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 2.2

03 December 2020

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 'setting a clear scope' paper, accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions developed as part of the RETF's discussion 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 Restriction Task Force has also published a "fit for purpose dossiers - good practice guide" in December 2020 to convey practical advice on the elements previously successful in simplifying restriction proposals. Reference to good practice tips from this guide have been added to this document and these should also be taken into account by the Dossier Submitters when drafting Annex XV restriction reports.

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

☞ Good practice tip: recommendations to Dossier Submitters from the Restriction Task Force

Please see Appendix I of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

☞ Good practice tip: General advice for dossier submitters

Please see Appendix II of the 'Fit for purpose dossiers – good practise guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

Summary (indicative length 1-5 pages)

This section will give a summary of the main report[1]:

- 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

☞ Good practice tips: considering grouping of substances into single restriction dossier

Please refer to Section 4 of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

☞ Good practice tip: summary

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

From Section 2.1 of 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

(effectiveness in reducing the identified risks, proportionality to the

[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.

Report (indicative length 40-70 pages)

> ☞ **Good practice tips: Thought-starter on how to regulate professional users' border-lining with industrial and consumer users under REACH restriction**
>
> Please refer to Section 5 of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

> ☞ **Good practice tips: considering 2nd hand, stocks and recycling**
>
> Please refer to Section 3 of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

> ☞ **Good practice tips: Uncertainties/lack of information**
>
> Please refer to Section 6 of the 'Fit for purpose dossiers – good practise guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

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

> ☞**Good practice tips**
>
> Please refer to Section 2.3 of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

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 necessary[2]*. 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*

[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.

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, 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

☛Good practice tips

Please refer to Section 2.4 of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

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 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:

[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.

- *Introduction*
- *Risk management options*
- *Restriction scenario(s)*
- *Assessment of restriction option 1*
  - *Economic impacts*
  - *Human health and environmental impacts*
  - *Other impacts*[5]*,*
  - *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 identified*6*. 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

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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.

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 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

☞Good practice tips:

Please refer to Section 7 of the 'Fit for purpose dossiers – good practice guide' accessible at: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

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 annexes[8]:

- 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 B[9]. However, the order of the headings may be further adapted if necessary, to improve the comprehensibility of the Annex[10].

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.9.4[11] Other sources (for example natural sources, unintentional releases)

B.9.5[11] Overall environmental exposure assessment

B.9.6[11] 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.

B.10.1 Manufacturing[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

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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)

12 Reflect the relevant headings used in section B.9

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)

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 identified[13]) 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 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	
Voluntary industry agreement.	
Information campaign.	
Economic policy instrument (taxation)	

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.

(II) Legislation other than REACH	
Cover relevant non-REACH legislation, such as: • *Amendments to the General Product Safety Directive* • *Harmonised classification under CLP*	
(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 1[14]

Give a short description of alternative 1

[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 economic feasibility of alternatives and Other information of alternatives

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.*

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 covered[15]*.*

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

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.

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 Options[16]

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

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

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 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