should look like, as well as on which elements RAC and SEAC should base their opinion and their recommendation for the review periods of granted authorisations.

Industry currently considers the outcome of an application for authorisation as uncertain until the very end of the process. Due to the fact that failing to obtain an authorisation can result in applicants being out of business, companies tend to provide as much information and evidence as possible in their applications, beyond what is actually needed, and consequently with an impact on application costs. We agree that fees are indeed not the main issue.

In this context, the Commission's suggestion of providing further indications on what elements are needed to prove "adequate control", "lack" or "non-suitability of alternatives", or "benefits outweighing risks", is a very welcome step and can in our view be very useful. Pre-Submission Information Sessions or reviewing applications with ECHA at an early stage is in our view indeed very helpful.

- ***The specific cases to be solved should be clarified***

We generally support the suggested specific cases to be solved, however, we recall that for products in scope of RoHS, including their spare parts, the application of the agreed Common Understanding needs to prevail. Finally, the discussion paper should also list the specific case of recycling. Orgalime looks forward to the future debate on the streamlining and simplification of the authorisation process and to providing our industries perspective on it.

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