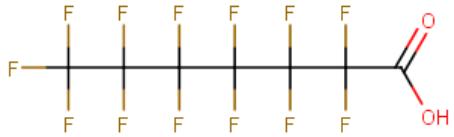
AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF

Perfluoroheptanoic acid and its salts

AS SUBSTANCES OF VERY HIGH CONCERN
under Articles 57 and 59 of Regulation (EC) 1907/2006
Adopted on 28 November 2022

This agreement concerns
Perfluoroheptanoic acid and its salts
EC number: -
CAS number: -
Molecular formula: $C_7HF_{13}O_2$ [1] $C_7F_{13}NaO_2$ [2] $C_7H_4F_{13}NO_2$ [3] $C_7F_{13}KO_2$ [4]
Structural formula:

[1]



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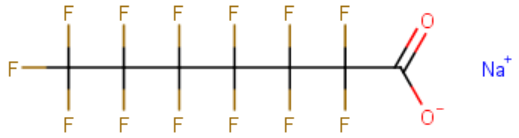

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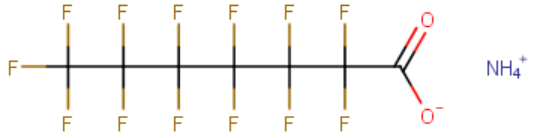

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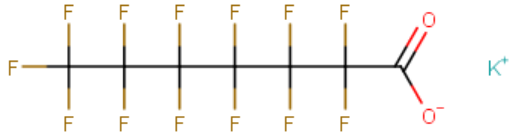

The Member State Committee agreed that:

1. **Perfluoroheptanoic acid and its salts are substances under**

    - **Article 57 (c) of Regulation (EC) 1907/2006 (REACH), which are toxic for reproduction.**
    - **Article 57 (d) and (e) of Regulation (EC) 1907/2006 (REACH), which are persistent, bioaccumulative and toxic as well as very persistent and very bioaccumulative (vPvB) in accordance with the criteria and provisions set out in Annex XIII of REACH.**
    - **Article 57 (f) of Regulation (EC) 1907/2006 (REACH), for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.**

2. **Perfluoroheptanoic acid and its salts must be added to the Candidate list of substances of very high concern**.

Annex 1: Scientific evidence for identification of substances of very high concern

The information below is based on Support Document (Member State Committee, 28 November 2022)

Perfluoroheptanoic acid (PFHpA) and its salts are identified as substances of very high concern in accordance with Article 57(c), (d), (e) and (f) of Regulation (EC) 1907/2006 (REACH) because in water under environmental conditions and in the human body these substances exist in the (dissociated) form of perfluoroheptanoate, for which there is scientific evidence of reprotoxic effects as well as Persistent Bioaccumulative and Toxic (PBT) and Very Persistent and very Bioaccumulative (vPvB) properties and of probable serious effects to the environment and human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH.

Toxicity for reproduction:

PFHpA is covered by index number 607-761-00-3 of Regulation (EC) No 1272/2008. Pursuant to Commission Delegated Regulation (EU) 2022/692 of 16 February 2022, PFHpA will be classified in the hazard class toxic for reproduction category 1B (H360D: 'May damage the unborn child') as well as Specific target organ toxicity — repeated exposure category 1, STOT RE 1 (H372: 'Causes damage to organs through prolonged or repeated exposure' (liver))[1]. Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that PFHpA and its salts meet the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

PBT and vPvB:

A weight-of-evidence determination according to the provisions of Annex XIII of REACH has been used to identify the substances as PBT and vPvB. Available relevant information, such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results, was considered together in a weight-of-evidence approach.

Persistence:

In general, the persistence of PFHpA and its salts can be explained by the shielding effect of the fluorine atoms, blocking *e.g.,* nucleophilic attacks to the carbon chain. High electronegativity, low polarisability and high bond energies make highly fluorinated alkanes one of the most stable organic compounds. It is not expected that the carboxylic group in perfluorinated carboxylic acids (PFCAs) or their salts alters the persistence of the perfluorinated carbon chain.

The persistence (P and vP) of seven long-chain PFCAs (PFOA/APFO (C_8-PFCA), PFNA (C_9-PFCA), PFDA (C_{10}-PFCA), and C_{11}-C_{14} PFCAs) and a short-chain PFCA (HFPO-DA (C_6-PFCA where two chains of three carbon atoms are joined by an ether bond)) has already been

[1] Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 18th ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation, this new harmonised classification applies from 23 November 2023. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

confirmed by the Member State Committee prior to their inclusion into the Candidate List. In the Risk Assessment Committee (RAC) opinion on the PFHxA (C_6-PFCA) restriction proposal it was concluded that PFHxA exceeds by far the trigger of being very persistent and clearly exceeds the threshold values for being "very persistent" (vP) as defined in REACH Annex XIII.

Considering the stability of the C-F bond and the read-across approach with PFHxA, HFPO-DA, PFOA, PFNA, PFDA and C_{11}-C_{14} PFCAs, it can be concluded that PFHpA and its salts will undergo, no or extremely limited, degradation in the environment.

Monitoring data support the above conclusion. The detection and/or quantification of PFHpA in remote areas such as the Arctic (in air, snow, fresh- and marine water (including sediments) and soil) and the Antarctic (snow), in locations far away from point sources, point towards persistence of PFHpA.

Based on a weight-of-evidence approach, it is concluded that PFHpA and its salts are very persistent. Annex XIII, point 3.2.1.(d) of the REACH Regulation requires that any relevant information for the assessment of the persistence of the substance be considered. Therefore, it is concluded that PFHpA and its salts fulfil the P- and vP- criteria in accordance with the criteria and provisions set out in Annex XIII of REACH.

Bioaccumulation:

Based on a direct comparison with the bioaccumulation criteria for aquatic organisms, PFHpA and its salts do not seem to be bioaccumulative in water-breathing organisms.

In air-breathing organisms results appear to differ between species. In rats, the elimination half-life for both males and females is less than 1 day. In pigs, however, much longer elimination half-lives have been reported with the highest values being in the order of 500 days. There was considerable variation between individual pigs though, resulting in a geometric mean elimination half-life of 74 days. The latter value corresponds to a biomagnification factor of 2.7, showing that PFHpA and its salts have the potential to biomagnify in pigs. Therefore, PFHpA and its salts should be considered very bioaccumulative (vB) in at least some air-breathing species such as the pig. The elimination half-life of PFHpA of 74 days fits well between values derived for PFOA (236 days) and PFHxA (4.1 days) that are the closest structural analogues differing only by one perfluorinated carbon in chain length.

Several studies in humans point to high elimination half-lives with the highest value being 3.3 years. As seen for other mammalian species, there is considerable variation between individuals, resulting in an average elimination half-life in humans that is at least 76 days. This value exceeds the range of guiding values for biomagnification of substances in humans that are considered to be in the range of 30 to at most 70 days and thus, the half-lives observed for PFHpA are high enough to reach higher concentration of PFHpA in the human body than in the food consumed. Further supporting high bioaccumulation potential of PFHpA and its salts in humans is the observed build up over the years in humans. Therefore, PFHpA and its salts are considered very bioaccumulative in humans.

This is in line with the close structural analogue PFOA that is one perfluorinated carbon in chain length longer than PFHpA. Although PFOA was not proposed and identified as a vPvB substance under REACH in 2013, the Persistent Organic Pollutants Review Committee (POPRC) concluded at its twelfth meeting in September 2016 that PFOA is persistent, bioaccumulative and toxic to animals including humans (UNEP/POPS/POPRC.12/11/Add.2). Under the POP regulation the B criterion for aquatic organisms is defined as 5000 L/kg, which equals the vB criterion under REACH. The POPRC thus concluded that the half-life in humans is of similar concern as the vB criterion for aquatic organisms.

Overall, taking all available information together in a weight-of-evidence approach, thereby giving the data from pigs and humans a high weight, a high bioaccumulation potential of PFHpA and its salts in humans and at least some other air-breathing mammalian species has been identified. Annex XIII, point 3.2.2.(b) of the REACH Regulation requires that data from the toxicokinetic behaviour of the substance be considered. Therefore, it is concluded that the vB criterion of REACH Annex XIII is fulfilled.

Toxicity:

PFHpA is covered by index number 607-761-00-3 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360D: 'May damage the unborn child') and STOT RE 1 (H373: 'Causes damage to organs through prolonged or repeated exposure' (liver))[2]. Therefore, the toxicity criterion of REACH Annex XIII is fulfilled. It is therefore concluded that PFHpA and its salts meet the toxicity criterion (T) in accordance with Annex XIII, points 1.1.3 (b) and (c), of the REACH Regulation.

Conclusion on the P, B and T properties
In conclusion, PFHpA and its salts meet the criteria for PBT and vPvB substances according to Article 57 (d) and (e) of the REACH Regulation.

Equivalent level of concern:

Based on the following assessment it is also concluded that PFHpA should be regarded as "substances for which there is scientific evidence of probable serious effects to human health and the environment which give rise to an equivalent level of concern to those of other substances listed in Article 57 points (a) to (e) of the REACH Regulation".

Intrinsic properties of PFHpA and its salts

Persistency:

PFHpA and its salts is expected to undergo extremely limited degradation in the environment and thus fulfils the persistent (P) and very persistent (vP) criteria in accordance with the criteria and provisions set out in Annex XIII of REACH.

Mobility:

Due to its low to very low adsorption potential (log K_{oc} 1.63-1.7), high water solubility (salts and dissociated form of PFHpA >1000 mg/L) and low tendency to volatise from water to air (Henry's Law constant of 6.38 $Pa \cdot m^3/mol$ for the ammonium salt) PFHpA and its salts predominantly resides in the aquatic compartment. These properties make PFHpA and its salts very mobile in the aquatic environment. Once PFHpA has entered the aquatic

[2] Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 18th ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation, this new harmonised classification applies from 23 November 2023. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

environment, e.g., surface waters, there are limited fate processes that would prevent it from being distributed to groundwater and to the marine environment. Monitoring data show that PFHpA or its salts has been detected in tap water, bottled drinking water and groundwater which supports the conclusion that PFHpA and its salts are mobile in water.

Removal from the environment and drinking water:

Since PFHpA and its salts have a preference for the aqueous phase in the environment, the most important compartment for removal of PFHpA and its salts is water. The same properties that make PFHpA and its salts mobile in the environment are also the reason why their removal is challenging. Due to the high aqueous solubility and the low sorption potential, PFHpA and its salts will only bind to a low extent to adsorption materials and will rather remain in the water phase during the purification process.

PFHpA is not readily removed with conventional or advanced surface water treatment processes. The methods available today to remove PFHpA from drinking water and lower the human exposure are expensive and not commonplace. The presence of PFHpA precursors may complicate water treatment processes even further as the precursors may behave differently through the purification steps and may break down to PFHpA and its salts either during or after purification.

Long-range transport:

Modelling and monitoring data indicate that the combination of extreme persistence and mobility lead to a high potential for long-range transport in the environment, which takes place via the atmosphere and oceanic currents. This may also apply to PFHpA-precursor substances to varying degrees. Occurrence of PFHpA in remote regions such as Arctic, Antarctic and high altitude remote areas in the European Alps has been confirmed by measurements in snow. PFHpA is detected in practically all compartments of the polar regions. Thus, vulnerable remote ecosystems are currently exposed to PFHpA.

Bioaccumulation and bioavailability:

PFHpA is very bioaccumulative in humans and in at least some other air-breathing mammalian species. Overall, taking all available information together in a weight- of-evidence approach, it is concluded that the vB criterion of REACH Annex XIII is fulfilled.

Enrichment in plants:

Studies have demonstrated the uptake of PFHpA in crops including lettuce, tomato, carrots, corn, radish and soybeans. From the plants PFASs can transfer to humans and wildlife through the food chain. Due to the uptake observed in crops, consumption of these by humans and wildlife will lead to inevitable exposure to PFHpA and its salts.

Toxicity:

PFHpA is classified in the hazard class toxic for reproduction category 1B (H360D: 'May damage the unborn child') and STOT RE 1 (H373: 'Causes damage to organs through prolonged or repeated exposure' (liver)) and therefore, the toxicity criterion of REACH Annex XIII is fulfilled.

Environmental toxicity and secondary poisoning:

The direct toxicity of PFHpA to aquatic and terrestrial species, such as algae, daphnids, fish, earthworms and plants, is assumed to be low and was not considered as the highest concern in the context of the present equivalent level of concern assessment. However, concern for secondary poisoning may be significant, as mammals show more toxic effects

of PFHpA than organisms from lower trophic levels. Relatively stringent safety levels may result from the fact that a particular food item such as terrestrial plants and fish are often the sole energy source for a specific mammalian species, leading to a relatively high PFHpA intake. Hence, PFHpA exposure may be of concern to wildlife. Secondary poisoning is therefore considered a relevant endpoint for the equivalent level of concern assessment.

Concerns arising from the substance properties

Several concerns are caused by these intrinsic properties of PFHpA and its salts. Overall, they have a very high potential to cause effects in wildlife and in humans exposed via environment, due to their persistence, mobility, potential for long-range transport, and toxicity. The very high persistence together with low adsorption potential and high mobility imply a very high potential for increasing pollution stock in the environment and for irreversible and increasing exposure of both wildlife and humans exposed via the environment. Also, their low adsorption potential and high water solubility imply that PFHpA and its salts are highly bioavailable for uptake via water. Together, these elements of concern lead to a very high potential for irreversible effects once effect levels have been reached, as well as an increasing seriousness of effects while exposures keep increasing.

Its properties make PFHpA (very) mobile in the aquatic environment and very difficult to remove from (contaminated) aqueous sites e.g., for drinking water remediation or groundwater clean-up. The usually applied techniques in wastewater treatment plants are not capable of removing PFHpA from the environment. Also for water treatment plants different studies show that even though different techniques are applied they do not effectively remove PFHpA from the water. But also studies investigating more advanced treatment techniques show a lack of removal of PFHpA. Once PFHpA has entered the aquatic environment, e.g., surface waters, there are limited fate processes that would prevent it from being distributed to groundwater and to the marine environment.

Due to its mobility and persistence, PFHpA is found in surface waters, groundwater, tap water and bottled water. Decontamination can only be achieved at high societal costs. Furthermore, PFHpA is classified as Repr. 1B and STOT RE 1 (liver) and humans will be exposed via consumption and use of drinking water. Water is used for drinking and cooking each day and it is the basis of all food over the whole life of humans. That is why its presence in drinking water is of high concern. Consequently, there is societal concern for the presence of PFHpA in drinking water that requires immediate action.

Due to the extreme persistence of PFHpA and its very long presence in the environment, results of toxicity studies may be of limited value as they do not regard cross generational effects. Additionally, PFASs are continuously introduced into aquatic ecosystems and are ubiquitously present in complex mixtures which is not covered by a single substance test. PFHpA has been measured in different species of wildlife, including polar bears which are listed on the IUCN red list of threatened species. Monitoring data indicates that birds and mammals show a concern for uptake via fish/plants contaminated with PFHpA. For these reasons also a safe concentration cannot be derived and a quantitative risk assessment cannot be performed.

Monitoring data indicate that often more than one PFAS can be identified in environmental samples suggesting that PFASs are likely to co-occur as contamination in soil, groundwater or drinking water. Literature indicates that different PFAS have similar, additive, effects, increasing the concern for serious effects in the environment.

Equivalent level of concern

The level of concern is considered very high due to the combination of the following concern elements:

- high potential for irreversible exposure due to very high persistence and, in the case of human exposures via environment, the difficulty to decontaminate the drinking water,
- high potential for increasing contamination and increasing fully bioavailable exposures, and the intrinsic properties cause difficulties to remove the substance after release,
- high potential for rapid and wide geographic scale contamination,
- high potential for causing serious effects (PFHpA fulfills the criteria for classification as Reprotoxic cat.1B and STOT-RE),
- potential to cause combined effects with other PFAS
- potential for inter-generational effects,
- high societal concerns.

The irreversibility of exposure to PFHpA due to its persistence adds to the concern. Furthermore, it may be difficult in practice to control exposure due to the high mobility of PFHpA (and its salts) and the fact that exposure may take place at a different location than where releases occurred and at a different moment in time. Furthermore, the high persistence and high mobility of PFHpA (and its salts) lead to a concern for co-exposure with other contaminants with similar health effects. Co-exposure may eventually occur and may last for a very long time, because natural degradation processes for these substances are slow or negligible. This is brought into the weight-of-evidence as supportive information.

Limitations of the available remediation techniques raise a concern that the removal of PFHpA and its salts from drinking water as well as wastewater and, may only be possible with high societal costs. Remediation of environmental pollution may be practically impossible due to PFHpA's (and its salts) high solubility in water, its low adsorption potential and its high mobility. Remediation is also difficult because PFHpA (and its salts) will quickly diffuse from contaminated sites.

Therefore, the substances are also identified as substances of equivalent level of concern having probable serious effects to the environment and human health to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 (REACH) according to Article 57(f) of REACH Regulation.

In conclusion:

In conclusion, perfluoroheptanoic acid and its salts meet the criteria for Reproductive toxicity according to Article 57(c) and PBT and vPvB substances according to Articles 57(d) and (e). The combined intrinsic properties which demonstrate scientific evidence of probable serious effects to human health and the environment and which give rise to an equivalent level of concern according to Article 57(f) are the following: very high persistence, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are reproductive toxicity. However, the combination of substance properties may also lead to yet unknown environmental effects that are not detectable in standard toxicity tests and that may only emerge after life-long exposure. Together, these elements lead to a very high potential for irreversible effects.

Annex 2: Procedure

1. On 26 August 2022, Netherlands presented a proposal under Article 59(3) and Annex XV of the REACH Regulation on identification of Perfluoroheptanoic acid and its salts as substances which satisfy the criteria of Articles 57 (c), (d), (e) and (f) of REACH.
2. On 2 September 2022, the Annex XV dossier was circulated to Member States and the Annex XV report was made available to interested parties on the ECHA website as required by Articles 59(3) and 59(4).
3. Perfluoroheptanoic acid and its salts received comments from both Member States and interested parties on the proposal.
4. On 16 November 2022, the dossier was referred to the Member State Committee (MSC) and agreed in the written procedure of the MSC with closing date of 28 November 2022.