Annex to the

ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): PFAS

IUPAC NAME(S): n.a.

EC NUMBER(S): n.a.

CAS NUMBER(S): n.a.

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

VERSION NUMBER: [INSERT VERSION NUMBER]

DATE: [INSERT DATE]

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Annex A Manufacture and uses [WP4]

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

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.

Annex B Information on hazard and risk

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. However, the order of the headings may be further adapted if necessary, to improve the comprehensibility of the Annex.

B.1. Identity of the substance(s) and physical and chemical properties [WP2]

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

B.1.1. Name and other identifiers of the substance(s)

Add text

B.1.2. Physicochemical properties [WP2]

Add text

B.1.3. Justification for grouping [WP2 + WP3]

Add text

B.2. Manufacture and uses (summary) [WP4]

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 [WP3]

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Add text

B.3.2. Classification and labelling in classification and labelling inventory/ Industry's self classification(s) and labelling

Add text

B.4. Environmental fate properties [WP3 ENV]

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

B.4.1. Degradation [support of WP2]

Add text

B.4.2. Environmental distribution [support of WP6]

Add text

B.4.3. Bioaccumulation [support of WP6]

Add text

B.4.4. Secondary poisoning

Add text

B.5. Human health hazard assessment [WP3 HH]

Subheadings not relevant/needed below can be removed.

Avoid too many details, we should limit the information to the level of detail needed for our dossier.

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

Add text

B.5.2. Acute toxicity

Add text

B.5.3. Irritation

Add text

B.5.4. Corrosivity

Add text

B.5.5. Sensitisation

Add text

B.5.6. Repeated dosed toxicity

Add text

B.5.7. Mutagenicity

Add text

B.5.8. Carcinogenicity

Add text

B.5.9. Toxicity for reproduction

Add text

B.5.10. Other effects

Add text

B.5.11. Derivation of DNEL(s)/DMEL(s)

Add text

B.6. Human health hazard assessment of physicochemical properties

Not relevant

B.7. Environmental hazard assessment [WP3 ENV]

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

B.7.1. Aquatic compartment (including sediments)

Add text

B.7.2. Terrestrial compartment

Add text

B.7.3. Atmospheric compartment

Add text

B.7.4. Microbiological activity in sewage treatment systems

Add text

B.7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

Add text

B.8. PBT and vPvB assessment [WP3 ENV]

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

Add text

B.8.2. Emission Characterisation

Add text

B.9. Exposure assessment [WP4 + WP6]

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

Add text

B.9.1.1. Summary of the existing legal requirements

Add text

B.9.1.2. Summary of the effectiveness of the implemented operational conditions and risk management measures

Add text

B.9.2. Manufacturing

Add text

B.9.2.1. Environmental release

Add text

B.9.3. Use 1: (add short title)

B.9.3.1. General information

Add text

B.9.3.2. Exposure estimation

Add text

B.9.3.2.1. Environmental exposure

Add text

B.9.4. Use x: (add short title)

B.9.5. Other sources (for example natural sources, unintentional releases)

Add text

B.9.6. Overall environmental exposure assessment

Add text

B.9.7. Combined human exposure assessment

Add text

B.10. Risk characterisation [WP4 + WP7 tbd]

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

B.10.1.1. Environment

Add text

B.10.1.1.1. Aquatic compartment (including sediment and secondary poisoning)

Add text

B.10.1.1.2. Terrestrial compartment (including secondary poisoning)

Add text

B.10.1.1.3. Atmospheric compartment

Add text

B.10.1.1.4. Microbiological activity in sewage treatment systems

Add text

B.10.2. Use 1: (add short title)

B.10.2.1. Environment

Add text

B.10.2.1.1. Aquatic compartment (including sediment and secondary poisoning)

Add text

B.10.2.1.2. Terrestrial compartment (including secondary poisoning)

Add text

B.10.2.1.3. Atmospheric compartment

Add text

B.10.2.1.4. Microbiological activity in sewage treatment systems

Add text

B.10.3. Use x: (add short title)

Annex C Justification for action on a Union-wide basis [WP0]

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:

C.1. Considerations related to human health and environmental risks

C.2. Considerations related to internal market

C.3. Other considerations

C.4. Summary

Annex D Baseline [WP7]

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

Annex E Impact Assessment

E.1. Risk Management Options [WP7]

E.1.1. Proposed option(s) for restriction

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.1.1.1. Proposed restriction option: (add short title)

Add text

E.1.1.2. Justification for the selected scope of the proposed restriction option

Add text

E.1.1.3. Other restriction option 1: (add short title)

Add text

E.1.1.4. Justification for the selected scope of the other restriction option 1

Add text

E.1.1.5. Proposed restriction option 2: (add short title)

Add text

E.1.1.6. Justification for the selected scope of other restriction option 2

Add text

E.1.1.7. Proposed restriction option x: (add short title)

Add text

E.1.1.8. Justification for the selected scope of the proposed restriction option x

Add text

E.1.2. Discarded 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 E-1. Possible other Union-wide options discarded at this stage

Option	Reasons for discarding this option
Non-legislative measures	
Voluntary industry agreement.	
Information campaign.	
Economic policy instrument (taxation)	
Legislation other than REACH	
Cover relevant non-REACH legislation, such as: Amendments to the General Product Safety Directive Harmonised classification under CLP	
Other REACH processes	
REACH Authorisation process	
REACH Art. 68.2	

E.2. Alternatives [WP3 + WP4 + WP7]

E.2.1. Description of the use and function of the restricted substance(s)

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 fulfilling the function

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.

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

E.2.3.1. Assessment of alternative 1

Add text

E.2.3.1.1. Availability of alternative 1

Add text

E.2.3.1.2. Human health risks related to alternative 1

Add text

E.2.3.1.3. Environment risks related to alternative 1

Add text

E.2.3.1.4. Technical and economic feasibility of alternative 1

Add text

E.2.3.1.5. Other information on alternative 1

Add text

E.2.3.2. Assessment of alternative 2

Add text

E.2.3.2.1. Availability of alternative 2

Add text

E.2.3.2.2. Human health risks related to alternative 2

Add text

E.2.3.2.3. Environment risks related to alternative 2

Add text

E.2.3.2.4. Technical and economic feasibility of alternative 2

Add text

E.2.3.2.5. Other information on alternative 2

Give any further relevant and available information.

E.3. Restriction scenario(s) [WP7]

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.).

E.4. Economic impacts [WP7]

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.

Report any further detailed assessment of the economic impacts of the proposed restriction.

E.4.1. Human health and environmental impacts

E.4.1.1. Human health impacts

Add text

E.4.1.2. Environmental impacts

Add text

E.5. Risk reduction capacity [WP7]

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.

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.

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*

E.6. Other impacts, practicability and monitorability [WP7]

E.6.1. Social impacts

Add text

E.6.2. Wider economic impacts

Add text

E.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.

E.7. Practicality and monitorability [WP7 with support from WP6]

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

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 (comparison of options) [WP7]

E.8.1. Comparison of Restriction Options

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 [WP3 + WP4 + WP7]

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

Annex G Stakeholder information [WP4]

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.

References [all – please use Endnote!]

Appendix X