Submitted on 13th October 2022

HEAL comments - SVHC identification proposal for Perfluoroheptanoic acid (PFHpA) and its salts as a SVHC

Reasons for proposing:

- **Toxic for reproduction (Article 57(c))**
- **Persistent bioaccumulative and toxic (PBT) (Article 57(d))**
- **Very persistent very bioaccumulative (vPvB) (Article 57(e))**
- **Equivalent level of concern having probable serious effects to human health (Article 57(f)**
- **Equivalent level of concern having probable serious effects on the environment (Article 57(f))**

The Health and Environment Alliance (HEAL) thanks the Dutch Competent Authority for its proposal and fully supports the identification of PFHpA and its salts as a substance of very high concern (SVHC) due to its reprotoxic properties (article 57(c)), its PBT properties (Article 57(d)), its vPvB properties (Article 57(e)), and its endocrine disrupting properties relevant for human health and the environment (article 57(f)).

PFHpA and its salts, herein referred to as PFHpA, is not registered for production or import under REACH and is not commercially produced. However, it is found all over the world in some of the most remote areas due to its environmental transformation. It is part of a larger group of PFAS substances and has been found to be a minor degradation product of many different PFAS with a fluorinated carbon chain of at least 7 carbon atoms. [1]

- **Toxic for reproduction (Article 57(c))**

As stated in the dossier, PFHpA's hazard classification, toxic for reproduction category 1B (H360D: 'May damage the unborn child') and STOT RE 1 (H373) (liver) fulfils the toxicity of REACH Annex XIII. We agree with this determination.

- **Persistent bioaccumulative and toxic (PBT) (Article 57(d))**
- **Very persistent very bioaccumulative (vPvB) (Article 57(e))**
- **Equivalent level of concern having probable serious effects on the environment (Article 57(f))**

PBT and vPvB weight-of-evidence

The Dutch Competent Authority has put forth clear evidence of PFHpA's PBT and vPvB intrinsic properties, applying the weight-of-evidence approach as per Annex XIII of REACH to justify its identification as SVHC under article 57 (d) and (e) respectively. The dossier has transparently presented findings supporting this proposal composed of standard tests, monitoring and modelling studies, grouping and read-across approaches based on PFHpA's analogues, and (Q)SAR results. In addition, the 2021 RAC opinion concluded that PFHpA is persistent, mobile, has long-range transport potential and potential for serious adverse effects.

Intrinsic properties and environmental fate

Due to PFHpA's extreme water solubility, with very low absorption potential, and low volatilization from water to air, the substance is extremely persistent and very mobile in aquatic environments. Based on these intrinsic properties, RAC determined that PFHpA far exceeds the threshold for both its persistent (P) and very persistent (vP) properties as defined in REACH Annex XIII.

Detection of PFHpA in Arctic and Antarctic environments far from point sources of contamination also provides clear evidence of the substances' extreme persistence and long-range transport, contaminating vulnerable remote ecosystems, endangered species (polar bears), and aquatic environments globally. [2]

The dossier notes that the Member State Committee has confirmed inclusion of the very persistent seven long-chain PFCA analogues ((PFOA/APFO (C8-PFCA), PFNA (C9-PFCA), PFDA (C10-PFCA), and C11-C14 PFCAs) and short chain PFCA (HFPO-DA (C6-PFCA where two chains of three carbon atoms are joined by an ether bond)) into the Candidate List. We agree that a grouping approach is appropriate for PFHpA. Further, the dossier has justifiably confirmed the relevant read-across of PFHxA, HFPO-DA, PFOA, PFNA, PFDA and C11-C14 PFCAs, due their C-F bond stability.

Drinking water contamination and challenges with remediation

PFHpA has been detected in ground and surface water globally as a result of its intrinsic properties, which has led to widespread drinking water contamination. Studies cited in the dossier have consistently found PFHpA and its analogues in bottled, tap, and ground/well water. [3] PFHpA's removal using conventional methods has been unsuccessful and even more advanced water treatments have proven insufficient at decontamination. Additionally, PFHpA precursors complicate matters as water purification processes may break down the substance, which may then be further dispersed into the environment. [4]

Bioaccumulation in birds, humans and other air breathing mammals

The dossier also provides evidence of PFHpA's ability to bioaccumulate in humans and other air breathing mammals. Studies have found PFHpA in crops, which provide clear evidence of food chain contamination and potential increased exposure in humans and wildlife. The Dutch Competent Authority rightly warns of environmental toxicity and secondary poisoning due to the uptake of PFHpA in food and water. Additional studies also found diet to be a source of PFAS exposure in pregnant women and children from six European countries, with fish consumption

associated with higher PFAS concentrations. [5] Finally, monitoring data has detected many combinations of different PFAS that may typically be used together. These studies indicate a variety of mixtures of different PFAS, as well as other substances in soil and water leading to more concerns over additive effects. The potential combined effects and ongoing cumulative exposures in wildlife and humans is of serious growing concern. In considering all of the above evidence, we strongly support the dossier's assertion that safe levels of exposure cannot be derived. [6]

The growing global ubiquity of the PFHpA in the environment, its irreversible contamination of water and food supplies, and the ability to bioaccumulate in mammals and birds are more than sufficient justification for ELoC for PFHpA identification as a SVHC under Article 57 (d) an (e).

- **Equivalent level of concern having probable serious effects to human health (Article 57(f))**

<u>Health Hazards</u>
Although little bioaccumulation has been observed in aquatic organisms, studies have found bioaccumulation occurring in humans, other mammals, and birds. Elimination half-lives varied significantly between species of mammals and also within the same species implying significant uncertainties between individual organisms. Studies evaluated in the dossier showed the geometric mean of half-lives in pigs to be approximately 74 days, with the highest and lowest ranges varying widely (highest value of 500) and a biomagnification factor of 2.7. We agree with the dossier's rationale that this value correlates well with PFOA (236) and PFHpA (4.1) and is appropriate for a read-across approach based on similar properties of substances. [6]

In humans, evidence suggests the average half-life to be over 76 days, but again wide variation was observed with the highest half-life value of 3.3 years. The dossier also importantly notes that the estimated half-life for PFHpA in humans is above the threshold of guiding values for biomagnification of substances in humans (30-70 days). [7] Studies noted in the dossier have demonstrated adverse health effects resulting from PFHpA exposure including reprotoxicity, liver damage, and endocrine disruption. An OECD TG 422 study suggested potential interference of PFHpA with the thyroid hormones *in vivo*, but the dossier notes that this is not considered in the ELoC assessment.

The dossier cites evidence demonstrating general population widespread exposues to PFAS, in addition to studies suggesting significant health burdens on vulnerable populations and potential future generations. Additional research looking at PFAS as a group and effects on vulnerable populations is also relevant to this proposal and further stresses the need for a grouping approach. A 2022 systematic review and meta analysis found that existing science suggests that exposure to PFAS may hinder vaccine antibodies in children. [8] Effects on the immune system and other developmental endpoints in children pose critical implications for long-term impacts on future generations' health and well-being. This observed effect is relevant to potential irreversible impacts on individual and population health meeting the ELoC criteria.

Other known adverse health effects associated with PFAS exposure in general and more susceptible populations include kidney damage and cancer. [9]

In considering the strong evidence presented in the dossier and external relevant studies of associated adverse health outcomes, we strongly support the dossier's conclusion that PFHpA meets ECHA's Guidance R11, page 11 in the identification of PFHpA as a SVHC due to its PBT and vPvB properties. The guidance states "vPvB substances are characterised by a particular high persistence in combination with a high tendency to bioaccumulate, which may, based on experience from the past with such substances, lead to toxic effects and have an impact in a manner which is difficult to predict and prove by testing, regardless of whether there are specific effects already known or not."

The Dutch Competent Authority has provided compelling evidence to justify the identification of PFHpA and its salts as a substance of very high concern (SVHC) due to its reprotoxic properties (article 57(c)), its PBT properties (Article 57(d)), its vPvB (Article 57(e)), and its endocrine disrupting properties relevant for human health and the environment (article 57(f)).

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[1] Dutch Competent Authority. (August 2022). Annex XV Report: Proposal for identification of a substance of Very High Concern on the Basis of the Criteria Set Out in Reach Article 57- Perfluoroheptanoic acid and its salts. Pg. 15-16.

[2] Ibid. Pg. 8.

[3] Ibid. Pg. 67.

[4] Ibid. Pg. 10

[5] Papadopoulou E, Haug LS, et al. (2019). Diet as a Source of Exposure to Environmental Contaminants for Pregnant Women and Children from Six European Countries. *Environ Health Perspect.* 127(10):107005. doi: 10.1289/EHP5324.

[6] Dutch Competent Authority. Pg. 11

[7] Ibid. Pg 8.

[8] Zhang, X. et al. (2022). Effects of exposure to per-and polyfluoroalkyl substances on vaccine antibodies: A systematic review and meta-analysis based on epidemiological studies. *Environ Pollution.* (306):119442. Doi: 10.1016/j.envpol.2022.119442.

[9] The International Federation of Gynecology and Obstetrics (FIGO), the Health and Environment Alliance (HEAL) and the University of California in San Francisco (UCSF), PRHE and Office of Sustainability, and Natural Resources Defence Council (NRDC). (2021). Fact sheet: How PFAS chemicals affect women, pregnancy and human development.