

ADDENDUM

TO THE GUIDANCE ON ANNEX XV FOR RESTRICTIONS AND TO THE GUIDANCE ON SOCIO-ECONOMIC ANALYSIS (SEA) – RESTRICTIONS

FORMAT OF ANNEX XV RESTRICTION REPORT

Version 2.1

17 May 2016

EXPLANATORY NOTE

1.1 Introduction

This format for an Annex XV restriction report replaces Appendices I 'Format for Restriction report' and II 'Information on how to fill in the Annex XV restriction report' of the *Guidance on Annex XV for restrictions* and section 5.2 "Reporting format" of the *Guidance on Socio-economic Analysis (SEA) -- Restrictions*, respectively.

This is an updated version of the format issued on 9 October 2015. It is based on the experience from the various restriction reports prepared under the REACH Regulation and the recommendations made by the Restrictions Efficiency Task Force (RETF) in 2014. The main changes from version 1.1 are:

- i) a new structure, where the report provides a detailed description of the restriction proposal in 30-50 pages, with supplementary detailed information provided in Annexes;
- ii) a new section has been added to allow the uncertainties and assumptions in the report to be highlighted;
- iii) the relevant part of the scope paper developed as part of the RETF's discussion is included as an Annex to this document (Appendix 1) and should be used when developing the Annex XV restriction report;
- iv) the introduction of the relevant recommendations on proportionality to the risk agreed in the RETF:
 - a. The Dossier Submitter must submit the following information to demonstrate proportionality to the risk:
 - i. an estimate of cost implications or savings (net costs) of the restriction
 - ii. description of the human health and environmental impacts of the restriction (i.e. risk reduction capacity), and
 - iii. quantification of the human health/environmental impacts when possible and meaningful.
 - b. It is clearly recognised that the quantification of human health and environmental impacts is not always possible.
 - c. Step-by-step approach (as suggested in the SEA guidance document) is necessary
 - d. When data are missing, use reasonable assumptions.
 - e. Carry out sensitivity analysis to identify the impact of most critical assumptions.
- v) some additional modifications added following the experience of using the format for developing restriction proposals and recommendations discussed the

ECHA/COM restrictions workshop in January 2016.

ECHA has also provided a style guide (also updated in April 2016) that should be followed by the Dossier Submitter to help with consistency between Annex XV reports. This is available on the ECHA website and should be considered as part of this format. ECHA has also provided a ready to fill in version of the format that meets the requirements of this document and the style guide.

The aim of the format is to meet the requirements set out in Title VIII (Restrictions) and Annex XV (Dossiers) to the REACH Regulation and Annex I of REACH Regulation related to the documentation of the information on hazard and risks. In addition, the need to take decisions in the most efficient and effective manner is also taken into account.

The format streamlines and clarifies how to document all relevant information in an Annex XV restriction report; its purpose is to assist Competent Authorities and ECHA in documenting the proposals for restrictions in a clear and transparent way.

This reporting format outlines how the final outcome of the work on an Annex XV restriction report should be documented. It does not describe the process, including the iterations that have been taken during the process of preparing the Annex XV restriction report. This process is described in the guidance documents.

Any confidential information should always be documented in separate annexes (in addition to the Annexes mentioned above) to make it easier to produce confidential and non-confidential versions of the report (a non-confidential version is required for the Public Consultation on the Annex XV report).

FORMAT OF ANNEX XV RESTRICTION REPORT

ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): [INSERT SUBSTANCE NAME(S)]

IUPAC NAME(S): [INSERT IUPAC NAME(S)]

EC NUMBER(S): [INSERT EC NUMBER]

CAS NUMBER(S): [INSERT CAS NUMBER]

CONTACT DETAILS OF THE DOSSIER SUBMITTER: [INSERT CONTACT DETAILS]

VERSION NUMBER: [INSERT VERSION NUMBER]

DATE: [INSERT DATE]

PROPOSAL FOR A RESTRICTION

Summary (indicative length 1-5 pages)

This section will give a summary of the main report¹:

- Scope and conditions of restriction(s), including the identity of the substance(s) and any derogations or conditions (this maybe in the format of a draft Annex XVII entry).
- Summary of the justifications for the restriction:
 - Identified hazard and risk
 - Justification that the proposed restriction is the most appropriate Union-wide measure (effectiveness in reducing the identified risks, proportionality to the risks, practicality, enforceability, monitorability)

Report (indicative length 40-70 pages)

This section should give a description of the restriction proposal and its justification to allow the reader to understand why the manufacture, placing on the market or use of the substance(s) within the scope of the restriction are not adequately controlled and need to be dealt with at Union level. If any section is short and self-contained with no supplemental information required, there is no need to add the corresponding Annex.

1 The problem identified

1.1 The hazard, exposure/emissions and risk

Describe here the identified risk(s) leading to the proposal of the restriction. Explain the hazard end-point(s) relevant for the purpose of the risk assessment, the related exposure levels and human population(s), vPvB/PBT emission estimations or environment compartment of concern and the characterisation of the risk; separate subheadings should be used if necessary². Describe which activities (manufacture, placing on the market, use(s)³ or end-of-life stage) result in the exposure or emissions that give rise to the risk including comparison with existing human biomonitoring and environmental monitoring data. Give also the evidence that the currently implemented risk management measures and operational conditions do not control the risk and that the existing regulatory risk management instruments are not sufficient. Supporting information, including relevant information on end-points that are not the main concern, can be reported concisely in relevant Annexes (Annex A: manufacture and uses, and Annex B: Information on hazard,

¹ The final restriction proposal does not need to be documented here rather this is the storey why the restriction is needed and is justified.

² Subheadings such as: Identity of the substances and physical and chemical properties; Justification for grouping; Classification and labelling; Hazard assessment; Exposure Assessment; Risk characterisation.

³ Taking into account that it is possible to restrict both the pre-marketing use of the substance in the formulation or production of mixtures/articles and the post-marketing use of mixtures/articles themselves, which may entail the use of the substance.

exposure/emissions and risk).

1.2 Justification for an EU wide restriction measure

Report the relevant arguments to justify that action is required on a Union-wide basis. Supporting information can be described in an Annex (Annex C: Justification for action on a Union-wide basis). This part could also be used by the Dossier Submitter to justify that a Union-wide basis is not required due to special national situation.

1.3 Baseline

Summarise here how the hazard, exposure and risks from the relevant use(s)⁴ would be expected to continue in the foreseeable future in compliance with current legislation that is without the proposed restriction. The baseline is also known as the 'business as usual' scenario. Supporting information can be reported in an Annex (Annex D: Baseline).

2 Impact assessment

The impact assessment is likely to be based on an iterative step-by-step approach (as suggested in the Guidance document on Socio-economic Analysis (SEA)):

- *Identification of all potential impacts (e.g. economic, environmental, social, health)*
- *Qualitative assessment of impacts (including an assessment of order of magnitude importance)*
- *Quantitative assessment of the main impacts (that are meaningful to quantify)*
- *Monetise the most significant impacts (that are meaningful to monetise).*

Impacts related to human health, the environment and the economy are likely to be the most significant impacts and are therefore the main focus. When data is missing, use reasonable assumptions. These assumptions could be built for example by extrapolating from information that is specific for a certain sectors (see section 3: Assumptions, uncertainties and sensitivities in addition). Supporting information and information on other impacts can be reported in an Annex (Annex E: Impact assessment).

If the scope of the impact assessment is different from the scope of the proposed restriction this should be clarified in this section along with any necessary justifications.

The following sections are set out to compare restriction options with each other, however, if it is more feasible to describe the impacts of the restriction options one by one, use headings:

- *Introduction*
- *Risk management options*
- *Restriction scenario(s)*
- *Assessment of restriction option 1*

⁴ Note that the use description used for risk assessment is not necessarily the same as the use description for the SEA. In this case, please map/describe how the uses correspond.

- *Economic impacts*
- *Human health and environmental impacts*
- *Other impacts⁵,*
- *Practicability and monitorability*
- *Proportionality to the risk*
- *Assessment of restriction option 2*
- *Assessment of restriction option 3 etc.*
- *Comparison of restriction options*

2.1 Introduction

Describe here the methodology used in the impact assessment and the boundaries of the assessment (e.g. geographic, temporal scope and supply chain related). Summarise also how well the scope of the assessment covers the scope of the restriction proposal (detailed discussion related to uncertainties can be reported under section 3 (Assumptions, uncertainties and sensitivities).

2.2 Risk Management Options

Describe the restriction options that have been assessed to deal with the problem identified⁶. Restriction options could differ, for example, in the activities covered, derogations proposed, or other conditions, such as entry into force dates. Briefly report also other discarded restriction options and risk management options such as authorisation or other Union legislation considered when preparing the restriction report, and the reasons for not assessing them in detail. More detailed assessment of all RMOs can be reported in an Annex (Annex E: Impact Assessment, section E.1. Risk Management options).

2.3 Response to restriction scenario(s)

Describe here what is (are) the likely behavioural response(s) of those affected by the assessed restriction options. If you think that the least costly response will not be selected, please describe in more detail the possible reasons under the section on Economic impacts.

One description of behavioural response may cover all restriction options, if appropriate. This scenario is used against the baseline when assessing the economic and human health and/or environmental impacts.

In addition, describe here the transitioning of those affected to alternatives and include a summary of the information on alternative substances and techniques. This could cover technical feasibility, risk reduction, economic feasibility and availability of alternatives).

Further information e.g. on costs and potential risks of the alternatives can be included in

⁵ Such as social, distributional and wider economic impacts.

⁶ Normally at least 2 restriction options would be analysed to allow the Committees to understand why the chosen option is being proposed (e.g. better risk reduction capacity, greater proportionality to the risk etc). However, if only one option is identified and assessed, the other restriction options screened and discarded should be set out in Annex E: Impact Assessment – section E.1.2 Other evaluated restriction options.

an Annex (Annex E: Section E.2. Alternatives and Section E.3: Restriction scenarios).

2.4 Economic impacts

Summarise here the economic impacts of each restriction option. The main economic impact is likely to be the additional cost to economic operators of complying with the restriction. Give these (net) compliance costs of the restriction options by comparing them with the baseline. Costs arising from issues such as recycling, stocks and second hand goods should also be covered.

Appropriate subheadings can be used as relevant⁷ and further information and assessments can be presented in an Annex (Annex E Impact Assessment Section E.4. Economic Impacts).

2.5 Human health and environmental impacts

Summarise here the human health and environmental impacts of restriction options by comparing them with the baseline. If quantification of impacts is not possible, describe them qualitatively and describe why quantification is not carried out. You would normally be expected to be able to give at least the emission reduction (as a proxy of the impact). Consider also the risks of alternative substances or technologies.

When relevant summarise here also the changes in emissions, exposure and risk due to the restriction option(s) to supplement the information on human health and environmental impacts.

Further information can be covered in an Annex (Annex E Impact Assessment – Section E.5. Human health and environmental impacts).

2.6 Other impacts

Describe here the possible social, distributional (including impacts on SMEs) and wider economic impacts of the restriction options. When relevant discuss also the affordability of the restriction.

Appropriate subheadings can be used as relevant and further information and assessments can be presented in an Annex (Annex E Impact Assessment Section E.6. Other impacts).

2.7 Practicability and monitorability

Summarise here the practicability (including implementability, enforceability and manageability) and monitorability aspects. Supporting information can be reported in an Annex (Annex E Impact Assessment Practicability and monitorability).

2.8 Proportionality to the risk (including comparison of options)

Summarise here the proportionality to the risk of the restriction options and compare them in terms of their health and environmental impacts (benefits), and economic impacts (costs). Consider both quantitative and qualitative information. Information may be

⁷ Subheadings could include Substitution costs, testing costs, costs of the recycling sector etc

presented also on distributional impacts, affordability etc. if relevant.

Describe also other impacts, enforceability and practicality aspects when relevant for concluding on the most appropriate option.

When useful summarise here possible results of the sensitivity analysis to identify the impact of most critical assumptions.

3 Assumptions, uncertainties and sensitivities

Describe here all the main assumptions used (e.g. what causal chains have been used to estimate health or environmental effects, what behavioural response(s) are assumed, what unit values and discount rate have been used, the methodological choices etc.) and the basis for these assumptions. Describe the main uncertainties in the assessment e.g. by carrying out a sensitivity analysis of the most critical assumptions and estimates.

Supporting information and a detailed assessment can be reported in an Annex (Assumptions, uncertainties and sensitivities).

The requirement to have specific question during the public consultation to test assumptions or reduce uncertainties may also be indicated here.

4 Conclusion

Give the chosen restriction option (the proposed restriction) in the form of an Annex XVII entry - not necessarily legally written but could be in ordinary language - with relevant conditions and summarise the justification for the choice made and why it is the most appropriate EU wide measure.

Annexes (no indicative length)

The Annexes should be used in a flexible manner to supplement the report. If there is no supplemental information to that set out in the report, the respective Annex does not need to be included. However, it is expected all dossiers would have at least the following annexes⁸:

- Annex A: Manufacture and uses
- Annex B: Information on hazard, exposure/emissions and risk
- Annex E: Impact Assessment
- Annex F: Assumptions, uncertainties and sensitivities
- Annex G: Stakeholder information during the preparation of the Annex XV dossier

Annex A: Manufacture and uses

Document the available information on the manufacture, placing on the market, export and uses of the substance on its own, in mixtures or in articles. Describe all stages of the life-cycle of the substance resulting from the manufacture and uses. If appropriate, use the descriptor system as described in the Guidance on information requirements and chemical safety assessment. Note that the use description used for risk assessment is not necessarily the same as the use description for the SEA. In this case, please map/describe how the uses correspond. In some cases sections A.1 and A.2 could be combined.

A.1 Manufacture, import and export of a substance

Report tonnage manufactured, imported or exported. Document the available information about the past trends in manufacture, import and export and, where relevant, the location and number of manufacturers. Where relevant, also document information on import and export of articles containing the substance.

A.2 Uses

Summarise here available information on the uses of a substance to get an overview. Uses may cover the use of the substance on its own or in mixture(s) and also uses of articles containing the substance. This information could be presented qualitatively or quantitatively.

For uses for which a restriction is being proposed, document the available information about the tonnage and past trends in use of the substance and, where relevant, location and number of users of the substance. The future trends should be reported in the baseline section/Annex.

A.3 Uses advised against by the registrants

Document here the uses advised against by the registrants, which are recorded in the CSRs. Give also the justifications given by the registrants.

⁸ Annexes may be numbered if some Annexes are left out

Annex B: Information on hazard, exposure/emissions and risk

General introduction

This Annex underpins the Hazards, exposure/emissions and risk section of the report, and should follow the relevant parts of Annex I to the REACH Regulation; thus the format includes all the main headings of a Chemical Safety Report (CSR) format, part B⁹. However, the order of the headings may be further adapted if necessary to improve the comprehensibility of the Annex¹⁰.

Guidance on completing this Annex can be found in:

- Sections 4 and 5.2 of the [Guidance on Annex XV for restriction](#)
- Section 2.3 of the [Guidance on SEA – Restrictions](#)
- [Guidance on Information Requirements and Chemical Safety Assessment](#)
- [Manual for the IUCLID CSR plug-in](#).

In developing Annex B, refer to any dossier, CSR or risk assessment submitted to ECHA or a Member State under the REACH Regulation as well as other relevant risk assessments submitted or carried out under other European Union legislation. It is not necessary to repeat this information in the Annex if it is assessed to be adequate for the purposes of the restriction proposal but to summarise and reference the original document. Report clearly which conclusions have been reviewed and which have been taken from the source document without further review. In addition, clarify where new information (available after the original document was dated) has been taken into account and how it changes any conclusions. The relevant headings should also be used to give an explanation if the interpretation of studies differs from those given in available CSRs in the registration dossiers or other dossiers referred to.

All assumptions and methodologies used in the preparation of the report should be clearly explained, and include an assessment of any remaining uncertainties in the analysis in terms of their overall significance to the conclusions. Note that where relevant, the information can be extracted directly from any IUCLID 5 dossier.

If the proposal covers several substances (grouping of substances) give sufficient information to justify the conclusions for all substances covered by the proposal.

In case of targeting to certain hazard end-points, some of the main headings from B.4 to B.8 may not be relevant for the particular case. This depends on the nature/scope of the proposal and if supporting information is presented on additional end-points that are not the main concern.

If a heading is not needed, state 'not relevant for this proposal' or 'described in the main report' under the heading.

⁹ For the purposes of this report template the manufacture and uses sections has been made as a separate Annex and only a brief summary of the essential elements needs to be included in Annex B.

¹⁰ Sub-sections B.9 (Exposure assessment) and B.10 (Risk characterisation) aim to document information differently than in the registrant's CSA and, therefore, these sections differ from the CSR format.

CSR headings (with some modifications)**B.1 Identity of the substance(s) and physical and chemical properties**

If the restriction proposal covers more than one substance (i.e. grouping of substances) a justification for grouping should be given here. Give also registration numbers where available.

B.1.1 Name and other identifiers of the substance(s)**B.1.2 Composition of the substance(s)****B.1.3 Physicochemical properties****B.1.4 Justification for grouping****B.2. Manufacture and uses**

Add a brief summary here of the information in Annex A that is relevant for the risk assessment that follows.

B.3 Classification and labelling**B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)****B.3.2 Classification and labelling in classification and labelling inventory/Industry's self classification(s) and labelling****B.4 Environmental fate properties**

Report here relevant environmental fate properties. Use only the subheadings relevant for the case.

B.4.1 Degradation**B.4.2 Environmental distribution****B.4.3 Bioaccumulation****B.4.4 Secondary poisoning****B.5 Human health hazard assessment**

Report here relevant toxic end points. Use only the subheadings relevant for the case.

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

- B 5.2** Acute toxicity
- B 5.3** Irritation
- B 5.4** Corrosivity
- B 5.5** Sensitisation
- B 5.6** Repeated dosed toxicity
- B 5.7** Mutagenicity
- B 5.8** Carcinogenicity
- B 5.9** Toxicity for reproduction
- B 5.10** Other effects
- B 5.11** Derivation of DNEL(s)/DMEL(s)
- B.6** Human health hazard assessment of physicochemical properties

Report here relevant physicochemical end points. Use only the subheadings relevant for the case.

- B 6.1** Explosivity
- B 6.2** Flammability
- B 6.3** Oxidising potential
- B.7** Environmental hazard assessment

Report here relevant environmental hazard end points. Use only the subheadings relevant for the case.

- B 7.1 Aquatic compartment (including sediments)**
- B 7.2 Terrestrial compartment**
- B 7.3 Atmospheric compartment**
- B 7.4 Microbiological activity in sewage treatment systems**
- B 7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)**

- B.8 PBT and vPvB assessment**

Report here when appropriate the conclusion of the assessment with relevant justifications. Use only the subheadings relevant for the case.

- B 8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII**
- B 8.2 Emission Characterisation**

- B.9 Exposure assessment**

Document in sufficient detail the exposure assessment carried out for the manufacture, for all relevant uses and the relevant life-cycle stages (including use of articles containing the substance and all relevant waste stages) identified in chapter B.2.2 and for which a restriction is proposed (i.e. uses in the scope of the restriction).

Describe where relevant and available, information on the total emissions to get a better picture of the impact of the proposed restriction.

Document the available information on the implemented and recommended risk management measures and operational conditions applied by the registrants and proposed to the downstream users during the manufacture and of each use described in the restriction proposal (where necessary in an exposure scenario). The exposure estimation needs to take into account of the implemented operational conditions and risk management measures.

Document also the existing legal requirements (based on section 5.2.3.1 of the [Guidance on Annex XV for restrictions](#)) that aim to reduce or limit emissions and exposures (reference can also be made here to Annex E Impact Assessment, section 1.3 Other Union-wide risk management options other than restrictions).

Report the assessment of all relevant exposures to different human populations (workers, consumers, humans exposed via the environment) and to different environment compartments including human biomonitoring and environmental monitoring data.

Describe the situations giving grounds for risk to human health or the environment or both.

Report also, where relevant, when the interpretations of the Dossier Submitter differ from the ones in CSRs.

When the restriction proposal is based on combined human exposure and/or aggregated or total exposure using estimates of total emissions, describe the situation in sufficient detail.

- B.9.1** **General discussion on releases and exposure**
- B.9.1.1** **Summary of the existing legal requirements**
- B.9.1.2** **Summary of the effectiveness of the implemented operational conditions and risk management measures**
- B.9.2** **Manufacturing**
- B.9.2.1** **Occupational exposure**
- B.9.2.2** **Environmental release**
- B.9.3** **Use 1: (add short title)**
- B.9.3.1** **General information**
- B.9.3.2** **Exposure estimation**
- B.9.3.2.1** Workers exposure
- B.9.3.2.2** Consumer exposure
- B.9.3.2.3** Indirect exposure of humans via the environment
- B.9.3.2.4** Environmental exposure
- B.9.x** **Use x: (add short title)¹¹**
- B.9.4¹¹** **Other sources (for example natural sources, unintentional releases)**
- B.9.5¹¹** **Overall environmental exposure assessment**
- B.9.6¹¹** **Combined human exposure assessment**
- B.10** **Risk characterisation**

Describe risk characterisation results and identify risks which are not sufficiently managed. This should be done for all relevant combinations of uses, exposure routes, exposure durations and human populations / environmental compartments. If possible, provide supplementary information on e.g. number of exposed workers and/or consumers, number of industrial sites, expert judgement on geographical relevance of pollution, demographic data of impacted area.

If risk characterisation is performed for manufacture or uses which are not suggested to be restricted these characterisations could be included for completeness.

¹¹ Add subheadings if more than one use is described and change the following subheadings accordingly (this should also be reflected in the risk characterisation section)

B.10.1 Manufacturing¹²**B.10.1.1 Human health**

B.10.1.1.1 Workers

B.10.1.1.2 Consumers

B.10.1.1.3 Indirect exposure of humans via the environment

B.10.1.1.4 Combined exposure

B.10.1.2 Environment

B.10.1.2.1 Aquatic compartment (including sediment and secondary poisoning)

B.10.1.2.2 Terrestrial compartment (including secondary poisoning)

B.10.1.2.3 Atmospheric compartment

B.10.1.2.4 Microbiological activity in sewage treatment systems

B.10.2. Use 1: (add short title)¹²**B.10.1.1 Human health**

B.10.1.1.1 Workers

B.10.1.1.2 Consumers

B.10.1.1.3 Indirect exposure of humans via the environment

B.10.1.1.4 Combined exposure

B.10.1.2 Environment

B.10.1.2.1 Aquatic compartment (including sediment and secondary poisoning)

B.10.1.2.2 Terrestrial compartment (including secondary poisoning)

B.10.1.2.3 Atmospheric compartment

B.10.1.2.4 Microbiological activity in sewage treatment systems

B.10.x Use x: (add short title)

¹² Reflect the relevant headings used in section B.9

Annex C: Justification for action on a Union-wide basis

This Annex underpins the Justification for action on a Union-wide basis section of the report. It relates to what is sometimes referred to as the “subsidiarity test”, i.e. demonstrating that the EU has the right to act and is better placed than the Member States to tackle the risk. If the Annex is short you can leave out the sub-headings:

- Considerations related to human health and environmental risks
- Considerations related to internal market
- Other considerations
- Summary

Further guidance can be found in section 5.3 of the [Guidance on Annex XV for restrictions](#) and section 1.2.2 of the [Guidance on SEA – Restrictions](#).

Annex D: Baseline

This Annex underpins the Baseline section of the report. Give here any additional information supporting the baseline.

Further guidance can be found in section 2.3 of the [Guidance on SEA – Restrictions](#).

Annex E: Impact Assessment

This Annex underpins the Impact Assessment of the report.

E.1. Risk Management Options

This section underpins the Risk management options section of the report.

Further guidance can be found in sections 5.4. of the [Guidance on Annex XV for restrictions](#) and sections 1.2.3, 1.2.4 and 2.4 of the [Guidance on SEA – Restrictions](#) (and the sections following thereof).

E.1.1 Proposed option(s) for restrictions

This section identifies and describes the proposed restriction option and any other potential restriction options (if any have been identified¹³) that will be further assessed; disregarded restriction options should be covered in the next section. Document here the scope, timing and other conditions of the proposed restriction and other potential restriction options (if any) and briefly justify why the proposed option has been selected. Use subheadings if necessary (e.g. Proposed restriction option; Justification for the selected scope of the proposed

¹³ The Dossier Submitter may identify more than one potential restriction option that offer different advantages e.g. different transitional periods that offer quicker control of the risks (short period) or lower costs (longer period). The Dossier Submitter may want to detail the assessment of both options and whilst favouring one, may want to present the information on the other so the Committees can understand the option proposed in more detail.

restriction option; additional restriction option; analysis of the additional restriction option).

E.1.2 Other evaluated restriction options

This section identifies and describes restriction options that have been identified and assessed but where the Dossier Submitter proposes not to take them taken forward. A brief justification why these options were not taken forward should be given.

E.1.3 Other Union-wide risk management options than restriction

This section should identify and briefly describe other Union-wide legal instruments (i.e. risk management options other than restriction under REACH) with a view of assessing which of them could be applied to address the risk identified in section B.11. This section may, where relevant, also cover possible Union-wide voluntary and economic instruments. It should be also briefly addressed why these non restriction options are not appropriate options to manage the risks. This information could be presented in tabular form, such as:

Table x. Possible other Union-wide options discarded at this stage

Option	Reasons for discarding this option
(I) Non-legislative measures	
<i>Voluntary industry agreement.</i>	
<i>Information campaign.</i>	
<i>Economic policy instrument (taxation)</i>	
(II) Legislation other than REACH	
<i>Cover relevant non REACH legislation, such as:</i> <ul style="list-style-type: none"> • <i>Amendments to the General Product Safety Directive</i> • <i>Harmonised classification under CLP</i> 	
(III) Other REACH processes	
REACH Authorisation process	
REACH Art. 68.2	

E.2. Alternatives

This section underpins the Restriction scenario(s) section of the report, and the following assessment of impact. In this section, document relevant available information on alternative substances and techniques. Include aspects that support defining what to consider and document on alternatives in the main report.

Further guidance can be found in section 5.5. of the [Guidance on Annex XV for restrictions](#) and sections 2.4, 2.5 and 3 of [Guidance on SEA – Restrictions](#) and the [Addendum on Calculation of compliance costs](#).

E.2.1. Description of the use and function of the restricted substances

Give a description of the use and function of the substance(s) to be restricted in such detail to allow the following assessment of alternatives to be put into context. Do not repeat in detail the information already given in Annex A but instead summarise the key elements.

E.2.2. Identification of potential alternative substances and techniques

Describe here the first screening of the alternatives, include details of alternatives which have been considered but are not subsequently discussed further in the following sections and provide justification for screening these alternatives.

Further guidance can be found in sections 5.5.3 and 5.5.3.1 of the [Guidance on Annex XV for restrictions](#) and sections 2.4 and 3.1-3.3 of the [Guidance on SEA – Restrictions](#)

E.2.3. Risk reduction, technical and economic feasibility and availability of alternatives

E.2.3.2. Assessment of alternative 1¹⁴

Give a short description of alternative 1

E.2.3.2.1. Availability of alternative 1

Further guidance can be found in section 5.5.3.2 of the [Guidance on Annex XV for restrictions](#).

E.2.3.2.2 Human health risks related to alternative 1

Further guidance can be found in section 5.5.3.2 of the [Guidance on Annex XV for restrictions](#) and section 3.4 of the [Guidance on SEA – Restrictions](#).

E.2.3.2.3. Environment risks related to alternative 1

Further guidance can be found in section 5.5.3.2 of the [Guidance on Annex XV for restrictions](#) and section 3.4 of the [Guidance on SEA – Restrictions](#).

E.2.3.2.4 Technical and economic feasibility of alternative 1

Further guidance can be found in section 5.5.3.2 of the [Guidance on Annex XV for restrictions](#), section 3.5 of the [Guidance on SEA – Restrictions](#) and the [Addendum on Calculation of compliance costs](#).

¹⁴ If it is considered more feasible to describe all alternatives in parallel, use headings: Assessment of alternatives; Availability of alternatives; Human health risks related to alternatives; Environmental risks related to alternatives; Technical and economical feasibility of alternatives and Other information of alternatives

E.2.3.2.5 Other information on alternative 1

Give any further relevant and available information.

E.2.3.2 Assessment of alternative x

Use the same subheadings and, if necessary, continue for other alternatives.

E.3. Restriction scenario(s)

This section underpins the Restriction scenario(s) section of the report. Based on information in the Section E.2 on alternatives, give here any additional information supporting the setting of the restriction scenario. This includes considerations on the behavioural response(s) of the affected stakeholders, i.e. which alternative is most likely to be implemented, if this is perhaps different from the cheapest option, or further justifies any derogations given (to that given in E.1.).

Further guidance can be found in section 2.4 of the [Guidance on SEA – Restrictions](#).

E.4. Economic impacts

This section underpins the Economic impacts section of the report. Subsections on substitution costs, testing costs etc may be added when relevant.

Present or summarise all relevant cost elements (including technical limitations of alternatives that were not possible to monetise) based on section on Technical and economic feasibility of alternatives. E.g. answering the questions: “What are the costs of the option? What is the timescale for the occurring costs?” Quantitative information on costs should always be given.

Costs arising from issues such as recycling, stocks and second hand articles should also be covered¹⁵.

Report any further detailed assessment of the economic impacts of the proposed restriction. Further guidance can be found in section 3.5 of the [Guidance on SEA – Restrictions](#) and its [Compliance costs addendum](#).

E.5. Human health and environmental impacts

This section underpins the Human health and environmental impacts section of the report.

Present/summarise all relevant changes in human health and environmental risks and impacts (qualitative/quantitative) building on Annex: Information on hazard and risk (B.10 Risk characterisation) and the baseline, e.g. answering the questions: “What are the changes in human health and environmental risk and impacts? Is the measure targeted to the identified risk? What is the timescale for the reduction of risk and impacts?”). Information on benefits should be presented at least qualitatively and quantified where possible. Where quantified impacts are presented then a further subheading (E.5.3 Quantification and monetisation of impacts) can be added.

¹⁵ The Commission and ECHA will look to provide further guidance on these issues during 2016/7.

E.5.1. Human health impacts

Building on the information in the main report, report any further assessment and valuation of the human health impacts of the proposed restriction. Further guidance can be found in section 3.4 and Appendix C of the [Guidance on SEA – Restrictions](#).

E.5.2. Environmental impacts

Building on the information in the main report, report any further assessment and valuation of the environmental impacts of the proposed restriction. Further guidance can be found in section 3.4 and Appendix C of the [Guidance on SEA – Restrictions](#).

E.5.3. Changes in emission, exposure and risk

Report here the risk reduction capacity of the assessed options (considering also the information on alternatives).

- Changes in human health risks or impacts
- Changes in the environmental risks or impacts
- Other issues

Further guidance can be found in section 5.6 of the [Guidance on Annex XV for restrictions](#) and sections 3.4.3 the [Guidance on SEA – Restrictions](#).

E.6. Other impacts

Summarise here social, distributional and wider economic impacts as well as affordability considerations of the assessed restriction option(s).

E.6.1. Social impacts

Further guidance can be found in section 3.6 and Appendix B.3 of the [Guidance on SEA – Restrictions](#).

E.5.6.2. Wider economic impacts

Further guidance can be found in section 3.7 and Appendix B.4 of the [Guidance on SEA – Restrictions](#).

E.5.6.3. Distributional impacts

Where possible, add here an assessment of the effect of the proposed restriction option(s) e.g. on small and medium size enterprises, different geographical regions, different socio-economic groups etc. When relevant, discuss also the affordability of the proposed restriction. Use sub-headings when useful.

Further guidance can be found in section 4.3 of the [Guidance on SEA – Restrictions](#).

E.7. Practicality and monitorability

Add here an assessment of the practicability and monitorability of the proposed restriction option(s).

For practicality (including implementability, enforceability and manageability), further guidance can be found in section 5.4.5.2 of the [Guidance on Annex XV for restrictions](#)

For monitorability, further guidance can be found in section 5.4.5.3 of the [Guidance on Annex XV for restrictions](#). Take into account that post-marketing use of the substance (in mixtures or articles) is usually much harder to monitor and enforce than use for formulation or production or placing on the market of those mixtures or articles.

E.8. Proportionality to the risk (comparison of options)

Report in this section the justification that a specific restriction option under REACH is the most appropriate Union-wide measure. The reference point for this comparison is the baseline. Further guidance can be found in section 5.4.5.4 of the [Guidance on Annex XV for restrictions](#) and sections 4.1 - 4.4 of the [Guidance on SEA – Restrictions](#).

E.8.1. Comparison of Restriction Options¹⁶

Briefly summarise the relevant Restriction Options in terms of their risk reduction capacity and costs (if more than one restriction option is compared – if only one option is proposed, this section can be left out). Consider both quantitative and qualitative information. Describe also other impacts, enforceability and practicality aspects when relevant for concluding on the most appropriate option.

E.8.2. Comparison of costs and benefits

Based on the information in the main report and annexes on economic, human health, environmental and other impacts, compare here the costs and the benefits of the restriction option(s). Consider both quantitative and qualitative information, especially if the benefits cannot be monetised or otherwise quantified. Describe also other impacts, enforceability, practicality and affordability aspects when relevant. E.g. answering the questions: Does the preferred option give a balance between costs and benefits? If other options are considered what is the balance between costs and benefits? What is the cost-effectiveness of the option(s) and what can these cost effectiveness figures be usefully compared too?

Annex F: Assumptions, uncertainties and sensitivities

Give here any additional information or analysis of assumptions, uncertainties and sensitivities.

Further guidance can be found in sections 2.5, 3.8, 4.3 and 4.4, as well as Appendix E) of the [Guidance on SEA – Restrictions](#) and on section 4.2.4 of the [Guidance on Annex XV for restrictions](#).

Annex G: Stakeholder information

Report here the stakeholder consultations carried out during the preparation of the restriction reports. Report also previous/other consultations on the same topic when

¹⁶ If only one restriction option is assessed this section can be omitted and the following section presented under the section above.

relevant for the case.

Further guidance can be found in section 5.7 of the [Guidance on Annex XV for restrictions](#) and section 2.2 and Appendix 1 of the [Guidance on SEA – Restrictions](#)

Appendix 1: RESTRICTION EFFICIENCY TASK FORCE PAPER - 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 restrictions proposed in conjunction with the risk assessment performed by the dossier submitter;
- by the boundaries within which the assessment of risks have 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 should the Dossier Submitter 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 an 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.

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 Appendix 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: CH₃P(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 list¹⁷ 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
- 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, these 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

¹⁷ The Annex XV Dossier should also consider this positive or negative list of articles.

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 XV¹⁸.

¹⁸

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

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, it should be simple for the two Committees to verify that the proposed restriction corresponds to the risk assessment. The situation can be more 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 in relation to the risk. However, it would be difficult for the Commission to further process these “non-assessed options” if they were not part of the public consultation.

Public consultation

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

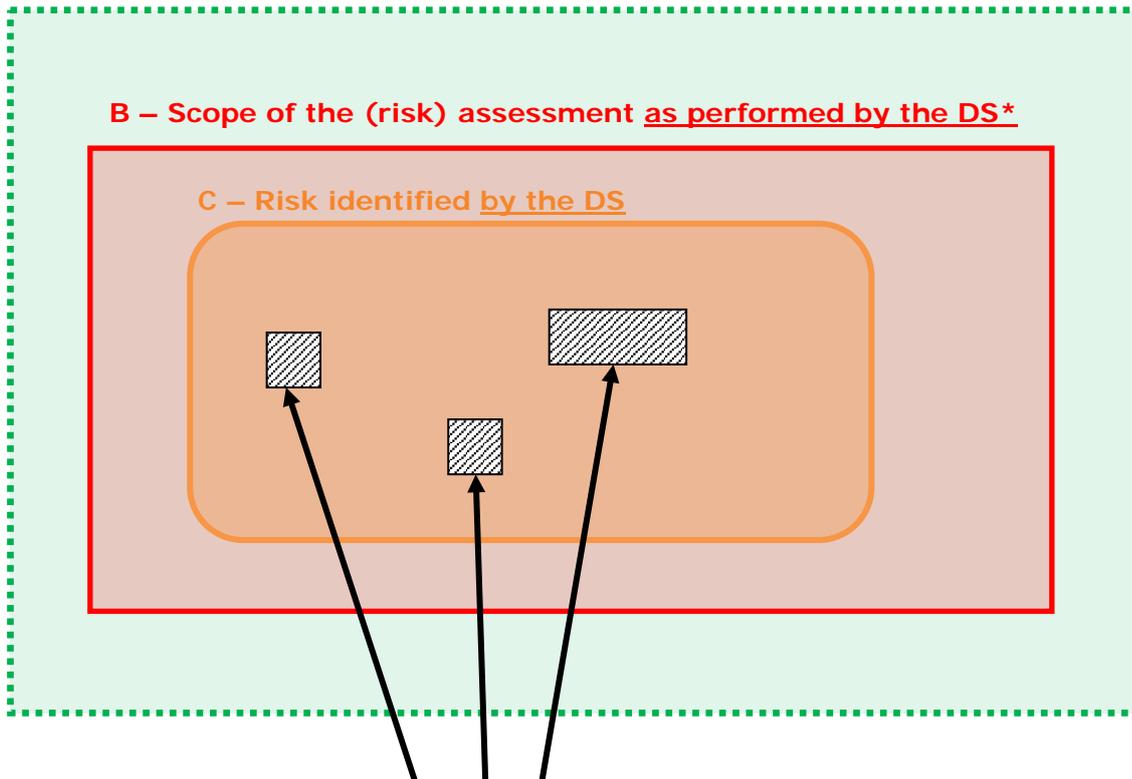
In its document CARACAL CACS/23/2013, the Commission considered the public consultation as a crucial step during the opinion making process and this has also been discussed within the task force.

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 scope of the 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.

Appendix 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)



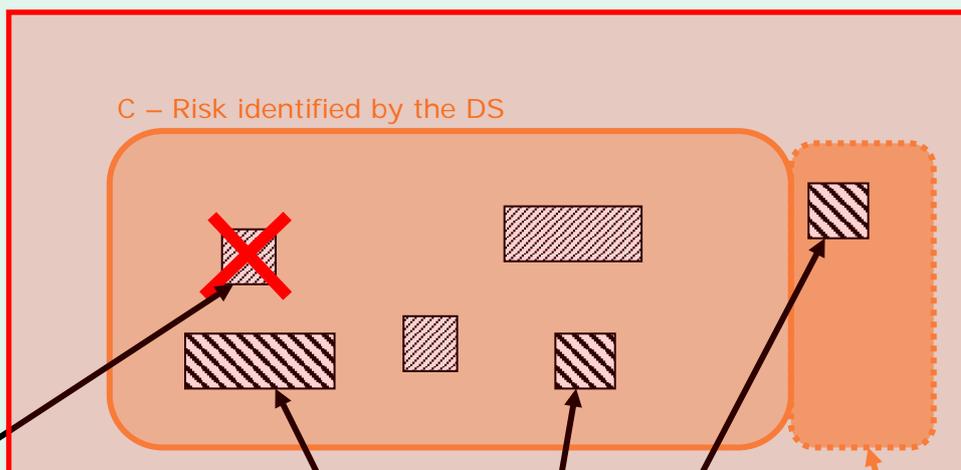
C – Exemptions based on socio-economic implications or lack of alternatives as proposed by the DS

*Exemptions based on adequate control of the risk are included in B

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

B - Scope of the (risk) assessment as performed by the DS = FOCUS of RAC/SEAC

C – Risk identified by the DS



D'' - Exemptions based on socio-economic implications or lack of alternatives as proposed by the DS but not supported by SEAC

C' – Additional risk as identified by RAC¹ (this includes exemptions based on adequate control risk as proposed by DS but not supported by RAC)

D' – Additional/new exemptions as proposed by RAC/SEAC, including exemptions proposed during the Public Consultation and validated by RAC/SEAC

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.