

## Public Consultation Guidance

This guidance is aimed at persons who wish to submit information in the public consultations on a restriction proposal (i.e. consultation on the Annex XV restriction report and consultation on the draft SEAC opinion). When sharing information please keep in mind:

- It is necessary to provide **supporting evidence** to justify the information submitted; if this is not done the Committees for Risk Assessment (RAC) and the Socio-economic Analysis (SEAC) will not be able to assess the information submitted.
- Information shared within the Public consultation on the Annex XV restriction report is likely to have a significant impact. However, you should send information as early as possible in the process<sup>1</sup>.
- Stakeholders from both the EU and outside EU are invited to submit comments.
- Information arriving after the closing date of either of the two public consultations or via other channels than the webform **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.

### What information can be submitted and the level of information needed

#### *Public consultation (6 months) on the Annex XV restriction report*

You may submit information to support or critique the restriction proposal, in the following categories (other information that falls outside these categories are of course welcome)<sup>2</sup>:

- **Scope or restriction options analysis**

*Responses 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 from the restriction proposal made by the Dossier Submitter. In addition, any restriction option in the Annex XV restriction proposal can be commented on or a new restriction option (such as a total prohibition, maximum concentration or migration limits, labelling, restricted sales practices, training etc.) can be proposed with*

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<sup>1</sup> Information received within 5 months of the start of the Public Consultation will be able to be included in discussions in the 2<sup>nd</sup> RAC and SEAC plenary discussions; these are often the key plenaries to shape the opinions of the Committees.

<sup>2</sup> 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.

*suitable justification in terms of both risk and socio-economic elements<sup>3</sup>. 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 can be submitted relating to the intrinsic properties of the substance(s) covered in the Annex XV restriction report. If the respondent submits a study on a particular hazard property that has not been assessed by the Dossier Submitter, then it would be helpful if a wider analysis of the hazard was also submitted considering the breadth of hazard information available, 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 the submitted study. Measured exposure information may also be submitted as well as information from modelling.*

- **Environmental emissions**

*Comments may be submitted on emissions to the environment and could include monitoring results 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**

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

- **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**

*Comments may be submitted on the availability and suitability of alternatives, (technical and economic), any information on risk or hazard etc. Evidence on the suitability of alternatives discussed in the Annex XV restriction report or on new alternatives would be welcome, e.g. test results.*

- **Information on costs**

*Responses may be submitted on the costs of the proposed restriction including costs of substitution, testing costs, remediation costs, etc.*

- **Information on benefits**

*Comments may be submitted on benefits (human health, environmental etc.) of the restriction, either qualitatively or quantitatively described.*

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<sup>3</sup> 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 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 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.

- **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**

*Comments may be submitted on any transitional period or deferred entry into force proposed e.g. is it sufficient to minimise costs and maximise benefits? Is it a sufficient time period for complex supply chain? Will it have any impact on stocks?*

- **Request for exemption**

*Responses may be submitted suggesting new exemptions or further supporting information on exemptions already proposed in terms of risks and costs.*

### **Public consultation (2 months) on the draft SEAC opinion**

You may submit information to support or critique the draft SEAC opinion that is agreed 9 months after the first public consultation was started. Any aspect covered in the opinion is open to comment but information relevant for the RAC opinion **will not** be taken into account.

Respondents may submit information in the following categories:

- **Scope of the restriction**

*Comments can be given on any issues related to the scope, such as the substances covered, any relevant concentrations limits and any derogations proposed (or not proposed).*

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

*Comments can be given on if an EU wide measure is needed.*

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

*Comments may be given on the proposed restriction option related to effectiveness, enforceability, monitorability, cost or benefits.*

### **Implications of incomplete, unsubstantiated or no information submitted in the Public Consultation**

When relevant and justified information is not provided via public consultations, these will be the assumptions 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 is low and that the restriction can be considered proportionate to the risk and affordable.*

- 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 could be withdrawn, if they are not sufficiently justified in the Annex XV dossier. Therefore, stakeholders affected by proposed exemptions are advised to provide justified information both on risks (human health or environment), and costs and benefits. *If no justified information is submitted* RAC and SEAC will assume that there is no need to withdraw or modify the initial exemptions.
- If new exemptions are requested, they have to be fully justified by risk or socio-economic arguments. It is necessary to submit a detailed explanation supported by technical and economic data, including the analysis of the available alternatives. Any information on alternatives should also include information on the risks as well as the socio-economic implications. *If no justified information is submitted* RAC and SEAC will assume that there is no need for that exemption.

### Is it your first public consultation?

Basic information on the restrictions process can be found at: <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction>.

Restriction proposals<sup>4</sup> submitted by Member States or ECHA will be published on ECHA's website here: <http://echa.europa.eu/web/guest/registry-of-submitted-restriction-proposal-intentions>. The proposals are not open for consultation at this stage as they are still going through a conformity check but this publication will allow you to start preparing for the future Public Consultation. You can contact ECHA (via restrictions functional mailbox: [restriction@echa.europa.eu](mailto:restriction@echa.europa.eu)) if you have any questions.

Once RAC and SEAC have agreed that the proposal is in conformity, the details of the public consultation will be published on ECHA's website and a notice included in ECHA's weekly eNews ([News and Events - ECHA](#)).

The public consultation of six months duration<sup>5</sup> then begins to allow stakeholders<sup>6</sup> to submit comments or additional information on the proposed restriction. Specific questions can be included in the public 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.

The opinions of RAC and SEAC will take into account the comments received in the public consultation. ECHA will publish the comments, together with the responses of the

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<sup>4</sup> 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.

<sup>5</sup> The duration of the public consultation is six months according to Article 69(6) of REACH.

<sup>6</sup> 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.

Dossier Submitter and the RAC and SEAC Rapporteurs, on its website after the end of the restriction process. In addition, ECHA will publish the comments received at the end of every month to allow all stakeholders to see the comments made: <http://echa.europa.eu/web/guest/restrictions-under-consideration>. An additional 60 day public consultation will be held at a later stage on the draft SEAC opinion to invite comments and inform the development of the SEAC final opinion. However, stakeholders are strongly advised not to limit their comments to this final round of the public consultation.

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