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Concerns: **Results of the public consultation on applications for low volumes and on extension of transitional arrangements for uses in legacy spare parts and proposed follow-up, including formats for simplified AfA**

Agenda Point: **7.1**

Action Requested: **For information and discussion**

Summary of results of public consultation on streamlining and simplification of the REACH authorisation application procedure – uses in low volumes and legacy spare parts

General overview

The Commission received 83 replies to the consultation: 6 from private individuals, 9 from public authorities, 29 from private companies, 7 from NGOs and 28 from trade associations. Out of the 83 contributions, 24 were submitted on an anonymous basis (i.e. the content of the contribution is publicly available, but not the identity of the submitter). All the contributions can be consulted at the following link:

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081

Part I: Streamlining and simplification of applications for authorisation for uses of substances in low volumes

The public consultation sought the views of stakeholders on three main questions:

- On the need to simplify the requirements for applications for authorisation for low volume uses
- On the maximum volume per legal entity which could be considered as "low volume"
- On the conditions that should be linked to low volume applications for authorisation:
    - Limitation to the applicant's own uses
    - Application of the maximum volume limit to all uses of the same substance by the same legal entity
    - Non-applicability to uses of a substance when the presence of the substance in mixtures or articles intended for consumers (above 0.1% concentration w/w) cannot be excluded
- On the draft templates for the different parts of a low volume application
- On whether a standard/default duration of the review period should be foreseen with the possibility to expand or shorten it and on its duration.

1) Justification for simplifying the requirements for applications for authorisation for low volume uses

A vast majority of respondents supported the view that the need for a simplified application for authorisation is justified. Different reasons were put forward in support of that view:

- Need for proportionality of the authorisation requirement, and to lower the cost of applying for low volumes (in particular when SMEs are concerned)[1].
- The fact that the registration part of REACH follows the rationale that the lower the volumes placed on the market, the lower the information requirements are.

A significantly lower number of respondents (including almost all NGOs) expressed an objection to simplifying applications for low volumes, for different reasons:

- the fact that no volume threshold has been set by the legislator for the authorisation requirement,
- the fact that there is not necessarily a link between the volume and the risk, but rather with the potency of the hazard and with the risk management measures in place,
- the need to ensure that also SMEs ensure proper control of the risks and

[1] Particular examples of disproportionality of cost were put forward by companies occasionally using mixtures containing chromates, at a value of €250-€2500 over one year, which require authorisation.

- the higher number of reported cases of infringement of OSH legislation by SMEs than by large companies.

A number of comments were made to qualify the proposal of simplification in the case of low volume applications:

- The simplified application should nevertheless still contain a justification demonstrating that the risk management measures in place ensure proper control of the risks and enabling to judge whether the legal requirements of REACH for granting an authorisation are met.
- With regard to worker exposure, it was suggested allowing applicants to present the risk assessment carried out under OSH legislation as a way to describe the risk and justify the risk management measures in place.

It was also noted that in any case low volume applications should normally include less details than an application for large volumes, and that therefore low volume applications do not need to be simplified. However RAC and SEAC should still have sufficient information at hand in order to be able to assess the uses applied for and justify their opinions. In that regard it was suggested that action is taken instead at the level of the fees to be paid to ECHA for authorisation applications, and that applications for authorisation are simplified in general, not only for low volumes. One respondent suggested to limit the low volume simplified applications to threshold substances, and exclude it for non-threshold ones.

2) Maximum volume

In the public consultation document the Commission suggested different possible volume limits for the simplified applications for low volumes, in the range of 10kg-100kg / year / legal entity, recognising that the volume limit should be lower than the minimum threshold triggering registration requirements.

Responses on this point were much more diverse than concerning the justification for a simplified application for low volume uses, with one-fourth of the respondents supporting a maximum limit of 100kg, and another one-fourth supporting a maximum volume limit of one tonne (on the basis that this is the threshold applicable in the registration area). The remaining replies were spread among those pleading for no simplified application for low volumes (a zero maximum limit as any other limit would be arbitrary), a maximum limit of 10kg, of 500kg, of 10 tonnes and of deciding on the limit on a case-by-case basis.

Arguments in favour of a 100 kg limit referred to the fact that this is a very small quantity of a substance used in a production process at industrial scale and the fact that it is a significantly lower volume to what is already considered low volume in the case of registration.

In support of a 10kg limit it was mentioned that the risk is related to the potency of the hazard and that any limit is arbitrary, and therefore a very low one should be preferred.

A suggestion was also made to create an additional category of volumes below 1 kg, for which only a notification-type application would be required.

In favour of volumes above 100 kg, it was argued that low volume applications should also be possible for upstream applications covering different downstream users and their aggregate volumes.

3) Conditions for applying the "low volumes" simplified application

3.a) Limitation to the applicant's own uses aggregating all uses of the same substance for the applicant

The majority of industry respondents objected to this limitation, mainly because of the concern that this would require applications for authorisation to be submitted at different levels of the supply chain at the same time, resulting in an increase of the bureaucracy within the supply chain instead of a decrease, and would create confusion for operators (who would have to find out whether an operator up their supply chain had applied for authorisation under the "normal" procedure or under the simplified procedure).

Other comments noted that joint applications should be possible also for low volumes, in order to help SMEs, and the need to specify what "own uses" are, should that limitation be maintained.

Furthermore, many industry respondents commented that the maximum volume should be related to the use, not to all the uses aggregated for the applicant, because otherwise a formulator could not apply under the simplified approach for his downstream users, if the volume limit was quite low. It was also noted that authorisation applications in REACH are always by reference to a use, and that the same logic should apply for low volume applications.

Some respondents noted that for many operators it may be difficult to calculate the volume they use, as they often do not know the amount of a substance in a mixture.

A concern with regard to the low volume applications was that companies may split up into different legal entities for different uses in order to benefit from this type of applications. Other respondents noted that the cost of creating legal entities for that purpose would be too high compared to the advantages, and therefore it would be unlikely to happen.

3.b) Exclusion of uses where the presence of the substance in mixtures or articles intended for consumers cannot be excluded

Views on this part of the proposal were rather split. In favour of this limitation was the argument that simplification would anyway not be possible as the applications for those uses would have to include an assessment of consumer exposure. The simplification for uses in cases where the substance is only used in industrial processes and is not present in final articles was supported by many industry respondents and public authorities.

Many arguments were put forward however against this proposal, namely the fact that once the article is produced, it falls outside the authorisation requirement, the fact that the exact concentration of a substance in an article is not always known and that hence this may create additional confusion and the need to test articles, the fact that the presence of a substance in an article does not necessarily translate into exposure and risk for the consumer, and that this approach would imply a discrimination vis à vis business-to-consumer products.

4) Comments on the draft templates for low volumes authorisation applications

Most respondents commenting on the templates supported in general terms the level of information required therein, and provided specific suggestions for improvement.

Specific comments on the templates include the following:

- On the CSR:
    - while many respondents welcomed the waiving of the vast majority of the hazard assessment requirements, some respondents still considered the required information on exposure assessment too detailed and burdensome and ask for the level of information to be further reduced, allowing for qualitative instead of quantitative information to be supplied;

- other respondents considered the level of the required information should be higher (need to include in the CSR the risk characterisation for indirect exposure of humans via the environment, need to include a section for PBTs and Article 57 (f) hazards).

– On the AoA and SEA: while some respondents asked for more detailed information to be required under those templates (e.g. quantification of the benefits of continued use for the applicant), others were of the view that the same level of documentation should be required for AoA and SEA as in other cases.

5) Duration of the review period: standard versus case-by-case, duration

A majority of respondents supported the idea of having a "default" review period for authorisations granted for low volume applications with the possibility that this period can be longer or shorter if the application justifies it. Most of them supported such a standard/default review period to be 7 years, while some preferred it shorter (e.g., 5 or 3 years) and others longer (e.g. 10 or 12 years). Particular sectors supported having generally longer review periods for the sector (e.g. pharmaceutical sector, aerospace sector, automotive sector). Respondents supporting a fixed review period argued that this would be in line with the reduced level of scrutiny required from the ECHA Committees in assessing applications. Those supporting a case-by-case review period noted there are no fixed review periods in the REACH Regulation, the need to take into account the timing of the availability of suitable alternatives and the diversity of possible cases which needs an assessment of each case in its own right.

Preliminary conclusions

There seems to be general support from industry and public authorities for developing specific, simplified procedure for authorisation applications for low volume uses, whereas almost all NGOs have expressed objections to this initiative.

From the data available on the first set of applications submitted in the start-up of the application for authorisation process, it is clear that for uses involving low volumes of a substance, the cost of making and processing a full-fledged application may be disproportionate as the risks from continued use in these low volumes are comparatively small and the potential for substituting the use of Annex XIV substances is probably limited. In such cases the Commission believes that the documentation to be submitted should be simplified, while still containing the key and adequate information legally required in an application for authorisation.

A crucial element in this exercise is to delimit the cases that can be considered as "low volumes". Whereas REACH gives an indication of "low" in the area of registration (substances manufactured or imported in quantities below one ton per year per legal entity), this approach has not been followed for authorisation, where no minimum threshold has been established by the legislators. However it should be noted that the proposal to simplify authorisation applications does not imply waiving the required information in an application. It constitutes a clarification, primarily for the applicants concerned but also for the authorities involved in the assessment of such applications, of what level of documentation is required in such cases, which should be less extensive than the one normally expected, while still complying with the legal requirements. In view of this, when considering a simplified application procedure, establishing a maximum volume lower than the minimum threshold for registration would be justified by the need to provide legal certainty to applicants. At the same time, the volume should also be realistic, so that it is not too low so that most uses would not be eligible. In that regard 100 kg per year would appear to be a reasonable limit.

The Commission has taken note of the concerns raised by a large majority of industry, on the potential negative consequences of limiting simplified applications to the applicant's own uses. Since the

objective of this initiative is to reduce bureaucracy and excessive costs of applications, especially for small users, it seems reasonable to allow applications to be submitted not only for the applicants' own, but also for uses downstream from the applicant.

Another element of the proposal considered the question whether the maximum limit should apply to all uses of the substance aggregated for the applicant. This is a matter that needs further reflection on the Commission's side, as applying the limit of 100 kg, while allowing the simplified procedure also for the formulation stage, may have implications on how many cases would be able to benefit from the simplified procedure.

Concerning the exclusion of cases where the substance is present in consumer mixtures and articles above 0.1%, further reflection is also needed from the Commission's side, in particular with regard to the case of consumer articles.

Finally, the Commission would propose setting a "default" review period of seven years, albeit leaving open the possibility that this period can be longer or shorter based on a justification in the application dossier.

Related to the simplification of authorisation applications is the question of the applicable fee. The Commission and ECHA are examining what reduction of workload can be expected for a simplified application for ECHA Committees and Secretariat, and the resulting reduction of the fees for submitting such an application.

Part II: Extension of transitional arrangements in Annex XIV to REACH for uses of substances in legacy spare parts

Reflections are also ongoing to simplify applications for authorisation for uses of substances in spare parts intended for articles which are no longer in production on the sunset date (commonly referred to as "legacy spare parts"). However a step-wise approach is warranted. In order to ensure that the supply of such spare parts is not disrupted while the necessary measures are being developed, the Commission intends to extend the transitional periods in Annex XIV (i.e. latest application date and sunset date) for the substances concerned, with regard to their uses in legacy spare parts. The questions put to the public in this context were three-fold:

- the definition of "legacy spare part";
- the uses concerned by this case of simplification, i.e. whether it should be limited to uses of substances in the production of articles (spare parts), or whether it should also cover uses of substances and mixtures for the repair of articles;
- the specific substances in Annex XIV which are effectively used in the production of legacy spare parts or in the repair and maintenance of articles which are or will no longer be produced after the corresponding sunset date.

1) Definition of "legacy spare part"

A large majority of respondents supported the proposed definition of legacy spare part in the public consultation document, i.e. "a separate part that can replace a part of an existing article. The article cannot function as intended without that part. The functionality of the article is restored or is upgraded when the part is replaced by a spare part".

Specific comments were made on the use of the terms "long-life durable article", because there is no definition of such a category of articles and it can be confusing and difficult to enforce. Some

respondents suggested abandoning the term, as the existence of spare part is in itself an indication that the article is durable.

Some respondents objected to the inclusion of "or is upgraded" in the definition of legacy spare part, as in their view this is not necessary for the proper functioning of the article. On this point, it is to be noted that this definition is already used in the RoHS Directive.

A particular concern has been put forward by the aerospace and the airline sectors with regard to the proposed limitation of the simplified authorisation applications to uses in legacy spare parts intended for articles whose production has ceased or will cease by the sunset date. In the view of this sector this will exclude from the simplification procedure a large number of aerospace articles for which serial production lasts very long, while at the same time the design and composition of such articles is dictated by the type-certificate issued by EASA before production of the article starts.

A particular comment concerned the need to be able to clearly identify the articles covered by this definition. Concerns were expressed about the distinction legacy versus non-legacy. A possible way to address this could be to include in the application for authorisation a declaration by the applicant that the article for which the spare part is intended is no longer produced. Finally, one comment pointed at the need to clarify that the simplified procedure should apply only for the substance that was used in the production of the original spare part.

2) Possible extension to substances used in the repair and maintenance of articles

A significant majority of industry respondents supported this possibility, which is of particular concern to some sectors, such as the airline industry and the antique vehicle organisations. The airline sector requested to extend the simplification to mixtures needed for the repair of any aircraft, and not only aircraft of out-of-production models. Maintenance, repair and overhaul (MRO) operators use a large variety of mixtures in the repair and maintenance of aircraft and are bound by the indications given by the aircraft producer for the different aircraft models. It was noted that the case of mixtures used in the repair of articles is different from that of legacy spare parts, because the supply chain is different, the technology is not the same as that used in the normal production of the article, and in many cases the equipment being repaired is produced outside Europe (i.e. airplanes in transit).

On the other hand, it was also noted that a distinction between repair of legacy and non-legacy cases is difficult to make. Some respondents suggested that a definition of "maintenance and repair" may be needed clarify what activities would that cover. In that respect, some views expressed support and others objected to considering the use of detergents or cleaning mixtures (whether or not recommended by the producer of articles) as maintenance.

3) Substances concerned by the extension of the review periods in Annex XIV

23 substances (out of the 31 substances currently listed in Annex XIV) were indicated by different respondents as being used (or probably used) in the production of legacy spare parts or in mixtures used in the repair of such parts[2]. In addition some respondents also indicated some substances which are on the candidate list but not included in Annex XIV as falling under this case. In most cases the information did not include volumes of the substance used, because the information was supplied at association level. In other cases, amounts going from very low amounts (less than 1 kg p.a.) to a few tonnes p.a. were indicated.

[2] Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP), Lead chromate, Lead sulfochromate yellow, Lead chromate molybdate sulphate red, 2,4-Dinitrotoluene (2,4-DNT), Trichloroethylene, Chromium trioxide, Acids generated from chromium trioxide and their oligomers, Sodium dichromate, Potassium dichromate, Ammonium dichromate, Potassium chromate, Sodium chromate, Formaldehyde, oligomeric reaction products with aniline (technical MDA), Bis(2-methoxyethyl) ether (diglyme), 2,2'-dichloro-4,4'-methylenedianiline (MOCA), Dichromium tris(chromate), Strontium chromate, Potassium hydroxyoctaoxodizincatedichromate, Pentazinc chromate octahydroxide.

Preliminary conclusions

The proposed definition of the scope for simplified applications for legacy spare parts appears to be supported by a large number of respondents, and therefore it will be taken forward as proposed.

A different matter is the possibility of applying the simplified application to uses of substances in parts intended for articles still in production after the sunset date on the basis that such products have to meet stringent sector-specific regulatory requirements. This case does not only concern spare parts, but also original equipment parts of articles, and simplification in that case would have a different purpose from that intended for legacy spare parts (which is to ensure the durability of articles for their intended life-time, and for which it is acknowledged that the objective of substitution is difficult to apply). The case of articles subject to type-approval requirements potentially covers a wide variety of products, with different levels of requirements and approval procedures. While for such articles changes in their design or their composition may require an administrative process (sometimes costly), this in itself does not mean that substitution of substances used in such products is not possible as a general rule. Considerations related to the time and effort needed for certification of changes in the article should normally be included in the analysis of alternatives. In fact, the first authorisation decision adopted by the Commission concerned an aerospace product, for which the period of time needed to eventually certify the most promising alternative identified by the applicant was taken into account when determining the review period.

Regarding the simplification of authorisation applications for mixtures intended for the repair of articles, it would seem reasonable to extend the simplified application to those cases for the same reason as that applicable to legacy spare parts, i.e. the need to ensure the durability of articles and prevent early disposal because of the impossibility of repairing them. This would not be the case for mixtures intended for maintenance as it may be difficult to define in general the operations/activities that this term should cover.

In order to avoid disruption of the supply of spare parts and the repair of articles while the simplified application proposal is being developed, the Commission will propose a three-year extension of the transitional periods set out in Annex XIV for the 23 substances listed therein that are used in legacy spare parts, in order to allow the establishment of the appropriate measures and the preparation of applications for authorisation for those uses. Although not all the Annex XIV substances were signalled by respondents to the public consultation, some of the respondents noted that there may be uses of substances of which they were not aware at the time of the consultation, and asked to extend the transitional periods for all the substances. The question to consider in view of this is whether the transitional periods for all Annex XIV substances for uses in legacy spare parts and repair of articles no longer in production after the sunset date should be extended, except for those substances for which the sunset date has already expired and which were not mentioned as being used in the public consultation (i.e. 5-tert-butyl-2,4,6-trinitro- m-xylene (Musk xylene), 4,4'-Diaminodiphenylmethane (MDA) and Hexabromocyclododecane (HBCDD)). The latter would ensure that all potential cases are covered by such an extension which is in any case relatively short in time.

MSCAs and stakeholder observers are invited to comment on the preliminary conclusions presented in this document.