AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

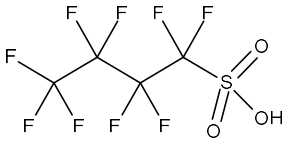
Perfluorobutane sulfonic acid and its salts

AS SUBSTANCES OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) 1907/2006[1]

Adopted on 11 December 2019

This agreement concerns

Substance names	EC Numbers	CAS numbers	Molecular formulas	Structural formulas
Perfluorobutane sulfonic acid (PFBS)	206-793-1	375-73-5	C4HF9O3S	
and its salts	-	-	-	-

[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Norway presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (6 August 2019, submission number SPS-014400-18) on identification of *Perfluorobutane sulfonic acid (PFBS) and its salts* as substances of very high concern due to their properties for which there is scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH Regulation.

The Annex XV dossier was circulated to Member States on 3 September 2019 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 18 November 2019 and discussed in the meeting on 9-11 December 2019 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

Perfluorobutane sulfonic acid (PFBS) and its salts **are identified as substances meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances for which there is scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 of the REACH Regulation.**

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Perfluorobutane sulfonic acid (PFBS) and its salts are identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) as there is scientific evidence 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.

Substance identification

PFBS-salts are fully indistinguishable from PFBS in the environment as the salts exist in their dissociated anionic sulfonate form, just like PFBS itself, and they are all a part of an acid-base equilibrium in water. Hence, all conclusions on different end-points apply to any and all salt forms, as well as PFBS itself.

Intrinsic properties of PFBS

PFBS is very persistent in the environment. Based on the available data abiotic or biotic degradation of PFBS at relevant environmental conditions is expected to be very slow or negliglible. This is supported by read-across to perfluoroalkane sulfonic acids with both shorter and longer chain lengths, which also have a very low degradability. PFBS shows a preference for distribution to the aqueous phase due to its high solubility in water (52.6 g/L at 22.5-24 °C for the potassium salt), its low sorption potential (log K_{OC} 1.2 to 2.7) and it is considered highly mobile in the environment.

The very high persistence, together with low adsorption potential and high mobility, imply a very high potential for increasing environmental concentrations and potential irreversible exposures of wildlife and of humans via the environment. Long-term, low dose exposure may potentially lead to currently unexpected or even still unknown effects. In particular, endocrine disturbances may be of relevance when considering such exposure. PFBS is bioavailable via the aqueous environment. Together, these environmental fate properties lead to a high potential for irreversible effects. Furthermore, there are high costs and technical challenges related to the removal of PFBS using end-of-pipe treatment.

The high global transport potential (characteristic travel distance, CTD 17616 km, P_{OV} = 220 days), is demonstrated by detection of PFBS in samples of surface water, snow, ice, air and marine water from remote areas such as the Arctic and the Antarctic. This is supported by scientific assessments of the mobility of PFBS, together with QSAR modelling

data. PFBS has also been found in biota like dolphins and whales, as well as green turtles and polar bears, which are both threatened species. This shows that PFBS is bioavailable, and that exposure may occur throughout the food chain and via drinking water and that this is already taking place worldwide.

Toxicological data relevant for human health assessment include effects on thyroid hormone disturbances observed in both rats and mice. These effects are serious and of particular concern since the developing foetus is dependent on maternal production of thyroid hormones. Evidence of effect on development and delay in pubertal onset was observed in mice and disturbed estrus cyclicity was observed in mice and rats. In addition, effects on liver, kidney and haematological system were observed in rats.

A serum elimination half-life of around one month (up to 46 days) has been measured in humans, which is considerably longer than the half-lives measured for rodents (less than 1 day). The limited data show that PFBS has at least a moderate bioaccumulation potential in humans. In pigs an average half-life of 43 days has been estimated.

The ecotoxicological data showing effects on reproduction in F0 marine medaka fish (lowered GSI, delayed oogenesis and reduced fecundity) at 9.5 µg/L PFBS fulfils the T criteria for the environment of Annex XIII of REACH (i.e. NOEC or EC10 for marine or freshwater organisms less than 10 µg/L). Exposure of wheat seedlings to PFBS resulted in reduced chlorophyll a content and shoot biomass together with a decrease in biomass and oxidative stress, which indicates a potential for phytotoxicity. Furthermore, PFBS has been found to cause effects on mRNA expression of hormone receptors in tadpoles and in genes associated with the thyroid pathway in avian neuronal cells, while thyroid hormonal disturbances have been observed in exposed marine medaka fish. Ecotoxicological studies, supported by *in vivo* studies in rodents and in vitro studies, provide evidence for adverse effects.

Overall, PFBS has a high potential to cause effects in wildlife and in humans exposed via the environment worldwide, due to its very high persistence, high mobility, potential for long-range transport, and observed adverse effects that are relevant for human health and the environment, and exposure via drinking water and food. The continuous and increasing exposure in human populations cannot be avoided if releases are not minimised. Similarly, wildlife populations cannot be protected from the total quantity of the substance released.

In addition, the potential for combined exposure to similar PFAAs substances is considered a supportive concern.

Scientific evidence of probable serious effects to human health and the environment is as follows:

- a moderate bioaccumulation potential in humans
- thyroid hormonal disturbances in rodents
- reproductive development deficiencies in mice
- disturbed estrus cyclicity in rodents
- effects on liver, kidney and haematological system in rats
- effects on reproduction in marine medaka (Environmental T)
- thyroid hormonal disturbances in marine medaka
- effects on mRNA expression of hormone receptors in tadpoles

The effects on thyroid hormones are serious since the foetus is dependent on maternal production of thyroid hormones important for e.g. growth, metabolism, reproductive organ and brain development. PFBS is also transferred to the foetus. The developmental effects are serious because they affect the embryos.

Based on the reported effects on reproduction in marine medaka PFBS fulfils the T criteria for the environment of Annex XIII of REACH (i.e. NOEC or EC10 for marine or freshwater organisms less than 10 µg/L). Thyroid hormonal disturbances in marine medaka are also observed. These environmental effects are supported by *in vivo* studies in rodents and *in vitro* studies, and provide evidence for adverse effects. In addition potential effects on hormone receptor expression in tadpoles are reported.

All these human health and environmental effects are serious because, in conjunction with environmental fate properties of PFBS (e.g. very high persistence, high mobility and long-range transport potential), they are potentially irreversible.

Equivalent level of concern

The level of concern is considered very high in particular due to the combination of the

following concern elements:

- Potential for irreversible and increasing presence in the environment
- Potential for irreversible and increasing contamination of surface water, marine water and groundwater
- Continuous presence in water results in continuous bioavailability
- Worldwide occurrence
- PFBS enters the biosphere via several routes
- Intergenerational effects, observed mother-to-offspring transfer
- Potential for delay of effects
- Potential for causing serious effects although those would not be observed in standard tests
- Derivation of future exposure levels and safe concentration limits will be highly uncertain
- High societal concern for the presence of PFBS in drinking water sources

PFBS has been detected in humans worldwide and in different species of wildlife, including in endangered species and in remote areas. The substance has been found to transfer from mother to offspring in humans, whales and in birds and may disturb development at sensitive life stages and in vulnerable populations. It may be difficult in practice to manage exposures due to the high mobility of PFBS and the fact that exposures may take place at a different location than where releases occurred and at a different moment in time.

The very high persistence and high mobility of PFBS together lead to a concern for co-exposure with other contaminants with similar effects on human health and the environment. It may be expected that PFAAs cause similar effects, and hence that their individual contributions add up to the total effect. Co-exposure may lead to additive effects 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 PFBS from drinking water may only be possible with high societal costs. Remediation of environmental pollution may even be practically impossible due to the high mobility of the substance. Furthermore, PFBS will quickly diffuse from contaminated sites.

In conclusion

The combined intrinsic properties justifying the inclusion as a substance 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 are the following: very high persistence, high mobility in water and soil, high potential for long-range transport, and difficulty of remediation and water purification as well as moderate bioaccumulation in humans. The observed probable serious effects for human health and the environment are thyroid hormonal disturbances and reproductive toxicity seen in rodents, and effects on liver, kidney and haematological system in rats, hormonal disturbances and effects on reproduction in marine medaka fish and effects on expression of hormone receptors in tadpoles. Together, these elements lead to a very high potential for irreversible effects.

Reference:

Support Document (Member State Committee, 11 December 2019)