

<p><b>Title:</b> Amending POPs Regulation Annex I to add PFHxS, its salts and PFHxS-related compounds and introduce a UTC limit for PFHxS in substances, mixtures and articles</p> <p><b>Date:</b> 30/08/2023</p> <p><b>BRU No:</b> <i>Provided by the BRU on sign-off</i></p> <p><b>Lead department or agency:</b> Department for Environment, Food and Rural Affairs</p> <p><b>Other departments or agencies:</b> N/A</p>	<b>De Minimis Assessment (DMA)</b>	
	<b>Stage:</b> Final	
	<b>Source of intervention:</b> Domestic	
	<b>Type of measure:</b> Secondary	
<b>Summary: Rationale and Options</b>	<p><b>Contact for enquiries:</b>  Analytical enquiries: <a href="mailto:Rebecca.Gibbard-Walker@defra.gov.uk">Rebecca.Gibbard-Walker@defra.gov.uk</a>  Policy enquiries: <a href="mailto:Lyndon.Ashmore@defra.gov.uk">Lyndon.Ashmore@defra.gov.uk</a></p>	
<b>Total Net Present Value</b> (2019 prices) £-0.06m	<b>Business Net Present Value</b> (2019 prices) £-0.04m	<b>Net cost to business per year</b> (EANDCB in 2019 prices) £0.00m

**Rationale for intervention and intended outcomes**

In 2022 perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds were listed as a persistent organic pollutant (POP) under the Stockholm Convention, a UN treaty to which the UK is a party. As a result, the UK has a legally binding obligation to restrict the manufacture, use, and placing on the market of these substances due to the harm they cause to human health and the environment. PFHxS, its salts and PFHxS-related compounds are man-made substances that have historically been used in a wide range of consumer goods and industrial processes although have since been phased out of use. The policy intervention will prohibit the manufacture, use, and placing on the market of PFHxS which, although not likely, could occur in the future without intervention. It will also ensure that international obligations to implement the addition of PFHxS to the Convention through domestic legislation are met and avoid potential reputational damage to the UK.

**Describe the policy options considered**

**Option 0 – Do nothing (baseline)**

In this scenario the amendment to the Stockholm Convention is not implemented through the POPs Regulation. The manufacture, use, and placing on the market of PFHxS, its salts and PFHxS-related compounds would continue to be allowed to take place in GB, and international obligations would therefore not be met.

**Option 1 – Amend POPs Regulation Annex I to add PFHxS, its salts and PFHxS-related compounds and introduce a UTC limit for PFHxS in substances, mixtures and articles (preferred)**

This option implements the addition of PFHxS, its salts and PFHxS-related compounds to the Stockholm Convention through domestic legislation, preventing manufacture, use, and placing on the market in GB, and meeting international obligations. It also introduces an unintentional trace contaminant (UTC) limit for PFHxS in substances, mixtures and articles, to allow traces of the chemical being unintentionally used in new products.

**Option 2 – Non-regulatory option**

In this scenario the amendment to the Stockholm Convention is not implemented through the POPs Regulation. This option would require industry to voluntarily eliminate PFHxS, its salts, and PFHxS-related compounds from manufacture, use, and placing on the market in GB. The manufacture, use, and placing on the market of PFHxS, its salts and PFHxS-related compounds would legally be allowed take place in the future, and international obligations would therefore not be met.

**Rationale for RTA rating**

Based on evidence from targeted Defra-led stakeholder engagement, there is no indication that PFHxS, its salts, or PFHxS-related compounds are intentionally produced or used in GB and as such, this policy intervention is not expected to have an impact on businesses, beyond the one-off familiarisation costs. It is also not expected to have a significant distributional impact, nor will it disproportionately burden small businesses. Overall, we are confident that the net costs to businesses are well below the +/- £5m threshold.

Will the policy be reviewed? No	If applicable, set review date: N/A
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Are these organisations in scope?	Micro Yes	Small Yes	Medium Yes	Large Yes
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Senior Policy Sign-off:	✓	Date:	09/08/2023
Peer Review Sign-off:	✓	Date:	16/08/2023
Better Regulation Unit Sign-off:	✓	Date:	30/08/2023

## 1.0 Policy Rationale

### Policy background

1. The United Kingdom (UK) is a Party to the UN Stockholm Convention on Persistent Organic Pollutants (POPs). POPs are substances which meet four criteria: they are persistent, toxic, bioaccumulative, and can travel across international borders. Parties to the Convention can, by consensus, agree to add a chemical substance to the list of POPs for elimination or for restriction.
2. PFHxS was initially proposed as a POP in 2017. Since then, UK stakeholders have had a number of opportunities to get involved in discussion – both UK and Convention led – before PFHxS was adopted for elimination under the Convention. This included public calls for information and opportunities to comment on draft risk profiles and risk management evaluation (RME) documents. Defra received no evidence to suggest that exemptions or derogations were required by industry.
3. The UK has an obligation to implement amendments to the Convention through its own domestic POPs Regulation which regulates the manufacture and use of POPs in Great Britain (GB) which are banned or restricted under the Stockholm Convention. Under the Windsor Framework, Regulation (EU) 2019/1021 on persistent organic pollutants (the EU POPs Regulation) applies directly in Northern Ireland (NI).
4. While the UK must intervene to prohibit the use of PFHxS, it is able to introduce certain exemptions for the unintentional trace contamination of the chemical in substances, articles or mixtures, to allow traces of the chemicals being unintentionally used in new products. This can be done by setting an unintentional trace contaminant level which defines the concentration at which a chemical can lawfully be found in a substance, article or mixture, where present unintentionally and in minimal amounts. A UTC limit provides more clarity to businesses.

### Problem under consideration

5. This intervention implements the UK's international obligations under the Convention through amending domestic legislation, namely the POPs Regulation.
6. By adding PFHxS to POPs Regulation this intervention would, on its own, prohibit the manufacture, use, and placing on the market of PFHxS in any setting and at any concentration. However, PFHxS can be found as an unintentional trace contaminant in certain substances, mixtures and articles, including at typically higher trace concentrations in concentrated fire-fighting foam mixtures. Therefore, a further intervention is needed to provide clarity to industry and prevent a disproportionate adverse impact. Without a UTC limit the limit of detection would apply, and any substances, mixtures or articles found to have any amount of PFHxS would be unlawful.

## Rationale for intervention

### Negative Externalities

7. PFHxS, its salts and PFHxS-related compounds are man-made substances that have historically been used in many consumer products and industrial applications. There are long-term economic impacts associated with pollution from POPs and environmental recovery. Manufacturers and users typically lack appropriate incentives to eliminate emissions from hazardous substances as they do not directly bear the costs of the pollution generated. The negative impacts created by the manufacture and use of PFHxS have a greater cost to society than the private cost incurred by the polluter. Although PFHxS is no longer manufactured, used or placed on the market in GB, a regulatory approach ensures that it can't take place in the future.

### Avoids reputational damage

8. Evidence indicates that PFHxS is no longer intentionally manufactured and used in GB, and that voluntary phase out is possible. However, the UK agreed to the common objective of eliminating PFHxS from global manufacture, use, and placing on the market to protect human health and the environment from POPs. The UK has an obligation to implement amendments to the Convention through its own domestic POPs Regulation. By not implementing the Stockholm Convention amendment through domestic legislation, the UK may be seen to be withdrawing from its legal commitment towards meeting this global objective.

### Policy objective

9. The aim of this policy intervention is to prohibit the manufacture, use, and placing on the market of PFHxS its salts, and related compounds, in line with the UK's obligations as a Party to the Stockholm Convention. This policy intervention will implement domestically the decision made by Parties, to list PFHxS, its salts and PFHxS-related compounds to the Convention, for global elimination, without specific exemptions.
10. This intervention will also establish a statutory UTC limit to define the concentration at which PFHxS can lawfully be found in a substance, article or mixture, *where present unintentionally and in minimal amounts*. Without a defined UTC limit the limit of detection applies, meaning that *any* article or mixture in which *any* value of the relevant substance is found is unlawful. The addition of a UTC for PFHxS provides clarity to industry of the UK regulatory position.
11. This instrument sets a UTC limit of 0.025 mg/kg for PFHxS and its salts where present in substances, mixtures or articles, and an equivalent limit of 1 mg/kg for PFHxS-related compounds. The instrument also sets a UTC limit of 0.1mg/kg for PFHxS, its salts, and PFHxS-related compounds where present in concentrated fire-fighting foam mixtures, which are used in the manufacture of Aqueous Film Forming Foam (AFFF).
12. The higher UTC limits for PFHxS, its salts, and PFHxS-related compounds where present in concentrated fire-fighting foam mixtures acknowledges the presence of PFHxS in some of these products. Setting a UTC for PFHxS in concentrated fire-fighting foam mixtures at the proposed level would ensure it is low enough to avoid the substance being used as an active ingredient in AFFF.
13. The intervention as described meets the UK's objective to prohibit the use of PFHxS, as agreed by the Stockholm Convention to which the UK is a Party. Additionally, the introduction of a UTC limit minimises impact to relevant businesses, while also providing clarity to industry in GB.

## Options considered

### Option 0 – Do nothing (baseline)

14. The amendment to the Stockholm Convention is not implemented through the POPs Regulation. Manufacture, use, and placing on the market of PFHxS, its salts and PFHxS-related compounds would continue to be allowed to take place, and international obligations would therefore not be met.

### Option 1 - Amend POPs Regulation Annex I to add PFHxS, its salts and PFHxS-related compounds and introduce a UTC limit for PFHxS in substances, mixtures and articles (preferred)

15. This option implements the addition of PFHxS, its salts and PFHxS-related compounds to the Stockholm Convention through domestic legislation, preventing manufacture, use, and placing on the market, and meeting international obligations. It also introduces an unintentional trace contaminant (UTC limit) for PFHxS in substances, mixtures and articles, to allow traces of the chemical being unintentionally used in new products.

### Option 2 - Non-regulatory option

16. In this scenario the amendment to the Stockholm Convention is not implemented through the POPs Regulation. This option would require industry to voluntarily eliminate PFHxS, its salts, and related compounds from manufacture, use, and placing on the market in GB. Manufacture, use, and placing on the market of PFHxS, its salts and PFHxS-related compounds would legally be allowed to take place in the future, and international obligations would therefore not be met.

## 2.0 Rationale for De Minimis Rating

### 2.1 Evidence

17. UK evidence has been gathered to understand the potential socio-economic impacts of banning PFHxS from manufacture and use, and to identify potential needs for specific exemptions. This has involved stakeholder engagement, analysis of UK registration, evaluation, authorisation and restriction of chemicals (REACH)<sup>1</sup> data, and desk-based research.
18. UK REACH data indicates that there are no GB manufacturers, downstream users or distributors of PFHxS, its salts, or PFHxS-related compounds in quantities above 1 tonne/year.<sup>2</sup> As part of Defra's stakeholder engagement, trade associations and industries related to potential applications of PFHxS were contacted, in addition to the UK Chemical Stakeholder Forum and UK regulators. Based on the information collected we are confident that PFHxS is not intentionally manufactured and used in GB.
19. Sites holding flammable liquids (e.g. chemical/petrochemical sites, and offshore gas/oil platforms) may maintain large stockpiles of per- and polyfluoroalkyl substances<sup>3</sup> (PFAS) based AFFFs, to use in the event of a flammable liquid fire.
20. Up until 2004, UK manufactured PFAS (e.g. perfluorooctane sulfonate (PFOS)) based AFFFs produced PFHxS as an impurity in the manufacturing process.<sup>4</sup> As AFFFs have an expected

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<sup>1</sup>UK REACH is a regulation that applies to the majority of chemical substances that are manufactured in or imported into GB.

<sup>2</sup> Production in or imports into GB of more than 1 tonne/year need to be registered under UK REACH. Chemicals manufactured in or imported to the UK (in the two years before 1 January 2021) have 'grandfathered' or 'notified' (downstream user import notification) their substances for accessing the UK market by Oct 2021. They are required to fully register those substance at a later date. The UK has extended deadlines to do so to Oct 2026, 2028, and 2030 (from Oct 2023, 2025 & 2027). Until that registration process is complete, we do not have full information available on tonnages of chemicals used in the UK.

<sup>3</sup> PFAS is a broad class of over 9000 synthetic, fluorinated organic chemicals (which includes PFOS and PFHxS).

<sup>4</sup> RPA (2004). Perfluorooctane Sulphonate Risk Reduction Strategy and Analysis of Advantages and Drawbacks. [PFOS - Risk Reduction Strategy..PDF \(publishing.service.gov.uk\)](#)

lifespan of 10-25years,<sup>5</sup> it is possible that some PFAS based AFFFs containing PFHxS still exist in stockpiles.

21. Sites holding stockpiles of old PFAS-based AFFFs, potentially containing PFHxS, can continue to use these foams but may face one-off familiarisation costs to read and understand the amended legislation. No additional transition costs will be required, e.g. from testing AFFFs for PFHxS, updating guidelines, or training staff. The cost benefit analysis for the preferred option is developed based on the assumption that there will be no impacts to GB businesses, beyond familiarisation costs for sites using PFAS-based AFFFs.

## 3.0 Costs and Benefits

### Option 0 – Do Nothing

22. Under this option the amendment to the Stockholm Convention to list PFHxS, its salts and PFHxS-related compounds in Annex A for global elimination is not implemented through the POPs Regulation.
23. Inaction could allow future manufacturing, placing on the market, and use of PFHxS, its salts and PFHxS-related compounds to take place in GB. While this is a highly unlikely outcome as GB users have already phased out use of PFHxS, it would lead to further emissions of PFHxS to the environment at all its life stages (during manufacture, distribution, use, maintenance and disposal). Even in the absence of further emissions, this option would result in reputational damage to the UK for not meeting its international commitments. Monetised costs and benefits associated with the do-nothing approach are expected to be zero although it would still be technically possible for industry to use PFHxS which could result in human health and environmental costs.

### Option 1 – (preferred option)

#### Summary

##### Costs

- One-off familiarisation to holders of PFAS firefighting foam (£0.07m, 2023 prices)

##### Benefits

- Avoided human health and environmental impacts (unmonetised)
- Avoided reputational damage (unmonetised)

##### Costs

##### Monetised costs

##### Familiarisation costs

24. Holders of PFAS firefighting foam stockpiles may be subject to a one-off familiarisation cost to understand the amended legislation. It is assumed that this will take one employee (senior official

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<sup>5</sup> Comment no. 1225 to the PFOA restriction proposal (ECHA, 2014) says "By far the largest part of the firefighting foams are stored for 10-25 years" (as cited in: ECHA (2019b). Annex XV report. Proposal for restriction of perfluorohexane-1-sulphonic acid, its salts and related substances. [Annex XV reporting format 040615 \(europa.eu\)](#))

or manager) at each site approximately 2 hours,<sup>6</sup> costing £22.08/hour in wages<sup>7</sup> (plus 22% as a non-wage labour cost uplift, as per Regulatory Policy Committee guidance).<sup>8</sup>

25. Evidence on the number of businesses impacted comes from desk-based research and stakeholder engagement conducted as part of a study commissioned by the Environment Agency on the socio-economic analysis of applying a UK REACH restriction on PFAS in firefighting foams.<sup>9</sup> The study highlighted a lack of detailed data and relied on expert judgement to fill some evidence gaps. The estimates of sites using firefighting foam have been summarised below (source in brackets) and are used as a broad indication of the order of magnitude.<sup>10</sup>

- 500 Chemical and petrochemical sites ([Tank storage Association](#), [UK Petroleum Industry Association Statistical Review](#), [Chemicals Business Association](#))
- 1000 Municipal fire brigades ([UK fire stations](#))
- 1000 marine applications ([NCTAD Review of Maritime Transport 2019](#))
- 250 offshore oil and gas platforms ([UK Oil and Gas](#))
- 40 airports ([Trainline](#))
- 150 military sites ([UK armed forces equipment and formations 2022](#), [RAF website](#))
- 400 Control of Major Accident Hazards (COMAH) sites ([European Commission Report](#))

26. Based on engagement with industry it was tentatively estimated that the share of PFAS foam accounts for approximately 40% of the UK firefighting foam market.<sup>9</sup> It has therefore been assumed that 40% of sites identified by the study could face familiarisation costs. This equates to 1340 sites that could be impacted, of which 880 are businesses.

27. Across all sites, familiarisation costs are estimated to be £0.07m. Costs to businesses are estimated to be £0.05m.<sup>11</sup> As NI is bound by the EU POPs Regulation under the Windsor Framework, UK costs were reduced by 3%, which is the NI share of UK population.<sup>12</sup> All familiarisation costs are expected to occur in 2023 and have been presented in 2023 prices.

## Benefits (unmonetised)

### Avoided human health and environmental impacts

28. The benefits typically associated with eliminating POPs are reduced emissions from manufacture and use, and harm to human health and the environment.

29. PFHxS has strong carbon-fluorine bonds which means that they are slow to degrade and are persistent in the environment. Due to the wide range of historical uses, they are also found widely in the environment, in biota, and humans globally.<sup>13</sup> A broad range of impacts from exposure to PFHxS has been observed in humans and animals. For example, exposure to PFHxS has been

<sup>6</sup> Environment Agency regulators have indicated that it takes them 2 hours to read and understand analogous legislation. We think it is reasonable to assume that it will take sites holding stockpiles of PFAS firefighting the same amount of time to familiarise themselves with the legislation that has been proposed in this DMA.

<sup>7</sup> ONS Annual Survey for Hours and Earnings (2022). [All data related to Employee earnings in the UK: 2022 - Office for National Statistics \(ons.gov.uk\)](#)

<sup>8</sup> Regulatory Policy Committee (RPC) (2019). RPC guidance note on 'implementation costs'. [RPC short guidance note - Implementation costs August 2019.pdf \(publishing.service.gov.uk\)](#)

<sup>9</sup> WSP (formerly Wood) (2022). Report for the Environment Agency on Persistent Organic Pollutants (POPs) – Cost Benefit Analysis POPs Annex IV for PFOA and PFHxS. [Unpublished]

<sup>10</sup> Sites where portable fire-extinguishers are used have are not included in the estimates. No evidence on the prevalence of PFAS-based firefighting was identified in the study.

<sup>11</sup> Businesses includes the following sites: chemical and petrochemical, marine applications, offshore oil and gas platforms, airports, COMAH sites.

<sup>12</sup> Source: Office for National Statistics, National Records of Scotland, Northern Ireland Statistics and Research Agency - Population estimates. [Employee earnings in the UK: 2021 - Office for National Statistics \(ons.gov.uk\)](#)

<sup>13</sup> UNEP (2019). UNEP/POPs/POPRC.15/7/Add.1. Report of the Persistent Organic Pollutants Review Committee on the work of its fifteenth meeting: risk management evaluation on perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS related compounds. <http://www.pops.int/Default.aspx?tabid=8052>.

associated with impact on liver function, lipid and lipoprotein metabolism, endocrine disrupting effects related to changes in serum thyroid hormones, and immune system impairment.<sup>14</sup> Although intentional manufacture and use is not taking place in GB, the change to legislation would prevent it from taking place in the future. These benefits are notional, and we would not expect them to materialise as industry are unlikely to revert back to using PFHxS.

### **Avoided reputational damage**

30. As a party to the Stockholm Convention, the UK has a legally binding international obligation to implement amendments to the Stockholm Convention domestically, such as through amending the POPs Regulation. This policy option is the only one that meets this commitment and shows that the UK is working towards the common objective of eliminating PFHxS from global manufacture, use and placing on the market. Avoided reputational damage cannot be monetised.

### **Business Impact Target Calculations**

31. It is assumed that the change to legislation will not result in any additional cost to business other than a one-off familiarisation cost of £0.05m. As an equivalent annualised cost this is well below the +/-£5 million de minimis threshold. There is no evidence that small businesses will be disproportionately impacted.

### **Risks and unintended consequences**

32. There is a risk that not all manufacturers and intentional users of PFHxS have been identified. This DMA has considered evidence from the EU REACH restriction report for PFHxS, which was led by the European Chemicals Agency (ECHA) when the UK was a member state of the EU, and socio-economic evidence in the RME for the PFHxS listing in the Stockholm Convention. UK stakeholders have had a number of opportunities to get involved in discussion – both UK and Convention led – before PFHxS was adopted for elimination under the Convention, so this is deemed to be a small risk.

### **Wider impacts**

#### *Equalities Impact Assessment*

33. We do not anticipate this intervention to raise any issues relevant to the public sector equality duty under section 149(1) Equality Act 2010 because there is no known intentional use of PFHxS in the UK, and minimal to nil anticipated impact of listing PFHxS in Annex I of the retained POPs Regulation.

#### *Justice Impact Test*

34. Defra has completed a Justice Impact test for this policy. There has only been one recorded prosecution since the enforcement regulations came into force in 2007, which was on 09/02/2011. Enforcement activity predominantly involves the use of compliance notices, of which there are approximately 12 a year in England. Therefore, the impact of this intervention on the justice system is deemed to be minimal to nil.

#### *Trade Impact*

35. There is no known manufacture or intentional use of PFHxS in GB and for this reason we expect trade in this substance to be minimal to nil.

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<sup>14</sup> IPEN expert panel (2019). PFHxS—Socioeconomic impact, exposure, and the precautionary principle, Available at: [https://ipen.org/sites/default/files/documents/pfhxs\\_socio-economic\\_impact\\_final\\_oct.2019.pdf](https://ipen.org/sites/default/files/documents/pfhxs_socio-economic_impact_final_oct.2019.pdf)



### 3.0 Post implementation review

1. **Review status:** Please classify with an 'x' and provide any explanations below.

<input type="checkbox"/>	Sunset clause	<input type="checkbox"/>	Other review clause	<input type="checkbox"/>	Political commitment	<input type="checkbox"/>	Other reason	<input checked="" type="checkbox"/>	No plan to review
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Regulations to be reviewed every five years to ensure continued suitability.

2. **Expected review date** (month and year, xx/xx):

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	Five years from when the Regulations come into force
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3. **Rationale for PIR approach:**

**Rationale for not conducting a PIR:**

A statutory PIR would not be proportionate because the impact of the policy intervention has been assessed to be below £5m. It is also the only policy option which sufficiently meets the UKs legally binding international obligations under the Stockholm Convention.

Manufacture, use, and placing on the market of PFHxS its salts, and related compounds will be monitored using UK REACH data, as any future manufacturers, users, or distributors of PFHxS in quantities above 1 tonne/year would be required to register under REACH or submit a downstream user import notification. This is a highly unlikely outcome as GB users have already phased out use of PFHxS.

Enforcement of the policy intervention will be led by the Environment Agency. The approaches taken to monitor compliance may include:

- 1) Identifying sectors at risk of operating outside the law through industry engagement or risk assessments, and raising awareness with the relevant sectors, and;
- 2) Potential compliance / enforcement campaigns depending on the likelihood of non-compliance.