November 2020

Inputting to the consultation phase of an Annex XV restriction report and SEAC draft opinion under REACH

This guidance[1] is aimed at stakeholders who wish to submit substantiated information in either of the consultations[2] on a restriction proposal (i.e. six months consultation on the Annex XV restriction report and two months consultation on SEACs draft opinion on the restriction proposal). Those most likely to be interested are companies, organisations representing industry or civil society, as well as authorities. Stakeholders from both the EU and outside the EU are invited to submit comments. When submitting information please keep in mind:

- It is necessary to provide **supporting evidence** to justify the information submitted in the consultation (see the examples in the addendum); if this is not done the Committees for Risk Assessment (RAC) and for Socio-economic Analysis (SEAC) may not be able to assess the information submitted.
- If required by article 22 of REACH, the registration dossier should be updated as soon as a substance is placed on Registry of Intentions. Additional information that is under the scope of the registration submitted during the consultation by registrant or downstream user (DU) should also be included in the registration dossier(s).
- If the information shared within the consultation on the Annex XV restriction report is to have a significant impact in the Committees discussions, it should be submitted early in the process (see the plenary plan in the specific information note for the restriction and the consultation page on ECHA's website for each restriction proposal). In any case, the information should be sent as early as possible in the process[3] and it should cover all the elements of the restriction proposal and not only on the risk covered in the Annex XV restriction report.
- Information arriving after the closing date of either of the two consultations or via other channels than the web form **will not** be taken into account by the two ECHA Committees.
- It is your responsibility to remove confidential information from the comments and attachments submitted as non-confidential status.

  If you need more time to collect information on certain aspects while other information is readily available, we advise you to file separate submissions so that information can be used optimally during the opinion development process.

What information can be submitted and level of information needed

Consultation (six months) on the Annex XV restriction report

You may submit information in the following categories (other information that falls outside

[1] This guidance was developed by the Restriction Task Force and was endorsed by Member States at the CARACAL-32 meeting in Nov 2019.
[2] The consultations referred to in this document were previously referred to as "public consultations". This change is to be in line with ECHA multilingual practice policy. Further information can be found at: https://echa.europa.eu/about-us/the-way-we-work/multilingual-practice
[3] While all information submitted within six months of the start of the consultation will be considered by RAC and SEAC, information received within five months of the start of the consultation will be able to be included in discussions in the 2nd RAC and SEAC plenary discussions; these are the key plenaries to shape the opinions of the Committees.

these categories is of course welcome)[4]:

- **Scope or restriction options analysis**

  Information can be submitted on the products (substances, mixtures or articles) or activities (manufacturing, placing on the market or use) or both that are covered by or omitted (or derogated) from the restriction proposal made by the Dossier Submitter. In addition, any restriction option in the Annex XV restriction proposal can be commented on. A new restriction option (such as a total prohibition, maximum concentration or migration limits, labelling, restricted sales practices, training etc.) can be proposed with suitable justification in terms of both risk and socio-economic elements[5]. Comments could also be made on the feasibility or appropriateness of the specific concentration or migration limits proposed by the Dossier Submitter.

- **Hazard or exposure**

  Information relating to the intrinsic properties of the substance(s) covered in the Annex XV restriction report can be submitted. If the respondent submits a study on a particular hazard property (e.g. respiratory sensitisation) where that property has not been assessed by the Dossier Submitter in their risk assessment, then it would be helpful if a wider analysis of the hazard was also submitted in the consultation. This is important if the breadth of hazard information available is extensive. Otherwise, unless the Dossier Submitter is willing to consider updating the background document to include such an analysis, it will be difficult for RAC to understand the relevance of an isolated hazard study. Measured exposure information, including appropriate contextual information, may also be submitted as well as information from modelling.

- **Environmental emissions**

  Information may be submitted on emissions to the environment. This could include monitoring results, including appropriate contextual information, in various environmental media e.g. rivers, lakes, soil, air etc and may relate to a specific industrial plant or an entire EU or national sector. The responses can also be on emission factors used.

- **Baseline**

  Information may be submitted on the assumptions made to justify the baseline for the proposed restriction as presented in the Annex XV report.

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[4] For example you can provide: updated technical data and market analysis, laboratory analysis, methodologies used for testing technical properties of alternatives, past and ongoing research studies on alternatives, incurred costs, envisaged costs of switching to alternatives, calculated and estimated emissions for a specific plant or for the entire sector at national or Union (EU) level, remediation costs, impact of environmental pollution, description of the supply chain, hazard and exposure data.

[5] If an alternative Risk Management Option (for example other EU legislation) is proposed as being more appropriate to control the risk than a restriction under REACH, then the justification should cover both the risk reduction capacity and the socio-economic factors. Only restriction options will be discussed by RAC and SEAC but information on other Risk Management Options will be included in the Opinions and the Background Document for the information of the Commission. A combination of different risk management options considered in the Annex XV dossier is also envisaged and stakeholders are encouraged to submit comments, looking at the effectiveness, practicality and monitorability of this combination.

- **Description of analytical methods**

  Information may be submitted on available testing methods in terms of technical suitability, limits of detection vs limit of quantification etc.

- **Information on alternatives**

  Information may be submitted on the availability (including the time scale) and suitability (technical and economic feasibility) of alternative substances and/or technologies, any information on their risk or hazard related to their manufacture or use, information on the rates of and potential for technological change in the sector(s) concerned, etc. Information on alternatives discussed in the Annex XV restriction report or on other alternatives identified would be welcome, e.g. test results.

- **Information on costs**

  Information may be submitted on the impacts of the proposed restriction on industry (including one-off and operating costs, costs of substitution, testing costs, etc.), on consumers, on the social implications (e.g. job losses) and on their distribution (in particular SMEs). If quantitative information is not available, qualitative information may also be submitted.

- **Information on benefits**

  Information may be submitted on benefits (for human health and the environment, as well as social and economic) of the restriction, either qualitatively or quantitatively described, and on their distribution. For example, avoided remediation costs.

- **Other Socio-Economic Analysis (SEA) issues**

  Information may be submitted on affordability, effects on SMEs, effects on stocks or recycling, supply chains, spare parts, market analysis, etc.

- **Transitional period/deferred entry into force**

  Information may be submitted on any transitional period or deferred entry into force proposed? Is it a sufficient time period for complex supply chain? Will it have an impact on stocks or other issues? For requesting a transitional period/deferred entry into force, the respondent should submit sufficient evidence on risks (e.g. emission levels) and socio-economic implications to justify their proposal.

- **Exemptions**

  Information may be submitted suggesting new exemptions or oppose or modify exemptions proposed by the Dossier Submitter. Further supporting information on exemptions already proposed in terms of risks and costs are also welcome. For requesting an additional exemption, sufficient evidence should be submitted during the consultation (e.g. as done for PFOA for an additional derogation[6]). Examples of the information required are included in the addendum to this paper.

[6] https://echa.europa.eu/registry-of-restriction-intentions

Consultation (two months) on the draft SEAC opinion

You may submit information to support or comment on the draft SEAC opinion that is agreed 9 months after the first consultation was started. Any aspect covered in the draft SEAC opinion is open to comments. At this stage the RAC opinion is finalised, hence information only relevant for the RAC opinion will NOT be taken into account. If the information concerns the practicality, the monitorability and the effectiveness of the restriction proposal, which both Committees previously evaluated, only SEAC will now take it into account.

Respondents may submit information in the following categories:

- **Scope of the restriction**

  Information can be given on any issues related to the scope[7].

- **Justification that an EU wide measure is needed**

  Information can be given on the need for an EU wide measure.

- **Justification that the restriction is the most appropriate EU wide measure**

  Information may be given on the proposed restriction option related to effectiveness, enforceability, monitorability, costs or benefits.

Implications of incomplete, unsubstantiated information or of no information submitted in the consultation

If relevant and justified information is not provided via consultations, the following assumptions will be made:

- *If justified information on costs is not submitted* or assumptions made related to the costs are not commented on, SEAC will assume that industry concern relating to the validity of the analysis is low. In the absence of justified opposing information SEAC will assume that the costs are considered acceptable by the industry.
- Where exemptions have been proposed by the Dossier Submitter, that are fully assessed in the Annex XV dossier, the exemptions are considered to be within the scope of the proposal and will be evaluated by RAC and SEAC. Such exemptions may not be supported by the Committees, if they are not sufficiently justified in the Annex XV dossier and information questioning the need for exemption is received. Therefore, respondents (e.g. stakeholders) affected by the proposed exemptions are advised to provide justified information on risks (human health or environment), costs, benefits and availability of alternatives. As long as the initial exemptions are sufficiently justified in the Annex XV dossier, *if no additional justified information is submitted (for examples please see the Appendices),* RAC and SEAC will assume that there is no need to change their opinion on supporting, withdrawing or modifying the initially proposed exemptions.
- If new exemptions are requested, they have to be fully justified by risk or socio-economic arguments. Therefore, to ensure the Commission has justifications for an exemption on both elements, it is important not to

[7] SEAC cannot give an opinion on issues that would change the risk assessment.

postpone submission of making exemption requests until the consultation on the SEAC draft opinion. It is necessary to submit a detailed explanation supported by technical and economic data, including the analysis of the available alternatives. Any information on alternative substances or technologies should also include information on their risks or hazards, as well as the socio-economic implications of implementing them. *If no justified information is submitted*, RAC and SEAC will assume that there is no need for that exemption.

Is it your first consultation?

Basic information on the restrictions process can be found at: https://echa.europa.eu/regulations/reach/restrictions/restriction-procedure

Restriction proposals[8] submitted by Member States or ECHA will be published on ECHA's website here: https://echa.europa.eu/registry-of-restriction-intentions. The proposals are not open for consultation at this. However, this publication will allow you to start preparing for the future consultation. You can contact ECHA via (restriction@echa.europa.eu) if you have any questions.

Once RAC and SEAC have agreed that the restriction proposal is in conformity, the details of the consultation will be published on ECHA's website and a notice included in ECHA's weekly e-News (https://echa.europa.eu/news-and-events/e-news-archive).

The consultation of six months duration[9] then begins to allow respondents (e.g. stakeholders)[10] to submit comments or additional information on the proposed restriction. Specific questions may be included in the consultation to guide stakeholders on any particular information they could provide to assist the Committees in their assessment; sometimes these questions are linked to the discussions of the two ECHA Committees to improve the information or to help to complete the evaluation in the submitted Annex XV dossier.

ECHA will publish the comments received at the end of every month to allow all respondents to see the comments others have made: http://echa.europa.eu/web/guest/restrictions-under-consideration. The opinions of RAC and SEAC will take into account the comments received in the consultation. ECHA will publish the comments, together with the responses of the Dossier Submitter and the RAC and SEAC Rapporteurs, on its website after the end of the restriction process. An additional 60-day consultation on the draft SEAC opinion will be held at a later stage to invite comments and to inform the development of the final SEAC opinion. However, respondent are strongly advised not to limit their comments to this final round of the consultation. If the information concerns the practicality, the monitorability and the effectiveness of the restriction proposal, which both Committees previously evaluated, only SEAC will now take it into account.

The consultation is publicised in ECHA's eNews. Registrants of the substance(s), CLP notifiers of the substance, Member States competent authorities, accredited stakeholders, alternatives manufacturers and CLP notifiers, and other identified stakeholders for the

[8] The Member State or ECHA submits the Annex XV Restriction Dossier consisting of the Annex XV restriction report and any additional study reports not already submitted to ECHA in the IUCLID format.

[9] The duration of the public consultation is six months according to Article 69(6) of REACH.

[10] Those most likely to be interested are companies, organisations representing industry or civil society, individual citizens, as well as public authorities and researchers or universities.

substance itself are also informed. It is assumed that this, along with industry's incentive to be informed about forthcoming regulatory action in relation to the substances that they use, is sufficient to ensure the involvement of most stakeholders.

Addendum: Good practice examples of information submitted in the consultation for exemptions.

Example 1

The Dossier Submitter proposed a restriction on a PBT substance (and its precursors) taking into account all the uses found in the registration dossiers and through a thorough discussion with stakeholders. The emissions from all uses were documented and the cost effectiveness of the reduced emissions as a consequence of the proposed restriction was calculated for each use (and overall) in line with ECHA's approach on PBT/vPvB substances.

After submission of the restriction proposal, a company discovered that one of its products was manufactured using a substance containing an impurity that falls within the scope of the proposed restriction. To support the continued use of the substance with the impurity they proposed an exemption to the restriction in the consultation of the restriction report.

To support their proposal for a derogation the company submitted the following as a justification:

- The concentrations and quantities of the impurity in the substance manufactured and/or placed on the market.
- The emissions of the substance from all the lifecycle steps, in this case estimated using standard emission factors and the volumes from bullet 1. This would include the waste phase.
- Details of the measures taken to minimise emissions during manufacture, formulation, service life and the waste phase as required by Annex I para 6.5 of REACH.
- An analysis of alternatives setting out the different substances explored as replacements or technical possibilities to avoid the impurity in the substance (such as further purification steps possible to reduce the level of impurity), and
- socio-economic impacts of the proposed restriction on the company (loss of turn-over/profit, job losses, down scaling of investment), downstream users and society.

The above information needs to be presented in a way that the scientific committees are able to assess the conclusions drawn properly (e.g. assumptions taken, calculations made, etc.).

This information was considered by both RAC and SEAC in their final opinions and a decision by the Commission on the exemption was taken.