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REV1

Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

Background

The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) check if the Annex XV restriction dossier conforms to the requirements of Annex XV of REACH and then develop opinions on the restriction proposal.[1] In the handling of almost 30 restriction proposals (19 of those already decided), the Committees have implemented many principles on how to handle the dossiers. In order to make the process more transparent and efficient, the Restriction Efficiency Task Force (RETF) recommended developing a Common Approach paper for the restriction process. Based on the experience by the Committees and the recommendations by the RETF the Framework for RAC and SEAC in checking the conformity and developing the opinions on restriction proposals was agreed at the RAC/34/2015/06 and SEAC/28/2015/04 in September 2015.

Since the agreement of the document, Restriction Task Force (RTF) has made further recommendations, developed several support documents, which were endorsed by the CARACAL and the Committees have gained additional experience of providing opinions on restriction proposals.

The ECHA Secretariat has now updated the document based on the experience gained and taking the RTF support documents into account. The document was introduced at the RAC working group in May 2021, RAC and SEAC written commenting rounds were arranged in May 2021. The updated document was introduced at the RAC/A/57/2021 and SEAC/A/51/2021 and finalised in June 2021. The Common Approaches to Conformity Check and Opinion Development are presented as Annexes.

[1] Restriction process: https://echa.europa.eu/restriction-process

Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

Preface

The processes of checking the conformity of a restriction dossier and developing the opinions of RAC and SEAC on restriction proposals are described in the working procedures of the Committees, which are supplemented by guidance in the conformity check and opinion templates themselves[2]. This framework note complements these documents. Common Approaches for conformity check and opinion development are annexed to this paper.

This note does not document all aspects of the Committees' work; rather, it concentrates on issues where the line to be taken may not be obvious and a Common Approach is needed for both Committees. Priority has been given to documenting the approach taken for issues that have been problematic in previous Committee discussions and to implementing the recommendations and the content of the support documents made by the Restriction Task Force (RTF)[3] and published on ECHA website under the restriction support pages (listed also in Annex 3).

It is to be noted that some of the support documents prepared by RTF and endorsed by CARACAL are guiding the Dossier Submitters in preparing the restriction dossiers. These documents need to be taken into account also by RAC and SEAC in checking the conformity and in developing the opinions. The documents include e.g. a good practice guide to make a simplified restriction proposal fit for the purpose and how to cover group of substances in a single restriction dossier.

The original note has been developed by the ECHA Secretariat, RAC and SEAC, and the relevant Commission services. It is now reviewed by the ECHA secretariat taking into account the experience gained in providing the opinions on restriction proposals and also taking into account the work done by the RTF. New review will be done as appropriate.

1. Purpose

The purpose of this note is to describe how RAC and SEAC carry out conformity checks and evaluate Annex XV restriction proposals, as well as:

- implementing the RTF recommendations that would not go to procedures or templates;
- providing consistency in opinion making by approaching issues in the same way; and
- allowing Dossier Submitters, and stakeholders to understand how the Committees would in general treat restriction proposals.

This note documents the interaction of the Committees with the Dossier Submitter, the Commission services and the stakeholder observers of the Committees. It also describes the support provided by the ECHA's Restriction Team (RT) to the (co-)Chairs, to the Committees and to the (co-)rapporteurs.

[2] Supporting documents can be found from ECHA's website:
http://echa.europa.eu/web/guest/about-us/who-we-are/committee-for-risk-assessment
http://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis
http://echa.europa.eu/web/guest/support/restriction
http://echa.europa.eu/web/guest/support/socio-economic-analysis-in-reach

[3] The Restriction Task Force consisted of the members from the Member State Competent Authorities, members from RAC and SEAC, members from the Commission services and from the ECHA Secretariat.

2. Guide to Dossier Submitters and its effect on Committees' work

In addition to the Guidance documents and format on how to prepare an Annex XV restriction dossier, several documents have been published to support the Dossier Submitters in preparation of the restriction proposals. The Restriction Task Force (RTF) has been the main driver in initiating such documents and before publishing they have been agreed by the CARACAL. At the stage of consulting CARACAL, stakeholders have the possibility to submit comments on the RTF documents. Adherence to the principles described in these guiding documents for the Dossier Submitters, should also be taken into account by RAC and SEAC in the opinion development where appropriate.

The documents are published on the ECHA website, once agreed and Annex 3 provides a diagram where to find those on our website.

3. Support from ECHA's Restriction Team

ECHA designates a Restriction Team (RT) around 4 months before the submission of the dossier. The RT usually consists of the Restriction Team Manager, a co-Manager, a Committees coordinator and a team assistant.

The RT supports the (co-)Chairs, Committees and (co-)rapporteurs of RAC and SEAC throughout the handling of the dossier and facilitates communication with the Dossier Submitter. The RT is especially required to keep the (co-)Chairs informed about the ongoing work in order for them to chair the meetings efficiently. In addition to preparing the preliminary conformity check report for an Annex XV dossier submitted by the Member State, the RT provides support by providing a partially pre-filled opinion template (including the text summarising the restriction proposal in the submitted dossier) to the (co-)rapporteurs, by commenting on different drafts submitted by the (co-)rapporteurs, e.g. presentations, conformity check report, recommendations and opinions. The comments by the RT might relate to the consistency with the previous opinions, editorials, other technicalities and sometimes related to the content. All comments are for the consideration of the (co-)rapporteurs.

If the restriction proposal has been submitted by ECHA, on a case-by-case basis the RT for the case will be different than the staff acting as a Dossier Submitter. In case the RT is the same than the DS, the RT still supports the (co-) rapporteurs in a relatively limited manner unless the (co-)rapporteurs request differently. As Dossier Submitter representative, the RT ensures correct understanding of the proposal by the (co-)rapporteurs. As secretariat, the RT ensures consistency and quality of the opinion. The Committees coordinator's role includes ensuring the separation of the roles and the independence of the evaluation.

The RT also supports the (co-)rapporteurs in preparing their responses to consultation comments on both the Annex XV report and the draft SEAC opinion.

Other support includes:

- Managing the consultations and providing information on them to the Dossier Submitter and (co-)rapporteurs;
- Facilitating the dialogues (e.g. preparation of draft agendas and action points, and chairing the sessions on the request of the (co-)rapporteurs (in case of ECHA's dossiers, the Committees coordinator chairs the dialogues on request of the (co-)rapporteurs);

- Coordinating the work of the (co-)rapporteurs and the Dossier Submitter;
- At the request of the (co-)Chairs - other information gathering from stakeholders or scientific support to the (co-)rapporteurs and the Committees;
- Liaison with the Forum working group on enforceability of the restrictions in the preparation of the Forum advice and the ECHA legal experts, if needed. Normally, no legal support is needed for developing the Background Document or the opinions but rather clarifications may be sought on the wording of the restriction proposal in some circumstances; and
- Interaction with the Commission services during the opinion making process (more info in section 7).

4. Treating information received during opinion development

It is not the task of RAC, SEAC or the RT to gather additional information or data. The opinion should be based on the information provided by the Dossier Submitter in the Annex XV dossier, on any information additionally provided by the Dossier Submitter to the (co-)rapporteurs, on the information received during consultations and on the Forum's advice. The Committees are not required to redo the Dossier Submitter's assessments; however, in evaluating them, they may choose to agree on different key studies, dose descriptors, exposure parameters, modified Risk Management Options, cost information, incorporation of information from the consultation if necessary, etc. The opinion should highlight how enforceability concerns raised in the Forum advice have been addressed. In this regard, if the Dossier Submitter has adequately demonstrated a risk or that the measure is proportionate to the risk (taking into account the Committees analysis), then the assessment of the Committees should be that the measure is justified unless information from the consultation calls this into doubt.

4.1. Information through consultation[4]

To maximise the benefits of the consultation, the Committees and their (co-)rapporteurs, together with the RT and the Dossier Submitter, identify the issues in relation to which they want to get more information through consultations. The basis for the questions could be the recommendations by the Committees to the Dossier Submitter to provide specific information after agreement on its conformity and important missing information, or uncertainties that the Dossier Submitter has communicated to the Committees through the Annex XV dossier. The consultation can also be used to verify key data and to validate the assumptions made in the Annex XV dossier.

Specific questions to interested parties will be published on ECHA's website as part of the consultation. During the consultation it is possible to supplement it by adding supplementary specific questions if a need for this arises during the opinion development. Such extension however, is an exception since adding the questions during consultation creates confusion. The reasons for supplementary questions need to be described when published.

The information note that is prepared by the (co-)rapporteurs together with the RT and the Dossier Submitter for the consultation on the Annex XV report, provides a short introduction of

[4] Consultation guidance is published on ECHA's Consultations website: https://echa.europa.eu/restrictions-under-consideration. The guidance was updated by RTF and endorsed by CARACAL in November 2020.

the proposed restriction and information on the deadlines of the consultation. It describes the scope and the conditions (e.g. concentration limit/transition period) of the restriction proposal, but also any proposed derogations, together with the information on the basis of which the Committees will evaluate the need for derogations (from both the risk and socio-economic impact perspectives). In addition, the information note highlights that information submitted through the consultation must be accompanied by relevant supporting data (especially related to additional figures of costs or when the comments are challenging the selected studies and DNEL derivation or the exposure assessment provided by the Dossier Submitter), enabling the Committees to evaluate the reliability/validity of the information.

The consultation guidance published on ECHA's website, provides further guidance for the stakeholders intending to submit comments during consultations. In addition, the guidance provides information on the assumptions expected to be made by the Committees if incomplete, unsubstantiated information or no information is submitted in the consultation.

As required by REACH, the RT notifies immediately the registrants of the relevant substance(s) about the start of the consultation. However, to reach other stakeholders, the RT also informs:

- the notifiers to the classification and labelling inventory of the relevant substance(s),
- registrants of the alternatives described in the Annex XV dossier or registrants of any other alternatives identified by the (co-)rapporteurs,
- notifiers to the classification and labelling inventory of such alternatives and
- other relevant stakeholders (e.g. those who have notified the substances listed on the Candidate list which are present in their articles, and those who have submitted downstream user notifications).

Simultaneously with the notification to the registrants, Member State Competent Authorities are also informed about the start of the consultation so that they can contact the relevant national associations and other relevant parties. ECHA may contact, after consulting and agreed with the (co-)rapporteurs, specific companies, branch organisations, NGO's or scientific experts to alert them to the consultation and invite them to submit information when deemed relevant.

If members of RAC or SEAC have information which is relevant to the case (especially new scientific publications), this information should preferably be submitted via the consultation to ensure transparency for all involved in the process.

The Committees evaluate the Annex XV dossier within the scope proposed by the Dossier Submitter. If information is submitted in the consultation that is outside this scope, and the Dossier Submitter decides that it is not possible to assess it, the information will not be given the same level of relevance in the Committees evaluations as information that is in the context of the proposal and explained in the opinion.

4.2. Information from the Dossier Submitter

The Dossier Submitter may contribute by providing further information and clarifications during the opinion making phase based on requests of the (co-)rapporteurs/Committees, especially those presented in recommendations following the conformity check but also in response to consultation comments. The contribution of the Dossier Submitter includes:

- Focused introductory presentation on the dossier (as agreed with the (co-)Chair of the

Committee on a case-by-case basis) to RAC and SEAC members during the meetings[5]. The outcome of the conformity check on the specific dossier is to be agreed at the plenaries;

- Preparation of the first version of the Background Document; this needs be done in close collaboration with the (co-)rapporteurs;
- Provision of input to other process-related documents, e.g. response to comments (RCOM) table related to the consultation;
- Participation in RAC/SEAC meetings in person or via a remote connection as an observer, when the Committees discuss, agree or adopt their relevant opinions, as this allows to get clarification by the Dossier Submitter in a smooth and efficient way.; and
- On request of the (co-)-rapporteurs, contributing to the (co-)rapporteurs dialogues or part of the dialogues and on the draft opinions.

The (co-)rapporteurs, the Dossier Submitter and the RT work collaboratively in the Restriction Support Group, which agrees to the input to be requested from the Dossier Submitter. In general, however, it should be the aim to limit additional information/assessment requested from the Dossier Submitter, i.e. the questions need to be proportionate to the restriction proposal and the questions should not in principle go beyond what is guided in the support documents provided to the Dossier Submitter.

The opinion should reflect the changes done to the original restriction proposal based on the information submitted by the Dossier Submitter.

4.3. Information from other routes

If the stakeholders (third parties) submit information after the consultation has ended, the Committees do not need to take this information into account. ECHA will forward this information to the Commission. If the Committees or the (co-)rapporteurs consider that further clarification related to the comment received is needed during the consultation or after it has closed from stakeholders who submitted information through consultation, the RT will request it. Where possible this information should also be submitted in the 6 month consultation on the Annex XV restriction report or the 2 month consultation on SEAC draft opinion for transparency. In any case, this information and any evaluation of how it has been taken into account can be added by the (co-)rapporteurs or RT in the relevant sections of the Background Document or as a separate annex to the Background Document.

If stakeholders submit information during the Committee plenaries, the stakeholders are requested to provide it via the consultation. If the consultation has ended[6], ECHA will forward this information to the Commission and the Committees do not take this into account.

Moreover, if additional information brought up in the consultation is not supported factually (e.g. no scientific evidence, unclear origin of the information), the Committees will not evaluate this information. Further information is given in the consultation guidance.

It is recognised by RAC and SEAC that the failure to obtain additional key information either from the Dossier Submitter or through consultation could potentially mean that the proposed restriction or derogation requested cannot be supported.

[5] From 2021 onwards RAC working groups on restrictions will be organised in addition to plenaries. SEAC working groups on restrictions are taking place on ad-hoc basis.
[6] Stakeholder observers are advised to use RAC and SEAC functional mailboxes for any contacts with ECHA secretariat.

5. Interface and collaboration of RAC and SEAC

While the REACH Regulation text describes the specific tasks of the two Committees in evaluating the restriction proposal it is obvious that their work necessitates close collaboration during the development of their opinions, particularly in relation to:

- the scope, level of detail and robustness of the proposal;
- the effectiveness of the restriction relative to other risk management measures in the dossier to reduce the risk to an acceptable level within a reasonable period of time and by means proportionate to the risk;
- the quantification of risks used in the health and/or environmental impact assessments;
- an assessment of the environmental and health impacts of the derogations or exemptions being proposed and of the transitional periods;
- available information on hazards/risks of alternatives, including their technical and economic feasibility; and
- the overall conclusions.

These aspects are discussed in the dialogues, where the (co-)rapporteurs from both Committees meet. When RAC and SEAC (co-)rapporteurs develop the opinions, the RT should be copied into correspondence between the SEAC/RAC (co-)rapporteurs to ensure good flow of information and especially to allow the RT to keep the (co-)Chairs informed of the ongoing work.

Furthermore, RAC will support SEAC in the health and environmental impact assessment. The fit for purpose document (see section 2.4) recognises this need by asking for risk assessment output that allows central tendency estimates to be derived in the impact assessment. ECHA secretariat will look for ways to improve this co-operation.

6. Flexible procedure for handling and analysing restriction proposals

The working procedure of the Committees describes the main roles and tasks of the Committees and their (co-)rapporteurs as well as of the RT for developing the opinions. In some cases deviation from this procedure is contemplated and the flexible procedure might be needed. The aim of the flexible procedure is to use the procedure more efficiently and to avoid unnecessary work. Examples of when and how to use the flexible procedure are described below.

The starting point to make restriction proposals according to Annex XV may differ and this might influence how the proposal is processed in the Committees. Typically the following type of restriction proposals are under consideration by the Committees:

- A restriction proposal for a substance/mixture/group of substances, not yet covered by the current restriction entries;
- Amendment of an existing restriction entry;
    - New use of a substance/mixture/group of substances proposed to be restricted;
    - Change in the existing restricted use(s);
    - Change in derogation;
    - Change in maximum concentration limit; or

- Additional substances added to a 'group' entry.

- Safeguard clause case (Article 129 of REACH)); and
- A restriction proposal for a substance on the Authorisation list incorporated in articles (Article 69(2) of REACH).

The considerations for a simple restriction proposal as described in the Fit-for-purpose document prepared by the RTF and also referred in a document endorsed by the CARACAL in June 2020 (CACS/12/2020)[7] on implementation of Article 69(2) can be taken into account, when a flexible procedure is proposed. A simple Article 69(2) restriction proposal could be proposed if there are no applications for authorisations for a use of a substance on the Authorisation list in articles in the EU. Another option could be when an authorisation decision ensures that there is no risk from the incorporation of the substance into articles within the EU but there is some evidence that the substance may be in the imported articles.

In the following cases, a flexible procedure could be used – this will be proposed to the Committee on the advice of the (co-)Chairs and the (co-)rapporteurs.

<u>All types of proposals</u>

- The Annex XV dossier might include sections for which the Committees consider that they do not need to be discussed at the meetings. These parts could be e.g. the hazard part (the Fit-for-purpose document states: 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) including clear references to the assessments used such as other EU opinions (e.g. SVHC agreements) or assessments (e.g. EU risk assessment reports under the former Regulation 793/1993, RAC opinions on the same substance and/or similar uses) where no further information has been provided by the Dossier Submitter. In such cases the (co-)rapporteurs can highlight this before the plenaries and the members may agree on the approach while commenting on the draft opinions. This agreement will be recorded in the minutes of the meetings and will be explained in the relevant section of the Background Document.

<u>Simple cases</u>

- When presenting the key issues at the meeting where conformity was agreed, the (co-)rapporteurs may indicate that the case is simple and Committees may decide that there is no need to discuss the restriction case in every plenary foreseen under the working procedure. One or more plenary discussions may therefore be skipped. At the first meeting where the first draft of the opinion is introduced and if the opinion is preliminarily agreed, it could be decided that if no substantial comments are received during the consultation or the advice of the Forum does not bring any new elements for consideration, RAC will use the written procedure or the possible fast track procedure[8] for the adoption of the opinion.
- SEAC could use the 2nd plenary meeting to agree on the SEAC draft opinion, and if no

[7] Second REACH review Action No 11(1): Interplay between authorisation and restriction – implementation of Article 69(2).

[8] Fast track procedure: something similar to the fast track procedure used in classification and labelling procedure: case to be included on the agenda of the plenary meeting, and if no comments are received during consultation of the members of the Committees, the opinion is regarded as adopted (or SEAC draft opinion as agreed). If comments are received the case will be discussed at the plenary meeting. Example where the second plenary was not needed is restriction proposal on two siloxanes (D4/D5).

substantial comments are received during the consultation on the SEAC draft opinion, the adoption of the SEAC opinion could be done via written procedure or the fast track procedure.

In addition, RAC may conclude on amendments or technical changes to an existing entry, on the basis of an argument presented in the Annex XV restriction report, that the risk was already known when the existing restriction was adopted and RAC does not need to assess this issue in the dossier. The change in risk reduction capacity of the proposed restriction will still need to be addressed.

If SEAC agrees with the Dossier Submitter that for minor changes to an existing entry, there are no other costs other than administrative costs related to the handling of the proposal and the benefits of clarifying the entry are clear, there is no need to make a cost effectiveness or cost benefit analysis and proportionality is demonstrated.

For simple restriction proposals both Committees are expected to carefully consider the proportionate assessment needed for the case.

7. Opinion that supports the Commission in the decision phase

The Commission follows the opinion development of the restriction proposals and participates as an observer at the RAC and SEAC plenary meetings. The RT will flag to the Commission any possible issues that require the Commission's attention as early as possible and the Commission will provide its clarifications, queries or contributions (especially on the regulatory aspects) as necessary in writing during the opinion making process or during plenary.

The opinions of the Committees do not need to have a completely developed final legal text as this is the task of the Commission. It is more important to describe fully to the Commission the objectives and suggested content of the restriction, i.e. that the opinions clearly indicate the elements that should be restricted and any activities that should be derogated together with supporting reasoning.

As regards uncertainties, the RTF prepared a document 'Description of uncertainties in the evaluation of restriction proposals'[9], which provides a proposal for an approach for how to handle data gaps and uncertainties. CARACAL agreed on the approach and in addition, it was agreed that ECHA secretariat will develop guidance with standardised wording for Dossier Submitters and Committees. The aim is to clearly state in a qualitative manner the uncertainties for both the hazard/risk assessment as well as for the socio-economic assessment, including the analysis of alternatives and consequences of uncertainties. This guidance is expected to be published by end of 2021.

In addition to the above, the following elements in the opinions are important for the Commission decision making and particular attention should be paid to them: the assessment of restriction options and the description of monitorability and enforceability.

The opinions should not repeat the details that are included in the Background Document. However, it is useful to provide in the opinion references to the specific parts, tables and figures of the BD.

9 https://echa.europa.eu/documents/10162/13641/rtf_uncertainties_consequences_inaction_en.pdf/0472008c-62c9-7b82-c71e-1bf318891c39

8. Technicalities

After receiving the Background Document from the Dossier Submitter including the Dossier Submitter's input based on the recommendations by the Committees and consultation, all additional information and analyses will in general be added to the document by the (co-)rapporteurs or the RT, in the form of RAC and SEAC 'text boxes', to reflect the development of the opinions. No further changes to the Background Document are envisaged unless relevant information becomes available e.g. during the consultation, that changes the previous information in the Background Document. The Dossier Submitter should clearly indicate that the changes are included due to the received information.

ANNEXES

Annex 1 Common Approach of RAC and SEAC in checking conformity of Annex XV restriction dossiers

Annex 2 Common Approach of RAC and SEAC in developing opinions on restriction proposals

Annex 3 List of RTF support documents published on ECHA website

Annex 1: Common Approach of RAC and SEAC in checking conformity of Annex XV restriction dossiers

1. Purpose

The purpose of this Common Approach is to describe how RAC and SEAC should focus their work so that they can efficiently, within the limited time available, use the conformity check of the Annex XV restriction dossier to establish if the information required in Annex XV to REACH is present for RAC and SEAC to undertake their evaluation during the opinion development.

2. Common Approach to conformity check

In the conformity check the Committees check if the Annex XV restriction dossier contains the elements described in Annex XV to REACH. The submission of the dossier 6 weeks before the formal conformity check starts gives more time for the RT and the (co-)rapporteurs to investigate the dossier and allows contacts with the Dossier Submitter, arranged by the RT, to clarify any unclear issues.

The conformity check template contains questions for both Committees to facilitate this check. Moreover, the 'Guidance for the conformity check' (see Appendix I) provides additional support to the Committees when conducting the conformity check. In addition, a separate set of recommendations is concurrently prepared for the Dossier Submitter to assist her/him to improve the quality of dossier by introducing recommended information in the Background Document. RAC and SEAC need, however, to prioritise and justify the recommendations so the Dossier Submitter understands how important the recommendations are in relation to each other and why the information is needed. The Dossier Submitter is of course not obliged to follow the recommendations but is advised to address each one at least at the relevant dialogue with the (co-)rapporteurs.

If the scope is unclear, the proposal can also be considered to be not in conformity. The Committees need to verify that the dossier contains information as specified in Annex XV of REACH and coherent with the impact assessment. If the restriction has a more general scope, RAC and SEAC should carefully compare the proposed restriction with the range of articles or uses covered by the risk assessment and the impact assessment of the Annex XV dossier and check that the scope of the proposed restriction is coherent and that all uses covered by the proposal are assessed or otherwise justified. If this is not the case, the Committees should consider the dossier to be not in conformity. If the Dossier Submitter clearly states the uncertainties and wishes to use the consultation to clarify these uncertainties, the Committees may consider to agree the dossier to be in conformity.

During the conformity check the Committees need to check as part of the verification of the scope whether the exemptions and the conditions of the proposed restrictions (e.g. concentration limit/transition period) have been sufficiently assessed.

Further information on what elements the Committees need to take into account on scope when checking the conformity is available in the document prepared by the RTF on 'Setting a clear scope'.[10] Unclear scope might also lead to misunderstandings during the consultation and

[10] https://echa.europa.eu/documents/10162/13641/restriction_setting_a_clear_scope_en.pdf/36045edb-5135-f188-265b-b641a4177c93

hence to subsequently unnecessary difficulties for the Committees when analysing the comments.

If the dossier is considered in conformity, the (co-) rapporteurs will present to the Committees the key issues identified in the dossier and considered by them as crucial for opinion development. The aim of this presentation and discussion is to facilitate drafting of the first opinion version by the (co-)rapporteurs for the first plenary discussion within the opinion development process.

If the dossier is not found to be in conformity by either or both Committees, if needed, a meeting between the (co-)rapporteurs and the Dossier Submitter can be organised by the RT soon after the Committees have given a decision with the reasons for non-conformity and the recommendations by the (co-)rapporteurs.

Appendix I: Conformity check guidance

Introduction

This guidance is aimed at helping (co-)rapporteurs and other Committee members to complete the conformity check for a restriction dossier; it complements the information already given in the Annex 1.

The aim of the conformity check is to ensure that an Annex XV dossier proposing a restriction includes all the information required in Annex XV of the REACH Regulation (Article 69).

During the conformity check (co-)rapporteurs should check whether the information presented in the dossier is sufficient and adequate to satisfy the legal information requirements described in Annex XV of REACH based on an initial screening. However, (co-)rapporteurs are neither expected to check the quality of the data used in the dossier (e.g., whether the tests used to describe the hazard in question are based on appropriate methodologies) nor to check whether the justifications given are well-founded (e.g., that there is a sound basis for a conclusion that a restriction under REACH is clearly more appropriate action than e.g. an EU wide environmental quality standard set up under the Water Framework Directive). A positive result of the conformity check does not take a stand on the quality of data included or on whether the action proposed in the dossier is justified.

All restriction dossiers are different and should be approached on a case-by-case basis; the level of sufficient information on a certain issue for one dossier is not always the same for another. It should be possible to adapt to different cases and this is why the conformity check questions use a rather flexible wording, e.g. “Does the report appear to allow an evaluation…”.

An Annex XV dossier that conforms may have imperfections/deficiencies. The information submitted in the consultation as well as any observations made during the conformity check should be used to further develop the Background Document for the opinions where identified concerns regarding missing information or insufficient data quality are resolved or appropriately addressed. The discussions during the conformity check should help identify any specific questions that can be addressed in consultation. The dossier should not be modified prior to the consultation apart from editorial changes. If a dossier conforms with the requirements in Annex XV to REACH, no further requirements to improve e.g. the structure of the report can be made before the report is published for consultation.

The outcome of the conformity check cannot be conditional, i. e. on submission of certain information or certain changes in the dossier by the Dossier Submitter. The conformity of a dossier must not be contingent on any additional information.

The outcome of the conformity check should be detailed in the conformity report. In the conformity report the Committees are requested to answer “yes” or “no” to each question. If the answer to a question is “yes”, any additional essential information needed related to that section should be given in the recommendations paper. If the answer to a question is “no”, the field is to be used to provide reasons as to why the report is not in conformity with regard to the question; these comments should clearly describe why the relevant section is not in conformity and, if possible, what steps the Dossier Submitter could take to bring the dossier into conformity. The comments are regarded as reasons to the Dossier Submitter for non-conformity as required in article 69(4) of REACH. A “no” answer to a single question would lead to the non-conformity of the whole dossier.

The conformity report and recommendations

During the conformity check process (co-)rapporteurs are advised to draft their recommendations with regard to desired information. The recommendations give an opportunity to point out essential information needs which may not be specifically required by Annex XV to REACH, but which are important for a Committee to formulate an opinion. The recommendations are especially useful in cases where the legal requirements of the Annex XV to REACH are fulfilled i.e., the dossier is agreed to be in conformity, but where the quality of the information provided in the dossier may not allow a Committee to formulate an opinion on the proposal. In such cases further 'desirable information' should, if possible, be provided during the opinion forming process as otherwise no opinion can be formed. The Dossier Submitter will be encouraged to provide the desired information. In addition, specific information can be asked for in the consultation. The recommendations could be used also as a basis of the agenda for the 1st rapporteurs' dialogue.

This guidance contains some detailed questions giving suggestions on issues that can be looked upon when filling in the conformity report. Since restriction dossiers are likely to vary and they may be targeted, the sub-questions might not be relevant for all cases and at the same time the list might not be exhaustive.

The discussion of the outcome of the conformity check and on the recommendations in the Committees is deemed most fruitful when done in parallel. The discussion in the Committees will give a support to the (co-)rapporteurs in their first deliberations on the opinion. However, *the decision of the Committee on the conformity of a dossier is to be taken independently of the recommendations given, and solely based on the outcome of the conformity check.*

Check of the Annex XV reporting format

The specified format of the Annex XV report may help you when going through it from a conformity check perspective. Note that for practical reasons, and if justified, deviations from the format are allowed provided the information as stipulated in Annex XV of REACH is provided.

Checking the proposed restrictions (RAC & SEAC)

Note: If there are several parts to a question, the yes-box should be ticked only if the dossier is found to be in conformity regarding all parts that are considered relevant for the specific dossier.

A1. Does the proposal specify the identity of the substance/mixture/group of substances in sufficient detail? (RAC)

The following could be checked: IUPAC name or chemical name, CAS No., EC No., molecular and structural formulas (when applicable), purity, impurities. *Level is sufficient if it appears to be possible for the relevant actors to comply with the restriction and for the enforcement authorities to supervise and enforce the restriction.* *The RTF support document on grouping may provide some additional information[11].*

A2. Does the proposal specify the scope of the restriction proposed in sufficient detail? (RAC

[11] https://echa.europa.eu/documents/10162/13641/rtf_grouping_en.pdf/ff64b22d-2f19-cdd6-ae79-b5553d46a422

and SEAC)

The RTF support document on setting a clear scope gives more assistance on judging the conformity of the scope[12].

The RTF support document on fit-for-purpose document may provide some additional assistance[13].

A3. Does the proposal include a summary of the justifications for the restriction? (RAC and SEAC)

Does the summary contain the following:

- *Identified risks that need to be addressed, including evidence that already implemented risk management measures are not sufficient.*
- *Justification that action is required on an EU wide basis.*
- *Justification that the proposed restriction is the most appropriate EU wide measure.*

Information on hazards and risks (mainly RAC)

B1. Where other relevant dossiers or chemical safety reports are submitted under the REACH Regulation and/or relevant risk assessments are submitted for the purposes of other EU legislation:

- Does the dossier refer to the information on hazard or risks that has already been agreed in any of the aforementioned contexts?
- Does the dossier appear to take into account information in those dossiers and reports? (RAC)

The following questions could be considered:

- *Has the Dossier Submitter considered the relevant CSR submitted by the registrants and provided justification if their conclusions on hazard or risk deviate from the conclusions in the registration dossiers?*
- *Has the Dossier Submitter used other recognised risk assessment reports (e.g. RARs under Regulation 793/1993) or EU scientific opinions (e.g. from EFSA, SCOEL) as the basis of its assessment? There is no need for the (co-)rapporteurs to extensively search for these assessments; ECHA can provide a non-exhaustive list if requested. If the Dossier Submitter has not followed the conclusions of the other EU scientific opinions, has it included a justification for this?*

The RTF support document on fit-for-purpose document may provide some additional assistance.

Note: A summary of key information from the above mentioned assessment reports or opinions is sufficient in the Annex XV dossier.

B2. Does the dossier appear to allow an evaluation of whether the approach used to identify the hazard and risk is in accordance with the relevant parts of Annex I of to REACH?

[12] https://echa.europa.eu/documents/10162/13641/restriction_setting_a_clear_scope_en.pdf/36045edb-5135-f188-265b-b641a4177c93

[13] https://echa.europa.eu/documents/10162/13641/rtf_fit-for-purpose_dossiers_en.pdf/a6b6d9c0-9e8b-5300-d84d-798d0aea9113

(RAC)

The following questions could be considered:

- Have the relevant steps (relevant for the case) for chemical safety assessment as described in Annex I to REACH been followed?

B3. Does the dossier appear to present sufficient information to allow an independent assessment of the hazard(s)? (RAC)

The following questions could be considered:

- *Are there adequate descriptions of the different data available (e.g. experimental data, monitoring information, Q(S)ARs)?*
- *Are the data evaluated (e.g. with respect to reliability)?*
- *Are there conclusions and summaries for the different relevant endpoints for which data are reported?*

B4. Does the dossier appear to present sufficient information on the uses of the substance(s)/mixture/group of substances and resulting exposure? (RAC and SEAC)

The following questions could be considered:

- *Are the manufacture and uses clearly identified both from a risk assessment as from an impact assessment (or SEA) perspective, described and listed in the report?*
- *Are reasons given for targeting the assessment, where relevant (e.g. targeting a certain sector or a certain type of risk)?*
- *Are exposure estimates derived for relevant uses and manufacture identified?*
- *Are the exposure estimates presented explained and the models used to calculate them described sufficiently (is it clear which risk management measures and operational conditions are assumed in the models)?*
- *Are monitoring data described sufficiently to allow evaluation of their representativeness and reliability? Is it clear which risk management measures and operational conditions were applied when monitoring emissions or environmental concentrations?*

B5. Are the risks to be addressed described in sufficient detail to allow an independent assessment? (RAC)

The following questions could be considered:

- *Does the dossier appear to make clear which combination of hazard and exposure causes the risk?*
- *Does the dossier appear to make clear which manufacture, uses and/or resulting life-cycle stages cause the risk?*
- *Does the dossier appear to allow a judgment on whether the identified risk is caused by the exposures arising from manufacture/uses covered by one registrant's CSR or by the combined exposure covered by CSRs of several registrants? Does the report appear to allow a judgement on whether the identified risks arise totally or partly from (as yet) non-registered substances (e.g. in case a substance is*

manufactured/imported below 1 t/a or the registration deadline is in the future?)

Note: Risks do not necessarily need to be described on a quantitative basis. In some cases qualitative or semi-quantitative descriptions may be appropriate.

It is to be noted that if the risk assessment shows that the Risk Characterisation Ratio for a threshold substance on its own or in combination with other related substances is below 1 for human health or for environment, the dossier cannot be considered to be in conformity with the requirements of Annex XV to REACH as an RCR of above 1 it is a prerequisite for considering that the risk is not adequately controlled. However, this is not applicable to non-threshold substances, PBT, vPvB and possible further categories of substances fulfilling the criteria for SVHC.

B6. Does the dossier appear to provide evidence that implemented risk management measures are not sufficient? (RAC and SEAC)

Does the dossier appear to allow an evaluation on whether the identification of risk takes into account implemented risk management measures and operational conditions?

Information on alternatives (RAC and SEAC)

C1. Does the dossier indicate whether or not any alternative substances and/or technologies have been identified and assessed?

As a minimum the dossier should include a statement that the Dossier Submitter has not identified any alternatives or has no available information on the identified alternatives.

The dossier is in conformity where part C documents what has been done to identify alternatives and that none has been identified. In such a case part E will assess (effectiveness and proportionality of) a situation where the function of the substance is no longer available to supply chains and society.

Justification that action is required on an EU wide basis

D1. Does the dossier appear to allow an evaluation of the reasons supporting action on an EU wide basis rather than action at national or local level? (RAC and SEAC)

Justification that a restriction is the most appropriate EU wide measure

E1. Does the dossier appear to allow an evaluation of the assessment of the proposed restriction and other identified RMOs in relation to their effectiveness (including risk reduction capacity, costs and proportionality), practicality (including information and justification facilitating the assessment of enforceability, implementability and manageability) and monitorability?

Does the dossier, for example, appear to allow an evaluation of:

- *the assessment of the proposed restriction and the identified other RMOs in relation to their effectiveness: is/are the proposed restriction/other RMOs*

a. targeted to the effects or exposures that cause the risk?

b. capable of reducing the risk within a reasonable timeframe?

c. proportional to the identified risk?

- *the assessment of the proposed restriction and the identified other RMOs in relation*

to their practicality: is/are the proposed restriction / other RMOs

a. implementable by the actors concerned?

b. enforceable by the authorities?

- *the assessment of the proposed restriction and the identified other RMOs in relation to their monitorability*
- *the overall assessment of the proposed restriction against effectiveness, practicality and monitorability concluding that another identified RMO would not perform better when these aspects are considered as a whole.*

E2. Does the assessment referred to in Question E1 appear to give sufficient background on the defined scope and conditions of the proposed restriction, other than those issues covered by Question A2? (SEAC)

For instance, does the dossier transparently identify types and sources of costs (and potential savings) due to the suggested restriction? Furthermore, does the dossier – qualitatively or quantitatively – describe/discuss the significance of costs from different sources? In general, does the dossier describe how the costs accruing from the restriction have been assessed in order to facilitate comparison of costs and benefits?

E3. Does the assessment referred to in Question E2 appear to give sufficient background on the defined scope and conditions of the proposed restriction? (SEAC)

For instance, why these uses are covered while other uses are not, why there are derogations included for certain uses, how the timeline from when the restriction would apply is defined, what is the background for a total ban?

Socio-economic Assessment of Proposed Restriction (SEAC)

This section gives the Dossier Submitter a chance to include a more extensive (more detailed or wider scope) economic analysis done on the restriction proposal. The section as such is voluntary, but naturally more information better facilitates the opinion formulation and decision making.

Information on stakeholder consultation (RAC and SEAC)

G1. Does the dossier describe whether any stakeholder consultation has been conducted? (RAC and SEAC)

E.g. who has been consulted, when and how.

G2. Does the dossier appear to allow tracking of how the results of any such consultations have been used in the development of the report? (RAC and SEAC)

Technical dossier

Does the IUCLID 5 dossier include adequate information on the substance identification? (RAC)

Does the IUCLID dossier include, for hazard information that has not been previously submitted to ECHA, Robust Study Summaries which appear to include sufficient information allowing a review of the relevance, reliability and adequacy of the data of relevance for the proposed restriction? (RAC)

Annex 2: Common Approach of RAC and SEAC in evaluating restriction proposals during opinion making

1. Purpose

The purpose of this Annex is to describe how RAC and SEAC evaluate restriction proposals and to implement the RETF recommendations. This is to allow the Committee's to focus their work so that they can efficiently, within the time available, develop good quality opinions on Annex XV restriction proposals to support the Commission's decision making.

2. Evaluation of the restriction proposal in general

The evaluation of the restriction proposal entails in particular whether:

- methods and parameters used for risk assessment and impact assessment are appropriate, following the guidance documents and applied consistently;
- quality of the scientific data is sufficient;
- conclusions are reached logically, in a consistent way;
- evidence is robust and focussed to the concern identified; and
- all relevant issues have been included and well justified and there are no omissions that would affect the outcome of the evaluation.

Ad-hoc groups (Rapporteurs' Support Group) consisting of interested RAC and SEAC members to support the (co-)rapporteurs are created based on the (co-)Chairs' decision in specific cases where it is expected that the Committee members may have very divergent views on the dossier, when the (co-)rapporteurs do not have access to necessary expertise, or when the case is otherwise very complicated. Non-committee members like the Dossier Submitter or stakeholders may be invited to these ad-hoc groups by the (co-)Chair of RAC and SEAC (in consultation with the (co-)rapporteurs and the RT).

The remits of RAC and SEAC are outlined in REACH, where the tasks of the Committees are described. The questions either to RAC or SEAC or both Committees in the conformity check template and in Annex 1 (Appendix I) can be used during the opinion making phase to indicate which parts of the Annex XV report will be evaluated by each of the Committees.

3. Extent of evaluation required

The Dossier Submitter's proposal, including the information included in the first version of the Background Document related to fulfilling the recommendations from the conformity check phase, should form the main basis for the Committees' to give their opinions. The information received through the consultation and the Forum's advice will be taken into account. After the conformity check phase only clearly justified additional requests for clarifications by the Committees to the Dossier Submitter are possible. Requests should clearly indicate for what purpose the further information is required and they need to be realistic so that the Dossier Submitter is able to submit this information within the time available. For example, if the benefits to the human health and/or the environment clearly outweigh the costs of the proposed restriction, requests for further information on benefits should usually not be made.

The level of detail of the evaluation by RAC and SEAC should be proportional to the concern set out in the Annex XV dossier.

The Committees should ensure that the Background Document reflects of the efforts made to collect information and consultations carried out.

In the absence of information, the Committees evaluate the assumptions described by the Dossier Submitter and if the consultation clarifies those assumptions, the Committees will evaluate this information. Absence of key information also needs to be flagged in the opinions, e.g. in a separate uncertainties section.

Article 69(2) cases

The Article 69(2) proposal would restrict a substance, which is on the Authorisation list and which is used in articles. In these cases, the hazardous properties have clearly been agreed at the Member State Committee level, when it has been agreed that the substance is a SVHC, or a DNEL or dose response function is already agreed related to authorisations. RAC will rely on this information without further evaluation. However, the exposures, and the risk reduction capacity of the restriction proposal as described by the Dossier Submitter will be evaluated by RAC. For example, RAC will not discuss the PBT status of a substance but will verify assumptions made relating to emissions and risk reduction capacity based on the proposal's ability to reduce those emissions.

This starting point (Article 69(2) cases) is unlikely to affect the evaluation SEAC needs to conduct, including the need for assistance from RAC on effects related to other endpoints than those on which basis the substance was included in Annex XIV.

In some cases, simple restriction proposals can be prepared for Article 69(2) cases. The evaluation by RAC and SEAC is expected to be proportional to the concern set out in the Article 69(2) restriction proposal.

4. Evaluation of risks

The basis for the evaluation is that hazard, exposure and risk characterisation of the relevant substance(s)/mixture/group of substances and use(s) described in the Annex XV dossier correspond to the scope of the restriction proposal.

If chemical safety reports in the registration dossiers are available, RAC (supported by the RT) will evaluate whether they have been used as a starting point and, if the Dossier Submitter has provided justification, whether their conclusions on hazard or risk deviate from the conclusions in the registration dossiers. If the conclusions of RAC deviate from those conclusions of the Dossier Submitter as well as the registrants, justification is to be provided in the opinion.

If the Dossier Submitter has used other recognised assessment reports (e.g. RARs under Regulation 793/1993, OECD SID reports) or EU scientific opinions (e.g. from EFSA, SCOEL) as a basis of its assessment and justified their use, RAC should refer to these reports or opinions unless new information received since their development or during the consultation leads to other conclusions. If the conclusions by RAC differ from those of the Dossier Submitter's, they will be justified by RAC. A summary of key information from the above mentioned assessment reports or opinions is regarded as sufficient in the Annex XV dossier; the ECHA secretariat can provide these references to RAC, if necessary. If the Dossier Submitter has used new information to justify why it deviates from other EU scientific opinions, RAC will evaluate the validity of this information.

RAC will analyse the uses and possible exposure scenarios in the proposal and verify that they are clearly described. In addition, RAC will evaluate whether the information provided supports

the description of the baseline of the dossier.

RAC and SEAC (within its remits) will also evaluate whether the dossier clearly demonstrates that existing risk management measures recommended by the manufacturers and/or importers are not sufficient and that other regulatory risk management instruments are not sufficient and/or more appropriate.

Moreover, RAC will evaluate the uncertainties in the risk assessment taking into account information received during the consultation and ensures that they are clearly described.

5. Evaluation of the alternatives

If the dossier explains how information on alternatives (alternative substances and/or techniques) described in the dossier has been gathered, showing that proportional efforts were made to describe available information on alternatives, this will be the basis for the evaluation by RAC and SEAC. In addition, the Committees need to evaluate the information submitted through the consultation. If the consultation information is not sufficiently supported with background information (e.g. costs of alternatives), the Committees need not use this information in the analysis.

RAC will evaluate the effects of the adoption of alternatives in reducing the identified risk and that the alternatives do not cause other risks that cannot be adequately controlled. SEAC may need to take into account if the alternative is not a 'drop' in solution and this may mean additional costs (reformulation, capital costs).

Moreover, the risk from certain alternatives will not always be clear, for example they may be under substance evaluation, there may only be indications of their hazard or exposure information may not be available. In the latter case it cannot be assumed that the benefits from moving from the substance in the proposed restriction will be off-set by using the alternative. However, suitable sensitivity analysis should have been undertaken by the Dossier Submitter that can be evaluated by the Committees, to take this uncertainty into account and measures such as reviews can be used to monitor the situation in the future.

For SEAC, the cost of moving to alternatives is often the most important part of the overall cost of the proposal. The plausibility of the cost estimates and benefits of moving to alternatives presented in the dossier will always be evaluated by the Committee.

6. Evaluation of the proportionality, effectiveness, practicality and monitorability of the proposed restriction

RAC and SEAC can refer to the lack of consideration by the Dossier Submitter of other risk management options but it will not propose substantially different risk management options from those identified and investigated by the Dossier Submitter or proposed in the consultation (and assessed for their risk and impact). Further consideration on additional risk management options can be found from the RETF paper on 'Setting a clear scope'.

When assessing proportionality SEAC will evaluate the impact assessment done by the Dossier Submitter, e.g. in a cost-benefit, cost effectiveness, break-even or compliance cost analysis or other appropriate method. SEAC needs to evaluate the likely economic impacts (i.e. socio-economic costs) and benefits to the society if a restriction enters into force. Thus, the Dossier Submitter needs to provide the resource impact (usually expressed in costs) to the society. However, the cost information needs to be provided in proportionate manner. In its evaluation,

SEAC ensures that the dossier covers all relevant cost and benefit elements[14]. If the restriction proposal has been estimated to have very low costs (low cost justification), SEAC needs to evaluate that this is indeed the case. If the cost impact is small, the information requirements, as well as SEAC's and RAC's evaluation is proportionate to this case.

If SEAC receives little information on costs and technical feasibility of alternatives during consultation, it will understand that the proposed restriction could be considered proportionate, or have little impact on the relevant sector.

The Guidance on Socio-Economic Analysis – Restrictions describes the step-by-step approach, which will be used by the Dossier Submitter. According to the approach the dossier should first contain the identification of all potential impacts (e.g. economic, environmental, health, social and distributional impacts), then a qualitative assessment of impacts (including an assessment of order of magnitude) and a quantitative assessment of impacts that are meaningful to quantify. The last step is the valuation of most significant impacts. However, SEAC recognises that quantification and valuation of human health and environmental impacts is not always possible. SEAC will thus evaluate the reasons provided by the Dossier Submitter why quantification of the impacts has not been conducted.

In the absence of concrete information in the Annex XV Restriction Dossier, SEAC will evaluate whether the Dossier Submitter has undertaken all reasonable efforts to gather information, that reasonable assumptions have been used in the dossier and whether appropriate sensitivity analysis has been done for the most critical assumptions. If no contradicting information is received in the consultation, SEAC assumes the assumptions and sensitivity analysis undertaken by the Dossier Submitter are reasonable.

[14] ECHA will provide information and methodology in addition to compliance costs. This comprises inter alia, how to estimate enforcement costs.

Annex 3: List of RTF support documents published on ECHA website