Template

Recommendations regarding an Annex XV restriction dossier

Helsinki, xxx

RECOMMENDATIONS

regarding the Annex XV dossier on: sid_substance_name_internal

This document indicates the information not currently included in the Annex XV restriction dossier that would be essential for the opinion development; the recommendations should be limited to those that are necessary for the Committees to complete their evaluation of the restriction and should be properly motivated as to the need and and then be prioritised in order of importance (for example high or medium priority). In addition the recommendations should clearly address what the Dossier Submitter is expected to do or provide. The dossier submitter is encouraged to provide the information during opinion development, normally in the background document submitted in week 20. If the information is not available to the dossier submitter, it is important to indicate the steps that the dossier submitter has taken in attempting to get the information. These recommendations do not have an effect on whether the Annex XV report conforms to the legal requirements.

Committee for Risk Assessment (RAC)

Concerning desirable information[1]:

The dossier would benefit from additional information in the following areas:

- [ ] *Proposed restriction*
- [ ] *Information on hazards and risks*
- [ ] *Information on alternatives*
- [ ] *Justification for required action at the Community level*
- [ ] *Justification that the restriction is the most appropriate community wide action*
- [ ] *Information on stakeholder consultations*
- [ ] *Substance ID*
- [ ] *Technical dossier*

Committee for Socio-economic Analysis (SEAC)

Concerning desirable information:

The dossier would benefit from additional information in the following areas:

- [ ] *Proposed restriction*
- [ ] *Information on hazards and risks*
- [ ] *Information on alternatives*
- [ ] *Justification for required action at the Community level*
- [ ] *Justification that the restriction is the most appropriate community*

[1] The lack of the desirable information would not cause the dossier to fail the conformity check.

wide action

[ ] *Socio-economic assessment*

[ ] *Information on stakeholder consultation*

[ ] *Technical dossier*

A. Checking the proposed restrictions (RAC & SEAC)[2]

A1. Does the proposal specify the identity of the substance (or the substances, when relevant) in sufficient detail? See Report section 1.1. and Annex B: B.1.

***RAC** rapporteurs' recommendations to the submitter:*

A2. Does the proposal specify the scope of the restriction proposed in sufficient detail[3]? See Summary, Report section 2.2. and Annex E: E.1.

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

A3. Does the proposal include a summary of the justifications for the restriction? See Summary and Report section 2.2.

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

A4. Does the proposal define any specific conditions that apply to the restriction(s)? See Summary, Report section 2.2. and Annex E.

Although the conditions are not obligatory, they are often highly recommendable to ensure implementability, enforceability, monitorability and effectiveness of the restriction. For instance:

- *concentration limit above which the restriction would apply*
- *time from which the restriction would apply, derogations from the restriction, e.g. conditions under which the use is not proposed to be restricted*

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

[2] Please remember to prioritise the recommendations

[3] Please see Annex I to the Conformity Check report for further guidance on assessment of the scope of the restriction.

B. Information on hazards and risks (RAC)

B1. Where there are other dossiers or chemical safety reports submitted under the REACH Regulation relevant for this restriction dossier, or to relevant risk assessments submitted for the purposes of other Community legislation or other fora such as OECD:

- *Does the report refer to the information on hazard or risks that has already been agreed in any of the aforementioned contexts?*
- *Does the report appear to take into account information in those dossiers and reports[4]?*

See Report section 1.1. and Annex B.

***RAC** rapporteurs' recommendations to the submitter:*

B2. Does the report 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 REACH? See Report section 1.1 and Annex B.

***RAC** rapporteurs' recommendations to the submitter:*

B3. Does the report appear to present sufficient information to allow an independent assessment of the hazard(s)? See Report section 1.1. and Annex B: B.4.- B.8.

***RAC** rapporteurs' recommendations to the submitter:*

B4. Does the report appear to present sufficient information on the uses of the substance(s) and resulting emissions or exposure? See Report section 1.1. and Annex B: B.9.

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

B5. Are the risks to be addressed described in sufficient detail? See Report section 1.1. and Annex B: B.10.

***RAC** rapporteurs' recommendations to the submitter:*

[4] This is to check that the requirement set in Article 69(4) of REACH is fulfilled in addition to demonstrating that the dossier conforms to the Annex XV requirements.

B6. *Does the report appear to provide evidence that implemented risk management measures are not sufficient? See Report 1.1. and Annex B: B.9.1.*

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

C. Information on alternatives (RAC and SEAC)

C1. *Does the report document whether or not any alternative substances or technologies have been identified? See Annex E: E.2.*

***RAC** rapporteurs' recommendations to the submitter:*

C2. *Where the report has identified alternatives, does the report appear to allow an evaluation of the information on risks related to the alternatives, availability of the alternatives (including time scales), technical and economic feasibility of the alternatives? See Annex E: E.2.*

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

D. Justification that action is required on a EU-wide basis

D1. *Does the report appear to allow an evaluation of the reasons supporting action on a EU-wide basis (rather than action at national or local level)? See Report 1.2 and Annex C.*

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

E. Justification that a restriction is the most appropriate EU-wide measure

E1. Does the report appear to allow an evaluation of the assessment of the proposed restriction and other identified RMOs against their effectiveness (including risk reduction capacity and proportionality), practicality (including information and justification facilitating the assessment of) and monitorability? See Report section 2 and Annex E: E.5., E.7., and E.8.

RAC *rapporteurs' recommendations to the submitter:*

SEAC *rapporteurs' recommendations to the submitter:*

E2. Does the assessment referred to in E1 appear to give sufficient background on the defined scope and conditions of the restriction? See Report Section 2 and Annex E: E.7. and E.8.

RAC *rapporteurs' recommendations to the submitter:*

SEAC *rapporteurs' recommendations to the submitter:*

E3. Does the assessment referred to in E2 appear to give estimates on the costs to the society due to the proposed restriction? See Report section 2.4 and Annex E: E.4.

SEAC *rapporteurs' recommendations to the submitter:*

F. Socio-economic Assessment of Proposed Restriction (SEAC)

F1. Does the report include further analysis (besides the one in Section E) of the socio-economic impacts of the proposed restriction? See Report section 2 and Annex E.

***SEAC** rapporteurs' recommendations to the submitter:*

F2. Does there appear to be a further need for

- *Evaluation of the net benefits to human health and the environment of the proposed restriction?*
- *Evaluation of the net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole of the proposed restriction?*
- *Comparison between net benefits and costs of the proposed restriction?*

See Report section 2. and Annex E.

***SEAC** rapporteurs' recommendations to the submitter:*

G. Information on stakeholder consultation (RAC and SEAC)

G1. Does the report describe whether or not any stakeholder consultation has been conducted? See Annex G.

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

G2. Does the report appear to allow tracking of how the results of any such consultations have been used in the development of the report? See Annex G.

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

Check if the report contains confidential data (RAC & SEAC)

Does the submitted information contain confidential data and are these presented in an addendum to the Annex XV report which can be separated from the report in order to ensure the report is non-confidential?

***RAC** rapporteurs' recommendations to the submitter:*

***SEAC** rapporteurs' recommendations to the submitter:*

Technical dossier

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

***RAC** rapporteurs' recommendation:*

Does the IUCLID 5 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** rapporteurs' recommendation:*