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]

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

Summary [WP0]

Provide a summary of the main report:

- *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

Report [indicative length 40 – 70 pages]

1. The problem identified

1.1. Hazard, exposure/emissions and risk

1.1.1. Identity of the substance(s), and physical and chemical properties [WP2]

OECD definition, with explanation.

Phys chem from FFF dossier.

For consideration: provide a non-exhaustive list?

1.1.2. Justification for grouping [WP2 + WP3]

Grouping based on persistence. Include brief text on subgroups (WP2) and borderline cases (WP3)

1.1.3. Classification and labelling [WP3]

Copy from FFF dossier.

1.1.4. Hazard assessment [WP3]

Copy from FFF dossier. Main concern is persistence and that should be described in detail. Other hazards limited (with some more information in Annex)

1.1.5. Exposure assessment [WP4+WP6]

Describe which activities (manufacture, placing on the market, uses and/or end-of-life stage) result in exposure/emissions that give rise to the risk, including comparison with existing human biomonitoring and environmental monitoring data.

1.1.6. Risk characterisation [WP4+WP7 (tbd)]

Tonnage/emission compared to non-threshold, i.e. emissions as proxy for risk including evidence that currently implemented risk management measure and operational conditions do not control the risk and that existing regulatory risk management instruments are not sufficient.

1.2. Justification for an EU wide restriction measure [WP0]

*Report the relevant arguments to justify that action is required on a **Union-wide basis,** i.e. that the EU has the right to act and is better placed than the Member States to tackle the risk. Supporting information can be described in Annex C.*

1.3. Baseline [WP7 + WP4]

Explain how the hazard, exposure and risks from the relevant uses would be expected to continue in the foreseeable future in compliance with current legislation (without the proposed restriction) = business as usual scenario.

2. Impact assessment [WP7]

Option 1: Assess each restriction option seperately[1]

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 [support of WP0]

Describe the restriction options that have been assessed to deal with the problem identified. 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.

2.3. 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).

2.4. Assessment of restriction option 1

2.4.1. 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.

[1] Delete headings in the unnecessary section – only one set of headings is required in the Impact Assessment section. The boxes are just to indicate there are 2 options here for presenting the information and should be deleted in the final opinion.

2.4.2. Human health and environmental impacts [support of WP3 and WP4]

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.

2.4.3. Other impacts[2]

2.4.4. Practicability and monitorability [support of WP5]

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 Annex E Impact Assessment (Section E.6. Other impacts).

Summarise here the practicability (including implementability, enforceability and manageability) and monitorability aspects.

2.4.5. Proportionality to the risk

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 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.

2.5. Assessment of restriction option 2

Add text and subheadings as above

2.6. Assessment of restriction option 3

Add text and subheadings as above

[2] Such as social, distributional and wider economic impacts.

2.7. Comparison of restriction options

Add text

Option 2: Assess all restriction options together

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. 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.

2.3. 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).

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.

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.

2.7. Practicability and monitorability

Summarise here the practicability (including implementability, enforceability and manageability) and monitorability aspects.

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 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 [WP3 + WP4 + WP7]

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.

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

4. Conclusion [WP0]

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.

5. References [all – please use Endnote!]