
# Webinar: Webinar: Towards faster regulatory action: ECHA's approach to assessing chemicals in groups

## Questions and answers

This document is based on the questions received during the webinar organised on 3 October 2023. Editorial changes have been made to improve clarity and similar questions have been combined.

The European Chemicals Agency does not accept any liability regarding the use that may be made of the information contained in this document. Use of the information in this document remains the sole responsibility of the reader.

For the most up-to-date advice, contact us or refer to our website.

| # | Question | Answer |
|---|---|---|
| 1 | "There is no consultation of stakeholders before publication however after publication we provide the possibility to send feedback to us." How is that feedback integrated after ARN publication? Is there a revision process? | Member States are consulted before the publication of an ARN. There is no consultation of stakeholders before publication however after publication we provide the possibility to send feedback to us. This information will be considered by ECHA later in case of an update which may come at a later time. Factual errors will be corrected from our side, but any disagreement will not necessarily trigger an update from ECHA's side. |
| 2 | ARN are not biding documents. How does ECHA plan to integrate ARNs in the coordination process with Member States and the Commission to plan regulatory management measures? | ARNs are informal assessments to support identification of candidates for REACH and CLP processes. Member States/Commission are consulted on the ARNs before publication and kept informed about their developments. Member States can decide to work further on individual substances and/or (sub)groups of substances and progress the candidates to formal REACH/CLP processes. The outcome of the |

| # | Question | Answer |
|---|---|---|
| | | ARNs has also been used to identify some candidates for the Commission's restriction roadmap. Ongoing work on the different substances/groups of substances is transparently communicated to MS and COM which support coordination. |
| 3 | As well as ECHA do other parties have input to the ARN development? e.g. member states competent authorities? | Member States competent authorities are consulted on all ARNs before their publication and can input where they see the need. |
| 4 | Why only Member states and not other interested stakeholders, does that not in a way contravene EU rules on accountability and good administration? | The consultation with Member States is to ensure a coordinated action from authorities' side as many of the substances we look at may have undergone some actions under other processes where some Member States may have been involved. As said already in the presentation this is an informal process, screening level assessment where ECHA has limited resources. The ARN work is to support identification of candidates for formal REACH/CLP processes where all stakeholders will be consulted. |
| 5 | How is that feedback integrated after ARN publication? Is there a revision process? | The feedback received is saved in our system for potential future update of the ARN. The ARNs reports may be updated after for instance hazard data have been generated, in other words when new information leading to change in the ARN becomes available. For that reason it may take some time before any update of the ARN is visible on our website. |
| 6 | Q on IUCLID v6.7 unexpected challenges, which might reappear in future. How do you work on data availability during these months, when some data migration is not working as it should? Do you go to CSR dossiers directly, do you always use both IUCLID technical dossier and CSR? | ECHA's screening and data analysis tools are maintained. If there is a planned IUCLID update we analyse what this means for our algorithms in collaboration with the IUCLID development team. If changes are necessary these happen prior to the IUCLID database migration. In this way we ensure business continuity. With regard to the CSR, it is available for data analysis and prioritisation but it is technically challenging given its document form. We would strongly advise to include all information in the IUCLID technical dossier, assuming that this is technically possible (i.e. there is a document/record to include the information, as is the case for toxicity studies and use information). The CSRs are of course used during the expert assessment, especially for subsequent regulatory processes. |
| 7 | Banning large groups of chemicals at once puts at risk the safety and wellbeing of medical device users as it is highly unlikely all uses will be captured and properly evaluated during a REACH restriction (as responses to the PFAS consultation have highlighted). How will this risk be mitigated? | We are only able to answer questions related to the content of the webinar. Please use our contact forms to submit your question: echa.europa.eu/contact |
| 8 | Chemical restrictions put EU medical device users at risk due to decreased device performance. Derogations are only granted if vast amounts of | Thank you for your question. We are only able to answer questions related to the content of the webinar. |

| # | Question | Answer |
|---|---|---|
| | data is submitted to justify 'essential use' and lack of alternatives. Why under REACH legislation is no one given responsibility for providing this data? | |
| 9 | Could you remind/clarify how are the "groups" formed? Tx. | We will address this during the presentation on Substance grouping approach. The creation of groups is based on structural similarity and, more specifically, on the presence of a substructure which is shared by all the group members. In the group generation process, we also take into account the existence of read-across/ categories provided by the registrants. |
| 10 | Do published ARNs clearly state the group type (explorative, hazard based, use based)? | The hazard profile of the group members in ARN will give an indication of the methodology considered for generating the group. For the use-based approach, the commonality at the use level is spelled out in the ARN. |
| 11 | Does ECHA (plan to) use IA for efficient screening of this enormous database and group definition? | Thank you for your question. Already now we are using as much as possible different IT technologies and models to enhance the grouping work to come out with broad set of substances which can be added to group. We are using machine learning for monitoring the registration database for new registrations/substances that could fall within existing groups. However, there is always an expert assessment following any AI/machine learning outcome. |
| 12 | How do the "category approaches" from the registration dossiers fit into the ECHA grouping approach? Tx. | The existence of categories in registrations is taken into account in the group generation process. If any of the substances retrieved via the chemical query belong to an existing category, all the category members are checked from a structural perspective and placed in the group only if fitting the group boundaries. However, it can happen that substances belonging to the same registration category end up in different ECHA's groups. |
| 13 | How do you ensure that less dangerous substances do not get an unnecessarily harsh classification as a result of grouping? | Some groups may be more heterogenous and contain substances with and without hazards within the same group. In those cases subgrouping may be used. The ARN report makes clear, why a certain hazard is expected – or not – for each group member and/or subgroup. Also the uncertainties related to the extrapolation of hazard properties are explained in the ARN report. |
| 14 | One ARN published suggests that a substance, although it has its own data showing no hazard, could still be classified based on the data of the other substances in the group due to similarity of structure... | In such cases, the reasons for extrapolation, and the uncertainties related to it, are explained in the ARN report. |
| 15 | How does ECHA prioritise substances for ARN assessment? What is the logic behind some groups substances being assessed first and others after? | A chemistry logic is considered to ensure that simple chemistries (e.g. where substances include only one chemical functionality) are addressed before the substances containing a combination of functionalities.<br>Substances that may be transformation/degradation products of other substances are expected to be addressed first (e.g. acids and alcohols would be addressed |

| # | Question | Answer |
|---|---|---|
| | | before the esters).<br>Chemistries covering a large number of substances registered at high tonnage are given priority over chemistries addressing substances registered at a low tonnage.<br>A target is to assess all the substances registered at >100tonnes per year and in the 'not yet assigned' region of the chemical universe.<br>There is also a need for some balance between explorative groups and hazard-based group (see the second presentation of the webinar) to ensure that substances with likely hazard are addressed in a timely manner.<br>All these considerations are factored in to prioritise the substances for ARN assessment. |
| 16 | How does the grouping for regulatory purposes within ECHA that has been presented here tie in with chemical regulations/restrictions planned under the Chemicals Strategy for Sustainability? | The Restrictions Roadmap is a tool to plan and progress restrictions and provides transparency on authorities' actions: it provides an overview of ongoing, planned and potential restrictions. This was one of the actions under the CSS. The ARNs are a source that inputs into the Commission's Restrictions Roadmap (substances or groups of substances where the first action is restriction or where restrictions is suggested but CLH is suggested as a first step): https://ec.europa.eu/docsroom/documents/49734<br><br>The suggestions made on regulatory actions in the ARN to the extent possible also consider the general context of the changing regulatory landscape. |
| 17 | How quick the CCH will follow after the ARN publication? | Depends on the workload, but it usually takes approximately 6-12 months from ARN finalization to opening of CCH workflow. If you see that your substance will be subject to CCH based on ARN report, you are encouraged to update your dossier, to enable evaluation based on the latest information available. |
| 18 | Is there a consultation process before the publication of an ARN? How does ECHA ensures equal opportunities to stakeholders to input on ARN assessment before publication? | Member States are consulted before the publication of an ARN. There is no consultation of stakeholders before publication however after publication we provide the possibility to send feedback to us. |
| 19 | REACH restrictions put the level of healthcare of EU medical device users at risk without adequately assessing the proportionality of this, as data on costs and benefits is typically lacking, violating Article 35 of the EU Charter of Fundamental Rights. Won't regulating chemicals by group be worse? | We are only able to answer questions related to the content of the webinar. |
| 20 | The approach to regulating PFAS in US states has been to introduce legislation to ensure companies provide data on uses and benefits of these chemicals before initiating restrictions. Is this not | We are only able to answer questions related to the content of the webinar. |

| # | Question | Answer |
|---|---|---|
| | an improvement to apply to REACH, especially where groups of chemicals will be regulated together? | |
| 21 | The ARN documents are described as iterative, therefore can Industry submit information, which may result in revised grouping, and if so how? Further if the ARN reports are iterative, is it foreseen that future revised versions will be published and if so, how often? | Your question will be addressed in the upcoming presentations. |
| 22 | The current REACH restriction process is deeply flawed, even for single substances, as insufficient information is available on uses and alternatives for authorities to make credible decisions (as reported by UmweltBundesamt). Will restricting whole groups of chemicals not just increase the problem? | The possibility to group substances under one Annex XV restriction proposal has been used in many restrictions that have been adopted, are being adopted or are under discussion. Restricting groups of substances has challenges but it is not a new concept. In addition to information from registrants, authorities can make use of calls for evidence during the restrictions preparation, and restriction proposals are subject to a third party consultation. |
| 23 | UmweltBundesamt have published reports, including 'Advancing REACH – The Restriction Procedure', which highlight how major data gaps in previous restrictions have hampered decision making. How will this failing be addressed before ECHA promotes the restriction of groups of chemicals simultaneously? | The possibility to group substances under one Annex XV restriction proposal has been used in many restrictions that have been adopted, are being adopted or are under discussion. Restricting groups of substances has challenges but it is not a new concept. In addition to information from registrants, authorities can make use of calls for evidence during the restrictions preparation, and restriction proposals are subject to a third party consultation. |
| 24 | The EU/ECHA clearly plan to restrict enormous numbers of chemicals. Will detailed info on which groups of chemicals face restriction, and when, be made available to avoid a vast waste of resources and time in developing new products/alternatives which will themselves be banned over the coming years. | Please note that any suggestion in an Assessment of Regulatory Needs is based on a screening level assessment. Often data generation is a first step, in many other cases harmonised classification is a first step. Whether or not a restriction will be proposed depends on the outcome of these steps and also on whether authorities will decide to prepare a restriction. See also PACT on ECHA's website to have an overview of planned, past or ongoing actions: https://echa.europa.eu/pact.<br><br>The ARNs are a source that inputs into the Commission's Restrictions Roadmap: https://ec.europa.eu/docsroom/documents/49734.<br><br>The Restrictions Roadmap is a tool to plan and progress restrictions and provides transparency on authorities' actions: it provides an overview of ongoing, planned and potential restrictions.<br><br>When authorities formally announce they will prepare a restriction proposal this intention is published on ECHA's website: https://echa.europa.eu/registry-of- |

| # | Question | Answer |
|---|---|---|
| | | restriction-intentions. |
| 25 | What is the legal basis in REACH for grouping substances for restriction purposes, knowing that REACH is based on the principle of "one substance one registration" and one risk assessment for each substance. Many thanks. | The possibility to group substances under one Annex XV restriction proposal has been used in many restrictions that have been adopted, are being adopted or are under discussion. So this is not new. There is nothing in REACH to prevent a group restriction. If this answer does not satisfy you, please send us your question using our contact form: echa.europa.eu/contact |
| 26 | What is the procedure for notifying ECHA and other stakeholders when a stakeholder disagrees with information and conclusions communicated through ARNs?<br><br>**Follow up**: but your presenter just advised that this button is not for use when a disagreement with the information would like to be publicly expressed. Please confirm what approach should be taken in this situation. thank you | On the ARN webpage there is a button "report an issue" that you can use to report to ECHA preferably the factual errors you may have noticed in the ARNs.<br><br>**Follow up reply:** You can of course use the button for expressing your disagreement as well. This information will be considered by ECHA later on in case of an update which may come at a later time. Factual errors will be corrected from our side but any disagreement will not necessarily trigger an update from ECHA side. |
| 27 | When a CCH in a Registration dossier starts, are the registrants notified via REACH-IT? | There are no automated notifications via REACH-IT. Information on substances and related regulatory activities can be found at: https://echa.europa.eu/pact |
| 28 | When a group is established, but a member of that group appears to have different properties, eg. is not reprotoxic (proven per OECD/GLP study) while others in the group are, I assume this substance will be exempt from the group approach? | The groups are primarily structure based and hence substances falling within the group structural boundaries are included. However, if it is already known on the basis of the existing data that substances may have different toxicological properties we will already propose subgrouping at the ARN stage. Keep in mind that substances in the same group will not necessarily be regulated in the same way. The group boundaries may also be refined at a later stage once more information becomes available. |
| 29 | Why does it take so long to take action when is know that regulatory measures are needed as e.g. for Flame retardants? | For aromatic brominated flame retardants ECHA concluded in its strategy for flame retardants that a wide and generic restriction would be needed for all such substances that are, or will be, PBT/vPvB. Further preparatory work may be needed before embarking on a restriction proposal.<br>For many other flame retardants data generation will start or is ongoing. Such data is needed to be able to determine the next steps or to confirm the suggestions in ARN.<br><br>See ECHA's strategy for flame retardants here. |
| 30 | Will ECHA publish a road map of ARN with all the groups planned for the years to come? | We do not plan to publish such a roadmap. Only via the published ARN reports and by following the ECHA Weekly Newsletter one can see which groups ECHA has assessed. |
| 31 | Will it be an updated restrictions roadmap? How is it related to the ARNs? | COM decides on the update of the Restriction Roadmap and considers different sources of information, among which ARN outcomes. |

| # | Question | Answer |
|---|---|---|
| 32 | Will regulatory actions also be done on (sub)-groups instead of individual chemicals? And if yes, what evidence do you need to conclude that a certain hazard applies to the entire group? | Assessment of regulatory needs may also refer to (sub)-group level actions. It is based on hazard information available at that point in time and it is a screening level assessment. The ARN document explains the basis of extrapolation, if used for that specific group of substances. If more data is generated, the regulatory hypothesis may be revisited. |