01 December 2021

Fit-for-purpose dossiers: Good practice guide (Restriction Task Force[1])

1. Purpose

The purpose of this good practice guide from the Restriction Task Force (RTF) is to convey practical advice on the elements previously successful in simplifying restriction proposals, with a view of developing fit for purpose Annex XV restriction dossiers. This guide is in addition to the assistance already provided here: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions (How to prepare an Annex XV restriction dossier) and here (Annex XV report format): https://echa.europa.eu/documents/10162/13564/annex-xv_restr_format_en.pdf/17a7d2d2-b769-41e4-afe6-c99d7c5d66f0. You will find some recommendations for Dossier Submitters from the RTF and some general advice in Appendices I and II respectively. This good practice guide is intended to be a "living" guide and will be updated when further good practice is identified.

2. Good practice guide: developing the Annex XV restriction dossier

2.1. Summary

- This should give the story of why the restriction is warranted and the key parameters that justify it. Remember many readers will only read the summary so it should be brief but give the key details.

2.2. Scope

Assistance with drafting the entry can be found in the RTF paper on a clear scope please, accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions. The following is some 'good practice' guidance to note in addition:

- Any limit value proposed should, for threshold substances, be derived from the DNEL/PNEC. However, another value may be used if justified and the impact of such a value assessed. For example, a limit could be set:

- corresponding to the lowest level detected in a mixture or article (e.g. 0.2% was the lowest level detected for BPA in thermal paper (no hazard related limit was derived);

- taking into account the individual concentration of the substance equal to or greater than either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or the relevant generic concentration limit specified in Part 3 of Annex I of Regulation (EC) No 1272/2008, or

- taking into account enforceability or implementability issues (e.g. the availability of test methods and quantification limits). For example, in the chromium VI in leather articles restriction a content limit of 3 mg/kg was set, related to the detection limit for the substance, but the impact was assessed and although the

[1] This paper was developed by the Restriction Task Force, consisting of representatives from Member State Restriction Dossier Submitters, ECHA's Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC) members and secretariat, and the Commission (DG ENV and DG GROW). It was endorsed at the CARACAL-37 meeting on 17 November 2020, and updated in December 2021 to include additional elements on AoA (Analysis of Alternatives).

limit set was above Lowest-Observed Adverse Effect Level for elicitation, it was assessed to be 80% effective reducing the risk.

- When there is no threshold (i.e. DNEL/PNEC) such as for a PBT/vPvB substance, specifying a limit value is difficult as it cannot normally be scientifically justified. The following are some possibilities open to the Dossier Submitter:

- Propose a total ban (i.e. without any threshold). Enforcement of such a total ban would be based on the availability/reliability of testing methods or to the limit of detection/quantification;

- Specify a limit in the restriction proposal, which is based on the availability/reliability of testing methods or to the limit of quantification. In the latter case, justification of the limit should make reference to the availability/reliability of testing methods or to the limit of quantification;

- Specify a limit below which a substance has no technical value in the mixture or article (e.g. in the lead in PVC restriction, the lead has no stabilising function below 0.1%), also taking into account the hazard of the substance.

- When both content and migration limits are considered, justification should be provided to avoid two divergent values;

- When the Dossier Submitter proposes exemptions, this must be based on the risk assessment, a socio-economic assessment or other justified considerations included in the Annex XV restriction dossier for this purpose;

- The terms “direct” or “indirect” relating to contact should be avoided unless fully described in the Annex XV restriction dossier;

- The term ‘intended for’ in terms of use should be avoided (c.f. dichlorobenzene restriction). In the microplastics restriction proposal on intentionally added microplastics the proposal did not mention intentionally added but instead the concentration limit set was at a level below which only unintentional impurities exist;

- If the frequency of contact is specified in the exposure scenario this may be reflected in the wording of the restriction entry (if needed) as was done with the phthalates restriction. Vague terms relating to the frequency of contact such as short, repetitive, long term, prolonged etc. should be avoided, if possible. If the frequency of contact is quantified in the restriction proposal the enforcement of this element should be assessed. Also “normal and reasonably foreseeable conditions of use” can be referred to (see guidance on substances in articles guidance). However, if the frequency of contact is well specified in the exposure scenario this may be reflected in the wording of the restriction entry (if needed) as was done with the phthalates restriction (entry 51 of Annex XVII);

- When considering a restriction for a group of substances, consideration should be given to include potential alternatives in the restriction if they may pose risk and could lead to regrettable substitution;

- When considering a restriction related to industrial use of a substance, it is the responsibility of the Dossier Submitter to document the justification for restriction and this should include an explanation why they are taking this approach as opposed to using OSH legislation. The relative regulatory speeds of the two legislative approaches are not sufficient justification in this regard. If there are existing occupational exposure limits or specific risk management for a substance

covered under the OSH legislation (CAD or CMD), a possible revision should be considered first under OSH legislation (e.g. a revised OEL);

- Guidance to implement the restriction should not be considered as a default document accompanying each restriction proposal;

- As far as possible, the scope (or, the exemptions, if applicable) should be clearly and exhaustively defined in the restriction proposal, rather than referring to a later guidance, which itself is not legally binding, and thus creates uncertainty in the enforcement;

- The RTFs papers concerning recycling (see Section 3), grouping (see Section 4) and how to regulate professional users border lining with Industrial and consumer users (see Section 5) could also be a reference related to scope issues.

2.3. The problem identified

- Registration dossiers are a starting point for restrictions, but they often suffer from a lack of information, especially on exposure. In such cases the Dossier Submitter may complement the registration information with a reasonable worst-case modelling or other assumptions and test them in the consultation on the Annex XV restriction dossier;

- If a recent hazard assessment is available, e.g. from an EU Agency, an EU Scientific Committee or the WHO, then this should be used in the dossier, unless there is information that justifies a deviation from such a European or international assessment;

- The minimum exposure information in the dossier should be a basic description of the situations in which humans or the environment are exposed and the reasons, why the Dossier Submitter assumes them to be exposed at all. The assumptions and their uncertainties need to be clearly described. The exposure assessment may be based on a worst-case scenario without any specific need to address each specific use or each specific exposure scenario. Measured data is not required but should be used where available;

- The risk assessment done by the Dossier Submitter should conclude that control of the risks identified is either adequate or inadequate (either through RCR>1, or other methods in case of non-threshold substances). If a dose–response relationship is available this can be used to show the population at risk and determine the risk reduction of any measure;

- For non-threshold substances, other than PBT/vPvB substances, in case a semi-quantitative assessment is not possible due to a lack of data (the normal case) it could be considered to also use the PBT type approach – such as the use of emissions as a proxy for risk (c.f. lead in PVC). This is in-line with Annex I para 6.4 to develop a qualitative assessment, where a DNEL or PNEC cannot be derived;

- Other substances may require a case-by-case approach to the risk assessment (e.g. the microplastics restriction was built upon extreme persistence) as in Annex I para 0.10;

- Exemptions (based on adequate control of risk) – any such exemptions must have been assessed in the risk assessment;

- Data from national sources, legislations, data collection including any available scientific report conducted by organisation or by voluntary actions of industry

should be considered by the Dossier Submitter in developing the proposal.

2.4. Impact assessment

- The Dossier Submitter should consider whilst assessing the need for a restriction if any existing EU legislation is more appropriate for managing the risk. If this is the case, the relevant Member State should submit the Annex XV restriction dossier to the European Commission. If the Dossier Submitter considers a restriction is the most appropriate measure, the Dossier Submitter is required to analyse their proposed restriction option(s) in the Annex XV restriction dossier (Annex XV requires the effectiveness, practicality, monitorability of the proposed restriction to be justified). Section 2 of the report and the Impact Assessment annex should contain the proposed Restriction option (one or more), any discarded restriction options and give a justification of why existing legislation, other RMOs or voluntary means are not suitable for dealing with the identified problem. The option for new (stand-alone) legislation need not be considered because such an option was analysed at the RMOA stage and discarded;

- Certain information on socio-economic parameters needs to be included in the Annex XV restriction dossier submitted by a Member State/ECHA, even if a full SEA is not carried out;

- The section 'Justification for Restrictions at Community Level' requires that the practicality of the restriction is assessed, including if it is implementable, enforceable and manageable; without any information on resource implications, on for example compliance costs for authorities and business, these three criteria will be challenging to judge against;

- As a minimum the dossier may include information on (groups of) actors affected by the restriction, main impacts expected, explanation of the approach proposed to assess the impacts (e.g. cost/benefit, cost-effectiveness, breakeven analysis, etc.), sources of information, main assumptions;

- Dossier Submitters may complement the SEA along the opinion-making process, depending on which information will be available through the consultation on the Annex XV restriction dossier and on the specific requests from RAC/SEAC;

- Exemptions from the proposed scope of the restriction (based on socio-economic implications) – any such exemptions must be based on fit-for-purpose socio-economic analysis (e.g. explaining consequences for certain sectors or society; and/or indicating that certain sectors/products would be disproportionately affected; and/or indicating that the net costs to industry, DUs, consumer or society clearly outweigh the net benefits to human health and environment);

- Impact assessment should aim to describe the most probable scenario in terms of impacts (central tendency estimates), which would cover largely all the mixtures and/or articles considered in the proposal. To achieve this, assumptions made in the risk assessment may need to be reconsidered. Reasonable worst-case scenarios in some cases may be used;

- For non-threshold substances other than PBT/vPvB substances, it could be considered to use the PBT type approach – cost-effectiveness (c.f. lead in PVC);

- The Restriction Task Force recommended that the Dossier Submitter submits at least the following information with regard to proportionality:

- An estimate of economic implications (costs or savings) of the restriction, as well

as considerations of its risk reduction capacity;

- If possible and meaningful, quantification of the human health/environmental impacts or, otherwise, a qualitative description of these benefits;

- The Dossier Submitter should undertake an Analysis of Alternatives (AoA) to provide information on whether equivalent function/s to those provided by the substance of concern can be obtained by other substances or technologies, and for assessing the net impact of the proposed restriction on human health and the environment.

- Firstly, the section on 'Information on alternatives' in the Annex XV report should provide information on the uses and function/s performed by the substance of concern as well as on the economic importance of the substance. Also, it is helpful to present data on the relative scope of uses – volumes and values of production, volume of substance use, etc. – so that the most important market segments can be identified and prioritised for a detailed examination.

- Secondly, the Dossier Submitter should identify and describe potential alternatives (be they alternative substances, technologies, or other innovative solutions) that could replace the use of the substance of concern.

- The Dossier Submitter should evaluate the technical and economic feasibility as well as the availability of the identified alternatives and properly document its evaluation and the criteria used to conclude on the performance of alternatives.

- The Analysis of Alternatives (AoA) is the place where the available information on alternative substances and technologies should be documented in the restriction proposal. It also is the starting point of the Impact Assessment as it typically determines the counterfactual, i.e. the scenario in which the substance of concern is restricted.

- There is no requirement to identify any specific alternative as the most appropriate one. Information on alternative substances or technologies may be found here:

- https://echa.europa.eu/search-sea

    - https://echa.europa.eu/substitution-to-safer-chemicals

    - https://echa.europa.eu/search-for-alternatives-for-substitution

  When determining the costs from substituting to an alternative (or mix of alternatives), it may be sufficient to assume the lowest cost alternative would be adopted (taking into account suitability). However, it should be considered if an approach of realistic mix of alternatives is more appropriate or the costs of other alternatives could be used in sensitivity analysis;

- In the AoA, development of a comprehensive risk assessment of each alternative is not needed but if risk information is already available it should be documented. The hazard information and any available information on the exposure to alternatives is sufficient to document.

- If the alternatives are unknown, or where there would be many potential substitutes, look for products or similar industrial processes that do not use the restricted substance and use information on those products or processes to gauge the impacts of the restriction (e.g. D4-D6 restriction or tattoo inks restriction approach).

- As alternatives may not be always developed until regulation enters into application (legislation has been shown to be a driver of developing alternatives) a transitional period may be used to allow industry to develop alternatives if a suitable alternative is not available. The timing of such a period must consider the risk and the socio-economic impact of the ongoing use of the substance and should be based on information submitted by stakeholders during the restriction dossier development or can be tested in the consultation on the Annex XV restriction dossier. The impacts of these transitional periods to human health and environment should adequately be described and assessed by the Dossier Submitter and the ECHA Committees.

- The findings from the Analysis of Alternatives (AoA) should be used by the Dossier Submitter for identifying the least-cost compliance scenario. However, the Dossier Submitter should keep in mind the need to predict what the response of industry would be to any restriction. Firms will not necessarily adopt one of the identified alternatives, but might instead decide to change their processes, relocate their businesses outside the EU, or (fully or partially) close. Identifying these scenarios and related impacts should generate a more accurate estimate of the welfare costs of a restriction, thereby excluding options which are clearly commercially unviable. Also, in the scenarios where the products relying on the substance of concern are expected to be removed from the market, it would be important to qualitatively evaluate how the consumer surplus might be impacted.

- The Dossier Submitter can also use the AoA to evaluate the proportionality of the restriction considering the substitution costs expected to occur under the restriction scenario and the expected reduction in risk.

- The findings from the AoA are also relevant for assessing the need to introduce possible derogations, which for example allow the continued use of the substance in certain applications where the evidence suggests that no suitable alternatives are available, the societal consequences would be substantial, and therefore a restriction might be disproportionate.

- The AoA can also provide information on whether the restriction might lead to regrettable substitution and this might be used to extend the scope of the restriction to include these alternatives and prevent such 'regrettable substitution'.

- The AoA can also serve to highlight evidence gaps and uncertainties and so invite contributions from third parties to fill those gaps.

- Finally, the AoA should have a clear presentation and list the key information sources. The analysis should also clearly describe all the gaps and weaknesses in available information. This is particularly relevant considering that in general the Annex XV report faces a relative information deficit over industry processes and alternatives, and this will always make undertaking an AoA a challenging exercise.

- For Guidance on how to undertake the AoA, please refer to the separate document on this topic which also includes examples of AoAs undertaken in the restriction dossiers.
  https://echa.europa.eu/documents/10162/17228/review_aoa_tei_echa_en.pdf/6e516ea4-4207-4197-1623-91c8ed702ef3?t=1638888614689

3. Consideration on second hand, stocks and recycling

- For guidance on how to consider **second hand articles, stocks and recycling**, please refer to the separate document on this topic, accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-

report/general-instructions.

4. Grouping of substances to be covered in a single restriction dossier

- For guidance on **grouping of substances to be covered in a single restriction dossier**, please refer to the separate document on this topic, accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

5. A thought starter on how to better regulate professional users' border-lining with industrial and consumer users under REACH restriction

- For guidance on **how to better regulate professional users border-lining with industrial and consumer users**, please refer to the separate document on this topic, accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

6. Uncertainties / lack of information

- Deficiencies in the dossier due to a lack of information should be clearly stated and qualified (how important are these for the decision-making?). A clear characterisation of the uncertainties is important as these may lead the Commission to invoke the precautionary principle (see also the RTF paper on uncertainties which has been the basis to implement Action 10 of the REACH review).

- It may be possible that some information could not be gathered during the Annex XV restriction dossier preparation (e.g. measured exposure information, costs of alternatives, other impacts). This should not prevent the submission of the dossier as long as the Dossier Submitter makes reasonable inquiries to find the information, records that in the dossier and makes relevant assumptions (e.g. uses reasonable worst-case modelling, assumes low costs etc). In these cases, the lack of information should not have a negative impact during the conformity check procedure (i.e. the dossier should not be found to be not in conformity), and the information should be gathered during the consultation (if possible). If relevant justified information is not submitted in the consultation it may be assumed that the assumptions used are correct. New information from registrants should also be included in the registration dossiers at the same time as the consultation submission is made.

- For guidance on **how to describe uncertainties in the evaluation of restriction proposals**, please refer to the separate document on this topic, accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

7. Conclusion

- The conclusion should briefly draw together the elements justifying the need for the restriction and present a possible draft Annex XVII entry. However, it should be remembered this draft entry is only one way of describing the scope of the restriction and that the Commission will provide the final Annex XVII entry.

- In general, the Annex XVII entry should address (where relevant):

- A clear substance ID (either specific EC/CAS identifiers or a well-defined generic entry);

- Any limit value for content or migration;

- The uses covered by the restriction (if it will not apply to all uses);

- Any exemptions;

- Any further conditions linked to the risk management of the substance(s) covered.

The Annex XVII entry should not contain:

- A review clause (because the restriction can be reviewed at any time by the European Commission or Member States). If a Member State wants the European Commission to take action for a review clause this should be raised during the REACH Committee meetings and the need for it should be justified in the Annex XV restriction dossier;

- Reference to a specific testing method when a migration limit or a content limit is already proposed on the basis of existing and available analytical method (see Forum guide for Dossier Submitters; (https://echa.europa.eu/documents/10162/13577/guide_on_enforcement_for_dossier_submitters_en.pdf/6c10f087-d932-4e73-a67d-8453b9a67c0b) and the compendium of analytical methods (https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf/3807683c-5340-4638-b5bc-5554635cdc8a).

Appendix I: Dossier Submitter relevant recommendations

Taken from the 'Recommendations from the Restriction Task Force', accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

Recommendation
Possibility for Dossier Submitters to meet bilaterally with ECHA > 6-9 months before submission of dossier (PRIM – Pre-Restriction Information Meeting): • A clear scope is a key issue to discuss. • Enforcement issues as a standard agenda point.
If requested, ECHA to 'host' Dossier Submitter's call for evidence to provide access to > 15000 newsletter recipients.
Provide a forum for the Dossier Submitter (if required) to discuss key issues (e.g. scope) with other Member States before submission.
Member States encouraged to work together or provide a possible pool of experienced Dossier Submitter contacts; those who gained more experience should share this experience with others to stimulate their participation.
MSCAs are suggested to consult their national Forum member at the drafting stage (before the dossier is submitted to ECHA) and National Forum member to cooperate with MSCA during the drafting process.
MSCAs and Forum members from submitting countries to take into account the Forum guide for developing Forum advice on Enforceability of Restriction Proposals (GDAERF), in addition to the Annex XV guidance, as help for the assessment of the enforceability of the Annex XV proposals.
GDAERF to be revised by Forum and then consulted with MSCAs to promote a common understanding of the enforceability assessment.
Other resources to be made available by ECHA - may be considered by Dossier Submitter and Forum member to assess enforceability.
Dossier Submitter to highlight key issues in dossiers, including uncertainties (e.g. in the scope), to focus and facilitate the evaluation of RAC/SEAC (e.g. in specific boxes).
Dossier Submitter's role in opinion making process to be clarified, especially to highlight where they are expected to give input into the process.
More dialogue is encouraged between the Rapporteurs and Dossier Submitter before the conformity check. • Dossier submitted two weeks earlier and dialogue thus possible between Dossier Submitter and Rapporteurs related to CC.
Substance ID to be clear (normally EC/CAS or groups, grouping justified) – ECHA to provide SID 'service' when requested by Dossier Submitter.
It is possible to improve access to data on costs through (commercial) databases: It is recommended that ECHA acquire access to a database that provides information on prices

Recommendation
and quantities of substances sold in the EU and rest of the world and make this information available to Dossier Submitters, subject to any commercial/contractual conditions (i.e. data aggregation may be required).
It is recommended that ECHA and COM discuss with Eurostat how it and MSCAs can access (easiest) their databases on e.g. products, population data, and foreign trade of the EU.
Dossier Submitter must submit the following information to demonstrate proportionality: • an estimate of cost implications or savings (net costs) of the restriction as well as consideration of its risk reduction capacity, and if possible and meaningful quantification of the human health/environmental impacts.
Dossier Submitter should undertake an Analysis of Alternatives (AoA) to identify the alternative substances and/or technologies able to meet the function/s provided by the substance(s) of concern, including an assessment of performance. The assessment should also cover the economic feasibility of alternatives, their availability as well as their health and environmental profile.
Dossier Submitter should use the AoA for assessing the need to introduce possible derogations, as well as assessing the risks of regrettable substitution.
Dossier Submitter should consider the findings in the AoA to identify the most likely response of the stakeholders to the restriction.
Dossier Submitter are encouraged to analyse socio-economic impacts in accordance with Annex XVI to support the restriction.
It is clearly recognised that the quantification of human health and environmental impacts is not always possible.
Dossier Submitter should investigate with any national institutes to obtain information e.g. costs of diseases.
Step-by-step approach (as suggested in the SEA guidance document) necessary: • Identification of all potential impacts (e.g. economic, environmental, social, health); • Qualitative assessment of impacts (including an assessment of order of magnitude); • Quantitative assessment of impacts (that are meaningful to quantify); • Quantify most significant impacts; • Approach likely to be iterative.
When data is missing, use reasonable and justified assumptions.
Carry out sensitivity analysis to identify the impact of most critical assumptions.
Use the consultation on the Annex XV restriction report for verifying key data and validating the assumptions.
ECHA to assist Dossier Submitter with gathering information on health and environment impacts during the Dossier Preparation stage starting during the PRIM and specifically when co-operating on any call for evidence.

Recommendation
Ensure all new guidance is accessible to the Dossier Submitter; consider use of summary document/quick guides with the reference to these recommendations.
Share names of consulting companies or consultants that have helped in preparation of restriction proposals; ECHA could keep a “master list” for everybody's information.
Share experience of Dossier Submitters who worked together in the preparation of an Annex XV dossier.
Member State to cover impact on SMEs in Annex XV dossier, even if only qualitatively.
Explore if ECHA’s framework contract could be used by Member States or if a joint framework contract could be established for procuring support by consultants.
Dossier Submitters are recommended to actively contact and consult stakeholders as soon as possible during the development of the restriction proposal, such as through a dedicated workshop with key stakeholders including researchers.
The current structure of the RoI should be reviewed to encourage stakeholders to submit early information to Dossier Submitters by clarifying the need for information to motivate derogations.
To explore whether REACH registration database can provide information on alternatives for same/similar uses across different substances.
ECHA and Member State to consider the need for market research training or other capacity building measures on market research.
ECHA and COM to draft guidance to help Dossier Submitters on how to best use wide scope restrictions (grouping approach, many uses), including to cover in the scope of the restriction unwanted ‘alternatives’, at the same time as the substance(s) in focus (avoiding regrettable substitution).
ECHA and COM to provide a paper to be agreed by the RTF exploring descriptions of professional use vs industrial use to inform Dossier Preparation, particularly useful for the definition of the scope.
ECHA, COM and Member State to further discuss the preparation of a list of substances for potential restrictions. ECHA/COM to prepare the first draft to be circulated to Member State. The list should provide inspiration to Member States considering restrictions. Consideration should be given to making the list publicly available (with clarifications on why the substance is on the list) and request industry to update registration dossiers or submit other information for further consideration and to remove substances where suitable evidence is received.

Appendix II: General advice

1. Discuss if co-operation on the dossier is useful

It has previously been discussed that some Member States have limited capacity and experience of restriction dossier preparation, especially regarding SEA, often with no economists in the REACH-CA team. Some representatives of smaller Member States have expressed an interest to become more involved in the restriction process and to co-operate with more experienced Dossier Submitters, such as ECHA.

Collaboration between Member States, or with ECHA, has been reported as being beneficial if there is clarity of roles and the organisation in the team. It was recognised that different points of view help to make the dossier better along with complimentary expertise. However, there may be differences in views that partners would not manage to solve, and this raises wider issues how to get broader agreement on cross-dossier issues, such as when is there a risk at EU level. These issues should be clarified at the beginning of such a collaboration.

ECHA is willing to collaborate on developing Annex XV restriction dossiers with Member States, through PRIMs, calls for evidence and other support, where resources allow (see previous RTF recommendations).

2. Conflict of Interest

Ensure there is a conflict-of-interest policy in place.

ECHA's MB adopted in February 2019 "Memorandum of Understanding (MoU) for ensuring the independence of Member State services to be provided to ECHA". The MoU states that:

> *More in particular when the Member States contribute to a regulatory process under the mandate of ECHA or when preparing opinions or decisions that will be reviewed by ECHA (and especially for the processes of Substance Evaluation, Restriction, Authorisation for which the Member States have concluded cooperation agreements with the Agency), the Member State Competent Authorities should be responsible for putting in place and maintaining a documented system ensuring that their experts, staff and subcontractors participating in the work at national level for services provided to the Agency, including experts appointed as (Co)-Rapporteurs, have no conflicting private interests which could affect their impartiality.*

3. Prepare RoI entry

Ensure the RoI entry is drafted and submitted to ECHA through: https://comments.echa.europa.eu/comments_cms/DossierIntentionRestrictions2010.aspx. There are 4 submission dates through the year (found at: https://echa.europa.eu/support/restriction) that introduce the restriction into the Scientific Committees cycle. If a dossier is submitted on a different date, they will be held until the next submission date before processing. In each RoI entry there is a call for stakeholders to submit information to the relevant Dossier Submitter.

For transparency reasons the dossier will be made public on ECHA's website approximately two weeks after submission.

4. Co-operation with ECHA

ECHA is prepared to help any Member States during their Annex XV preparation from

providing advice to co-operating with dossier preparation. ECHA can help with SID advice, call for evidence preparation (including any introductory WebEx that is agreed, such as with the microplastics dossier), workshop preparation, entry review (Q&A perspective) etc.

5. Prepare Annex XV report format

The following stages describe how ECHA prepares a typical Annex XV restriction proposal.

5.1. Introduction

The following steps describe how ECHA manages a dossier and not all steps may be necessary at the Member State level.

5.2. Hold project initiation / problem identification

- Decide on strategy for information gathering;
- Identify interim deliverables, timelines, and persons responsible for development;
- Write project plan.

5.3. Hold scoping review (after initial information gathering)

- Decide/refine problem identification and further information needs;
- Identify any need to update the project plan e.g. additional deliverables, timelines, and persons responsible for development of scoping report.

5.4. Prepare scoping report (using Annex XV format)

- Consultation with Commission/management (ECHA Dossiers)/ECHA (Member States Dossiers) in terms of general lines to take.
- Identify interim deliverables, timelines, and persons responsible for development of a draft report (Annex XV dossier) based on scoping report.

5.5. Produce and review draft report

- Draft report and decide on Annex requirements (they do not need to be lone standing documents and do not need to repeat what is in the main report; their intention is rather to provide the technical details that support the conclusions in the main report).

5.6. Draft Annexes (as necessary)

- Annexes should not duplicate information in the main report (as a rule, an Annex is only needed if it does contain relevant information that is left out from the main report for conciseness).

5.7. Prepare IUCLID

- Only needed if there is new hazard information that has not been previously submitted to ECHA.