**Template**

# Outcome of the conformity check of an Annex XV restriction dossier

Date of receipt: sbm_first_submission
Annex XV dossier submission number: sbm_submission_no_first

# Outcome of the conformity check of an Annex XV dossier proposing restrictions at EU level

Please see the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals for further guidance on making the conformity check and its Annex on setting a clear scope developed by the Restriction Efficiency Task Force.

**Substance concerned:**

1. Chemical name: sid_substance_name_internal
2. EC No.: sid_ec_number
3. CAS No.: sid_cas_number

**Member State (or ECHA) submitting the proposal for restriction:**
**lec_submitter/ECHA**

**Final outcome of the conformity check by RAC & SEAC**:

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|---|
| The dossier does ***(not)***[1] **conform** to the requirements of Annex XV of the REACH Regulation. |

The conformity check was conducted by:

**Committee for Risk Assessment (RAC)**

**Rapporteur**: [name, surname]
**Co-rapporteur**: [name, surname]

**RAC decision on the outcome of the conformity check** [dd/mm/yyyy]:

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|---|
| Concerning required information:<br>[ ] The dossier conforms to the requirements of Annex XV of the REACH Regulation.<br>[ ] The dossier does not conform to the requirements due to shortcomings in:<br>[ ] Proposed restriction<br>[ ] Information on hazards and risks<br>[ ] Information on alternatives<br>[ ] Justification for required action at the EU level<br>[ ] Justification that the restriction is the most appropriate community wide action<br>[ ] Information on stakeholder consultations |

[1] Delete as appropriate

| |
|---|
| [ ] Substance ID<br>[ ] Technical dossier |

**Committee for Socio-economic Analysis (SEAC)**

**Rapporteur:** [name, surname]
**Co-rapporteur**: [name, surname]

**SEAC decision on the outcome of the conformity check** [dd/mm/yyyy]:

Concerning required information:

[ ] The dossier conforms to the requirements of Annex XV of the REACH regulation.
[ ] The dossier does not conform with the requirements due to shortcomings in:
- [ ] Proposed restriction
- [ ] Information on hazards and risks
- [ ] Information on alternatives
- [ ] Justification for required action at the EU level
- [ ] Justification that the restriction is the most appropriate EU wide action
- [ ] Information on stakeholder consultations
- [ ] Technical dossier

**Annexes to the outcome of the conformity check**

**Annex I:** The conformity report template with details of the conformity check performed
**Annex II:** The substance identity check report is annexed if more explanation is given.[2]

[2] Delete if Annex II is not needed.

## ANNEX I. CONFORMITY REPORT[3]

## I. Check of the Annex XV report on: [Chemical name]

### A. Checking the proposed restrictions (RAC & SEAC)

A1. Does the proposal specify the identity of the substance (or the substances, when relevant) in sufficient detail? See Report section 1.1.1 and Annex B: B.1.

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

A2. Does the proposal specify the scope of the restriction proposed in sufficient detail (see Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals Appendix II for more detail on assessing the scope; the relevant part of the guidance should be taken into account when assessing this question)? See Report section 2.2 and Annex E: E.1.1.

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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|---|
| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

### B. Information on hazards and risks (RAC)

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

[3] It is important to bear in mind that the conformity check is not an evaluation of the dossier but is intended to ensure there is information to fulfil each requirement in Annex XV to ensure a meaningful assessment of the dossier can be undertaken.

[4] The rapporteurs **should** provide reasons in this part of the conformity report why the report is **not** in conformity in relation to the relevant question. If the rapporteurs have comments on the relevant question when the report **is** in conformity, these comments should be given in the form of concrete and prioritised recommendations for the Dossier Submitter in the recommendations part of the conformity report (other document).

- Does the report refer to the information on hazard or risks that has already been agreed in any of the aforementioned contexts?
- Does the report appear to take into account information in those dossiers and reports[5]?

See Report section 1.1. and Annex B.

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

B2. Does the report appear to allow an evaluation of whether the approach used to identify the hazard and risk is in accordance with the relevant parts of Annex I of REACH? See Report section 1.1 and Annex B.

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|---|
| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

B5. Does the report appear to address the risks in sufficient detail to allow an independent assessment ? See Report section 1.1. and Annex B: B.10.

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

## C. Information on alternatives (RAC and SEAC)

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

## D. Justification that action is required on an EU wide basis

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

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| **RAC (for risk related considerations):Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC (for market related considerations): Yes ☐ No ☐**<br>[Reasons][4] |

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

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

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| **RAC (for effectiveness regarding risk reduction capacity, practicality and monitorability): Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC (for effectiveness regarding proportionality, practicality and monitorability): Yes ☐ No ☐**<br>[Reasons][4] |

E2. Does the assessment referred to in E1 appear to give sufficient background on the defined scope and conditions of the restriction , other than those issues covered by Question A2? See Report Section 2 and Annex E: E.7. and E.8.

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

E3 Does the assessment referred to in E1 appear to give estimates on the costs to the society due to the proposed restriction? See Report section 2. and Annex E: E.4.

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

## F. Socio-economic Assessment of Proposed Restriction

Socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI of the REACH Regulation, giving additional information to Section E. Such information comprises changes in employment or wider economic impacts (e.g. international trade or competition) as well as any additional information (other than that presented in part E) on economic, human health and/or environmental impacts.

## G. Information on stakeholder consultation (RAC and SEAC)

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

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| **SEAC: Yes ☐ No ☐**<br>[Reasons][4] |

# II. Technical dossier

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

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

Does the IUCLID 5 dossier include, for hazard information that has not been previously submitted to ECHA, Robust Study Summaries which appear to include sufficient information allowing a review of the relevance, reliability and adequacy of the data of relevance for the proposed restriction?

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| **RAC: Yes ☐ No ☐**<br>[Reasons][4] |

# ANNEX II. SUBSTANCE IDENTITY CHECK REPORT

[The substance identity check report can be added here if providing additional relevant information.]