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(agreed at RAC-34 and SEAC-28)

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[1]. 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 implement the recommendations made by the Restriction Efficiency Task Force (RETF)[2].

The note has been developed by the ECHA Secretariat, RAC and SEAC, and the relevant Commission services. It will be reviewed after a sufficient number of cases have been assessed using this approach.

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 RETF 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 about 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 Chairmen, to the Committees and to the (co-)rapporteurs.

[1] 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

[2] The Restriction Efficiency 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. 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 Co-ordinator and a team assistant.

The RT supports the Chairmen, Committees and (co-)rapporteurs of RAC and SEAC throughout the handling of the dossier and facilitates communication with the Dossier Submitter. In addition to preparing the preliminary conformity check report for an Annex XV dossier submitted by the Member State, the RT provides support 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 and other technicalities. Content related comments are for the consideration of the (co-)rapporteurs.

If the restriction proposal has been submitted by ECHA, the RT still supports the (co-) rapporteurs in a relatively limited manner unless the (co-)rapporteurs request differently.

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

Other support includes:

- Managing the Public Consultations and providing information on them to the Dossier Submitter and (co-)rapporteurs;
- Facilitating the dialogues (e.g. preparation of draft agendas and actions points, and chairing the sessions on the request of the (co-)rapporteurs) and coordinating the work of the Restriction Support Group (RSG)[3] work with the revision and finalisation of the Background Document;
- At the request of the Chairmen - the other information gathering from stakeholders or scientific support to the RSG 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).

3. 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, any information additionally provided by the Dossier Submitter to the (co-) rapporteurs, on the information received during public consultations and the Forum's advice. The Committees are not required to redo the Dossier Submitter's assessments; but, in

[3] Restriction Support Group: (co-)rapporteurs, the Restriction Team and the Dossier Submitter.

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 public consultation if necessary, etc.

3.1. Information through public consultation

To maximise the benefits of the public consultation, the Committees and its (co-) rapporteurs, together with the RT and the Dossier Submitter, identify the issues in relation to which they want to get more information through public 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 public 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 public 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 public consultation creates confusion.

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

As required by REACH, the RT notifies immediately the registrants of the relevant substance(s) about the start of the public 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 public 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 public 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 public 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 public 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.

3.2. 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 Public Consultation comments. The contribution of the Dossier Submitter includes:

- Focused introductory presentation on the dossier (as agreed with the Chairman of the Committee on a case-by-case basis) to RAC and SEAC members during the plenary meetings where the outcome of the conformity check on the specific dossier is to be agreed;
- 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 public consultation;
- Participation in RAC/SEAC meetings 'in person' 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. There is also a possibility for the Dossier Submitter to follow the plenary discussions via a WebEx connection; 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.

3.3. Information from other routes

If the stakeholders (third parties) submit information after the public 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 information is needed during the public consultation or after it has closed from stakeholders who submitted information through public consultation, the RT will request it. Where possible this information should also be submitted in the 6 month public consultation of the Annex XV restriction report or the 2 month Public Consultation of 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 and as a separate annex to the Background Document.

If stakeholders submit information during the Committee plenaries (orally), this is added in the minutes of the meetings. The stakeholders are requested to provide it via the public consultation. If they submit information in writing, this information shall (also) be given through the public consultation. If the public consultation has ended, ECHA will forward this information to the Commission and the Committees do not take this into account.

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

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

4. 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 proportional to the risk;
- the quantification of risks used in the health and/or environmental impact assessments;
- 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 chairs informed of the ongoing work.

Furthermore, RAC will support SEAC in the health and environmental impact assessment. This common understanding of impact assessment is further clarified in a separate document to be prepared by a RAC/SEAC Impact assessment expert meeting (ongoing work). When adopted by the Committees, the document will be published.

5. 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).

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

All types of proposals

- The Annex XV dossier might include sections for which the Committees consider that they do not need to be discussed at the plenaries. These parts could be e.g. clear references to the 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 plenary and will be explained in the relevant section of the Background Document.

Simple cases

- When presenting the key issues at the plenary 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 be skipped. At the first plenary 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 public 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[4] for the adoption of the opinion.
- SEAC could have the 2nd plenary meeting to agree on the SEAC draft opinion, but if no substantial comments are received during the public consultation of the SEAC draft opinion, the adoption of the SEAC opinion is 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

[4] 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. Existing working procedures will be updated to implement this way of working.

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.

6. 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 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.

7. Technicalities

After receiving the Background Document from the Dossier Submitter following the 1st rapporteurs' dialogue (including Dossier Submitter's input based on the recommendations by the Committees and public 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 is envisaged unless relevant information becomes available e.g. during the public consultation, that changes the previous information in the Background Document. The Restriction Support Group will update the Background Document.

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 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 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 public 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 RETF on 'Setting a clear scope' (see Appendix II). Unclear scope might also lead to misunderstandings during the public consultation and 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 public 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 public 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 public 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 public 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 dossier

The specified format off the Annex XV dossier 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 if 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.*

A2. Does the proposal specify the scope of the restriction proposed in sufficient detail (see Appendix II for more detail on assessing the scope; the relevant part of the guidance in Appendix II should be taken into account when assessing this question)? (RAC and SEAC)

The guidance in Appendix II gives more assistance on judging the conformity of the scope.

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?*

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? (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 1it 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:

2.1. 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?

2.2. 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?

2.3. the assessment of the proposed restriction and the identified other RMOs in relation to their monitorability

2.4. *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?

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?

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

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)

Appendix II: Setting a clear scope[5]

RESTRICTION EFFICIENCY TASK FORCE

SETTING A CLEAR SCOPE

A common understanding for a clear scope of Annex XV restriction proposals

The scope of the Annex XV dossier is defined by the specific restrictions proposed in conjunction with the risk assessment performed by the dossier submitter, in particular by the boundaries within which the assessment of risks has been performed and the analysis of the degree to which those risks are controlled.

This paper was discussed and agreed by the Restriction Efficiency Task Force (RETF) at its meeting of 8-9 October 2014.

Dossier Submitter

A. Why the DS should define a clear scope?

The boundaries of the risk assessment are determined by the dossier submitter on the basis of several considerations, including policy, and therefore do not need scientific justification; however, they need to be coherent from a scientific perspective because the scope of the Annex XV dossier in turn influences:

- **the harmonisation achieved by the restriction –**RAC will verify whether there is inadequately controlled risk and the Commission will decide whether there is unacceptable risk.
- **the efficiency of the measure – SEAC will verify the proportionality of the measures and whether the exemptions based on socio-economic implications or lack of alternatives are well justified.
- **the possibility** for RAC and SEAC **to diverge from the restriction suggested** (within the limits of the restrictions proposed and the risk assessment provided) without having to launch a new restriction process.
- **the content of the public consultations**, which is crucial to enable all relevant stakeholders to participate in the process.

[5] This Appendix reproduces the paper on setting a clear scope agreed by the Restrictions Efficiency Task Force. RAC and SEAC have not endorsed the paper as a whole but only the sections relevant to their function.

B. What are the critical elements enabling a Dossier Submitter to suggest a clearly defined restriction?)

As stated in its document to CARACAL CACS/23/2013 (page 5), the Commission believes that "*In order to develop a draft restriction proposal, the Commission needs to obtain clarity on the following items:*

- *the concern to be addressed ((eco-)toxicological effect of concern, human health/environmental effect; targeted population/environmental compartment),*
- *the objective (expected outcome/benefits of the implementation of the proposed measure),*
- *the proposed measure (scope and enforcement tools, where appropriate), […]"*

Enforcement is also an additional reason for requiring a clear scope.

As far as the proposed measure is concerned, the following elements are therefore critical for defining a clear scope in the proposed restriction and should be assessed in the risk assessment in the Annex XV dossier (also presented diagrammatically in Annex I):

B. 1. Identification of substances (column 1 in Annex XVII)

The Dossier Submitter:

- should preferably provide the EC (and/or CAS) number for each substance for which a restriction is proposed
- can propose restrictions for an entire group of substances, for instance when the identified risk relates to a common chemical structure or degradation product of the substances (e.g. "X and its compounds")
- should, when a big group is targeted, try to identify it by using the chemical formula (example: CH3)P(OH)X with X equal to F, Cl, O, etc.)

All of the substances for which a restriction is proposed should be assessed in the Annex XV dossier. If only some of them are assessed, the Dossier Submitter should justify why the results are valid for the others (Justification for grouping).

B.2. Provisions (column 2 in Annex XVII)

1) Limit value for content/migration

Any limit value proposed should, for threshold substances, be based on the DNEL/PNEC or another value if justified. When there is no DNEL/PNEC, the justification for the limit should, for example, make reference to the availability/reliability of testing methods or to the limit of detection of the best performing method, if the intention is to achieve 'zero content/migration'. When both values are considered, justification should be provided to avoid two divergent values.

2) Uses

- The restriction can contain a (non-exhaustive) positive or negative list[6] of specific uses (e.g. in certain articles, type of articles, etc.)
- The restriction can target the function of one specific substance or a group of substances, e.g. flame retardants in articles supplied to the general public
- The restriction can take the form of a total ban or a ban with exemptions

[6] The Annex XV Dossier should also consider this positive or negative list of articles.

- The restriction can be based on the substance being 'not present above a certain limit' in a specified category of articles/mixtures
- The description of the uses or articles should relate to the target population (in terms of intended protection)
- Where relevant, the feasibility of referring to a production category should be examined (Eurostat PRODCOM Codes or CN (HS) code, or both)

3) Exemptions

- When the Dossier Submitter proposes exemptions, this must be on the basis of the risk assessment, a socio-economic assessment or other justified considerations included in the Annex XV dossier for this purpose.
- All proposed exemptions should be presented in the public consultation with the justification from Annex XV.
- All proposed exemptions must be reviewed and assessed by RAC and SEAC.
- When the exposure scenario is based on the worst case, the Dossier Submitter should clearly define any articles to be included in the restriction and how the extrapolation from this scenario was done for these articles and, if some articles have been excluded, suitable justification should be provided.
- The difficulties that arise when the target of the exposure scenario is a particular sub-population which is then extrapolated to a larger one need to be further discussed.

4) Conditions

- The terms "direct" or "indirect" relating to contact should be avoided unless fully described in the Annex XV dossier.
- The term 'intended for' in terms of use should be avoided (cf DCB example).
- Vague terms relating to the frequency of contact such as short, repetitive, long term, prolonged etc. should be avoided, if at all possible, as there is a need to quantify contact and even if the frequency of contact is quantified in the exposure scenario, this is difficult to enforce. Moreover, if we look at the case of Nickel, ECHA took two years to provide a scientific quantification that still needs to be 'translated' into more practical guidance.
- ECHA should provide mini-guidance on the general principles of certain methodologies, with a list of examples dealt with so far by RAC (e.g. phthalates and lead for "mouthing time")
- "Normal and reasonably foreseeable conditions of use".
- Misuse: if targeted by the Dossier Submitter, may exceptionally be considered in the Annex XV dossier if it relates to known or reasonably foreseeable exposure and creates concern for human health or the environment to be addressed at Union level, and there is no other appropriate EU legislation to tackle the problem

RAC and SEAC

A. Question from the conformity check template: Does the Annex XV dossier specify the scope of the restriction proposed in sufficient detail?

In order to reply positively to this question the Rapporteur should consider that the following elements are included in the Annex XV dossier:

- All the relevant elements discussed in the previous point shall be observed (in particular the relevant elements under 'B. 1. Identification of substances' and 'B.2. Provisions')
- The risk assessment done by the Dossier Submitter concludes that control of the risks identified is either adequate or inadequate (either through RCR≥1, or other methods in case of non-threshold substances).
- Exemptions (based on adequate control of risk) – any such exemptions must have been fully assessed in the risk assessment
- Exemptions (based on socio-economic implications) – any such exemptions must be based on comprehensive socio-economic analysis (e.g. indicating severe consequences for certain sectors or society; or indicating that certain sectors/ products would be disproportionately affected; or indicating that the net costs to industry, DUs, consumer or society clearly outweigh the net benefits to human health and environment) .

B. How to assess whether the scope is clear at the conformity check?

As stated in its document to CARACAL CACS/23/2013 (page 10), the Commission believes that if the scope of the suggested restriction is not clear to the ECHA Committees, then the dossier cannot be considered to be in conformity with the requirements of Annex XV[7].

The clarity of the suggested restrictions should be read within the general meaning of "the scope' as described at the beginning of this paper. The suggested restriction must be coherent with the risk assessment of the Annex XV dossier. In the case of restrictions targeted at a specific product group restriction, it should be simple for RAC and SEAC to verify that the proposed restriction corresponds to the risk assessment. The situation can be a bit complex for restrictions with a more general scope. In this case RAC and SEAC should carefully compare the proposed restriction with the range of products covered by the risk assessment of the Annex XV dossier and check that the scope of the proposed restriction is coherent and fully assessed. **If it is not the case, RAC and SEAC should not consider the dossier "in conformity" and may try to clarify this aspect with the Dossier Submitter.** This is crucial before launching the public consultation in order to provide information for the public consultation which is fully in line with the scope.

C. How to consider additional risk management options within the scope proposed by the Dossier Submitter?

The Dossier Submitter usually proposes the preferred option as the "suggested restriction", RAC and SEAC should evaluate other options mentioned in the Annex XV dossier in a separate or combined way and therefore all these options should be part of the public consultation so that relevant information is collected and affected stakeholders participate on time.

Unless other options are only an adaptation of the suggested restriction or come from the public consultation and are fully documented, options not included in the Annex XV dossier should not be assessed by RAC and SEAC. Such "non-assessed options" may be part of the background document (following the boxes approach), if RAC and SEAC are of the opinion that it could/would constitute the best option. It would be difficult for the Commission to further process these "non-assessed options" that were not part of the public consultation.

[7] This issue was not agreed by all members of the RETF.

Annex II contains some examples of previous restrictions discussing the scope and how the scope evolved during the opinion making.

Public consultation

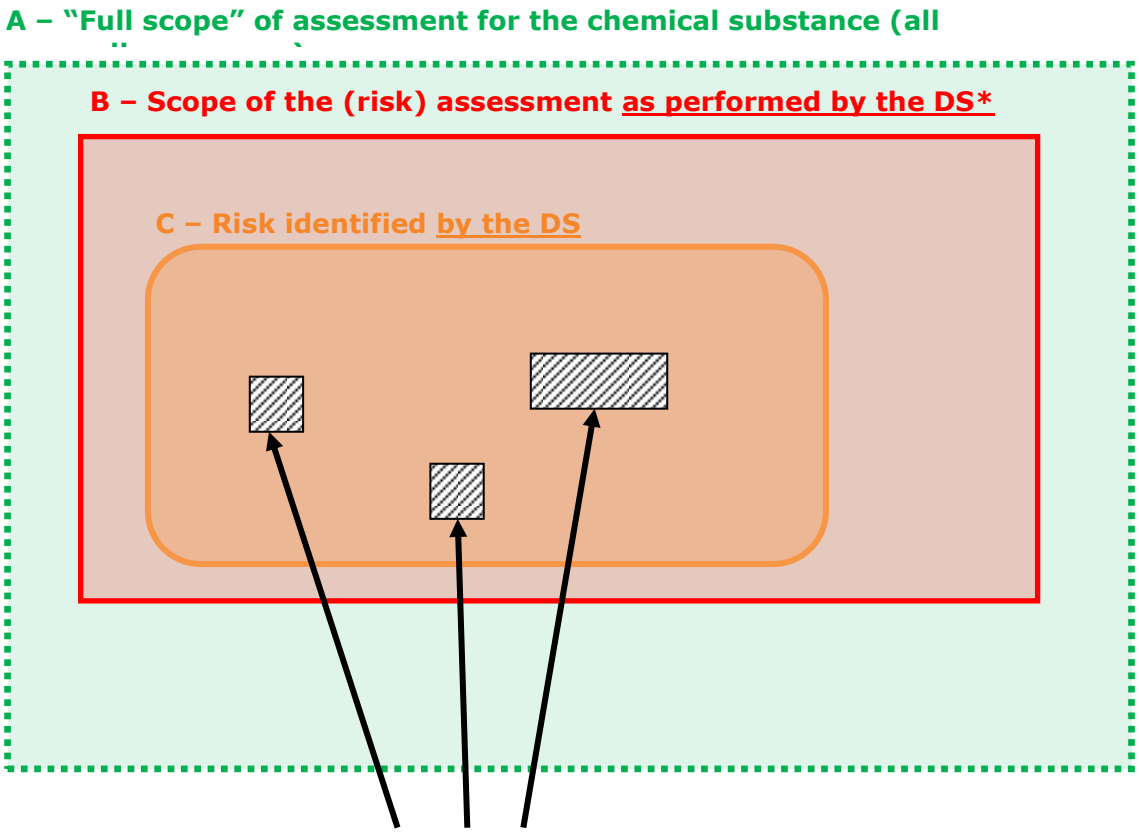
How to define clear the scope before launching the public consultation?

In its document CARACAL CACS/23/2013, the Commission considered the public consultation as a crucial step during the opinion making process and this has also been discussed within the task force.

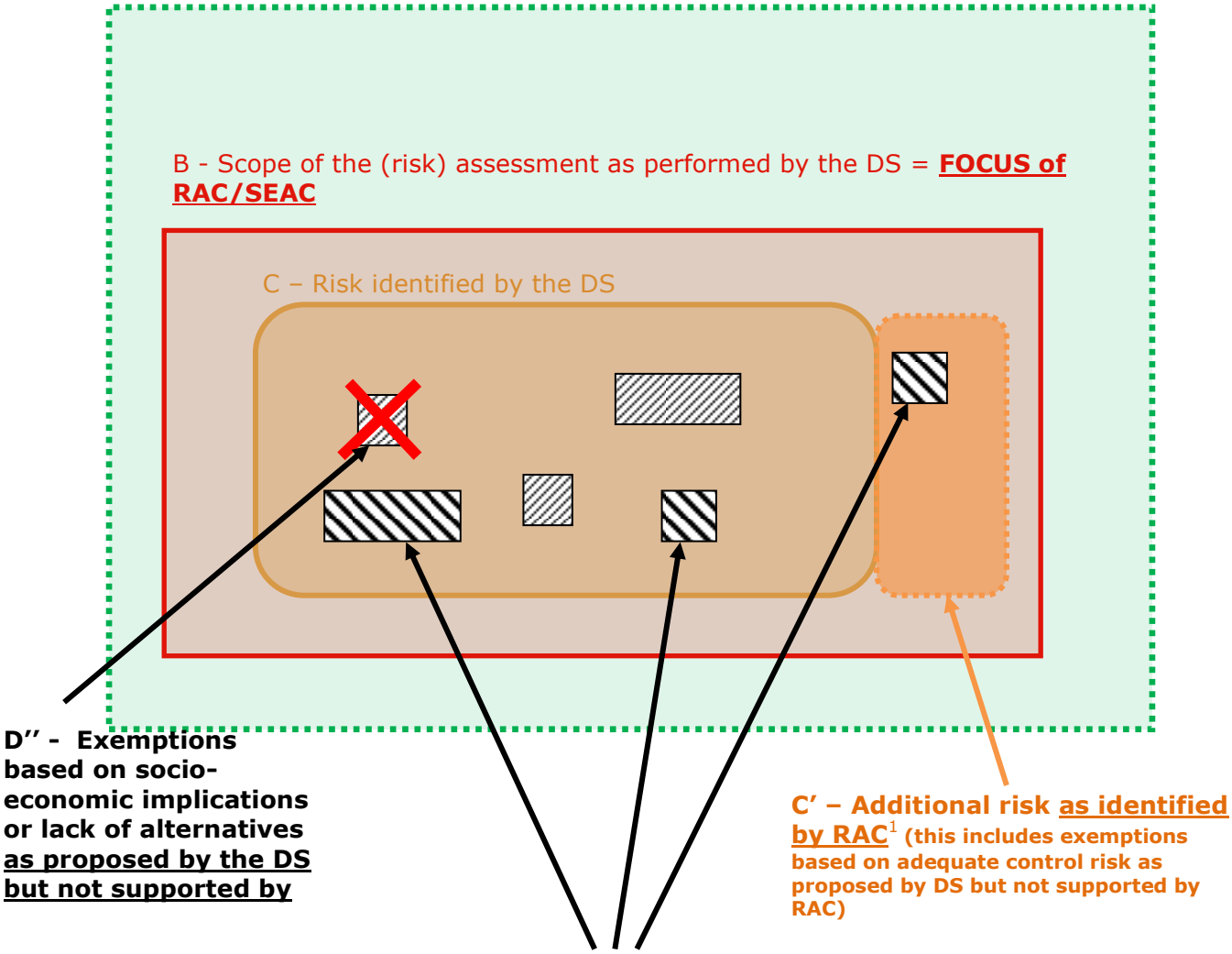
In order to obtain the right contribution from the public consultation, before launching it, there is a need to clarify the scope at the conformity check. We would like to avoid comments which are not targeting the proposed restrictions.

The proposed restriction should be part of the public consultation within the meaning of the clarification in column 1 and 2 of Annex XVII which includes conditions, exemptions etc.

Annex I: Scope of the risk assessment and the proposed restriction as submitted by DS and assessed by RAC/SEAC



A – "Full scope" of assessment for the chemical substance (all uses, all exposures) = NOT RELEVANT for RAC/SEAC assessment



[1]: Note that RAC can express different views than the DS in both directions, i.e. either wider or narrower scope, but within the limits of the scope of the risk assessment as performed by the DS.

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 Chairmen's 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 Chairman 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 public 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 public 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.

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 public 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 public 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 public consultation. If the public 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 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 public 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' (see Appendix II of Annex 1).

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) 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 elements[8]. If the restriction proposal has

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

been estimated to have very low costs (low cost justification), SEAC needs to verify 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 public 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 Public Consultation, SEAC assumes the assumptions and sensitivity analysis undertaken by the Dossier Submitter are reasonable.

estimate enforcement costs.