Risk Management Option Analysis Conclusion Document

Substance Name: Perfluorobutane sulfonic acid (PFBS), its salts and related substances

EC Number: 206-793-1

CAS Number: 375-73-5 (and 59933-66-3)

Authority: Norway

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

PFBS is a short-chain PFAS. Several Member States are involved in regulatory work on similar substances. Germany will perform a Substance Evaluation of 2-[methyl[(nona-fluorobutyl)-sulphonyl]amino]ethyl acrylate (MeFBSAC, CAS 67584-55-8) in 2018. MeFBSAC may degrade to both PFBA and PFBS. Denmark has indicated in PACT that they assess PFBA. We will coordinate our work on PFBS and PFBS-related compounds with Germany and Denmark.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restriction under REACH	X
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	x
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

The identification of PFBS as an SVHC according to REACH article 57 f) should be considered for the following reasons:

1. PFBS is P and vP

Based on the structure (physico-chemical properties), experimental degradation data and read across to the long-chain analogues, PFBS fulfils the persistent criterion (P) and the very persistent (vP) criterion of REACH. It may even be categorised as extremely persistent, since no degradation is to be expected under environmentally relevant conditions.

2. PFBS is mobile and is frequently detected in water monitoring studies

PFBS has high aqueous solubility and low adsorption potential and is therefore very mobile. Due to the low adsorption potential PFBS does not bind to particles but stays dissolved in the water phase and is able to reach water bodies. PFBS is one of the dominating PFAS in river and/or sea water in several studies in Europe and has also been found in drinking water. PFBS is not removed by conventional water treatment processes. Hence, the substance may irreversibly contaminate drinking water sources and the aqueous environment. This may lead to increased levels in the environment and may in the long term represent a considerable level of concern for human health and wildlife.

3. PFBS is long-range transported

PFBS and its volatile precursors are long-range transported. Environmental monitoring studies have detected PFBS in remote areas. Oceans are likely to be the ultimate sink and PFBS has been detected at higher levels than PFOS and PFOA in deep Arctic waters.

4. Enrichment in plants

Studies have shown that PFBS and other short-chain PFAS tend to be taken up in plants and enrich in the edible parts of the plants. The short-chain PFAS were found to concentrate in plants at a considerably higher rate than the long-chain analogue PFOS. This indicates that humans (and herbivores) could be exposed to PFBS through crops.

5. Potential for protein binding

PFBS is able to bind to proteins in blood and tissues. This may affect tissue distribution/accumulation and may be of toxicological significance. PFBS has shown some potential for binding to and activating peroxisome proliferator-activated receptors (PPARs). Moreover, PFBS was shown to bind to serum albumin, liver fatty acid binding protein (L-FABP) and a thyroid hormone transport protein transthyretin (TTR). In general, studies show a PFAA protein binding affinity that depends on chain length and a chain-length with C4 is reported to have the lowest binding affinity. However, PFAAs containing the sulfonic acid group may bind stronger to proteins than the carboxylic acid counterparts.

6. Concentrations in human tissues and wildlife

PFBS is detected in blood/plasma from several European and non-European populations, currently the concentrations in the general population are low or in some studies not detected. However, increasing concentrations have been observed in blood following contamination of drinking water with PFBS. Some fluorochemical industry workers had significantly elevated serum concentrations. Furthermore, elevated PFBS serum concentrations were observed in children living near fluorochemical plants in China. These data indicate a potential for elevated blood and tissue concentrations in a situation with increasing exposure to PFBS following continued use and contamination of the environment.

Results from environmental monitoring studies show that PFBS has been detected in large air-breathing vertebrates like killer whales, where it was also shown to be transmitted to the foetuses, and in dolphins. A recent study in the Arctic detected PFBS in all the polar bear plasma samples analyzed.

7. Concern for possible long-term adverse effects

Data on the toxicity of PFBS in animals have identified the liver, kidneys, stomach, and haematological systems as target organs, available data is not sufficient to meet the CLP criteria for classification. However, the half-life for PFBS is considerably higher in humans compared to rats, therefore effects observed in laboratory animals might lead to an underestimation of adverse effects in humans. Furthermore, some results indicate that PFBS may have endocrine disrupting properties, in particular effects on thyroid hormones. There are also indications that PFBS may induce immunotoxicological effects, like asthma.

The potential impact on human health and wildlife due to elevated levels and long term/life-long exposure is difficult to predict.

In summary, PFBS is not expected to degrade under environmentally relevant conditions and it has a potential for long-range transport. It is highly mobile and contamination of water resources and drinking water has been observed. It may also enrich in edible plants. Moreover, PFBS has a potential for binding to proteins in animal and human tissues. Possible adverse effects due to long-term/life-long exposure cannot be excluded. Given the irreversibility of environmental contamination a threshold concerning the level of risk caused by the continued manufacture, use and emissions of PFBS in the long term cannot be derived with any certainty. Therefore, PFBS exhibits properties that give rise to an equivalent level of concern to PBT/vPvB substances. According to REACH PBT Guidance the specific concerns related to PBT/vPvB substances is due to their potential to accumulate in parts of the environment and to the fact that the effects of such accumulation for human health or wildlife may be unpredictable in the long term.

Taken together, the available data show that PFBS exhibits properties that give rise to an equivalent level of concern to PBT/vPvB substances. PFBS should therefore be identified as a substance of Very High Concern (SVHC) according to REACH article 57 f) and included in the Candidate List.

3.2 Restriction under REACH

The concerns related to PFBS summarised above show that restrictions on the substance, including salts and PFBS-related substances, could be necessary in the future. There is some production and use of PFBS-related substances in Europe, but to our knowledge, the major part takes place in China. Hence, one important source of PFBS-related substances in EU is imported articles. Stricter regulations on the production and use of PFBS and related substances in EU (i.e. authorization), may result in a shift of industrial production and use of the substances out of the EU, without affecting the content in imported articles. A similar shift was seen for PFOA when concern over its effects on health and the environment was raised, and the substance was to be phased out from use in western companies (Wang et al., 2014). Hence, authorization is not considered the best regulatory approach for PFBS and PFBS-related substances.

Restriction would be a more effective risk management measure for PFBS and PFBS-related substances. A restriction may limit the level of substances in articles (including imported articles), and it may cover a group of substances, such as PFBS, its salts and its precursors. Such an approach is the basis for the regulation of PFOA under REACH, Commission Regulation (EU) 2017/1000. A restriction will ensure that the amount of PFBS and related substances in articles in the EU, irrespective of whether they are produced in EU or the rest of the world, will be reduced.

More information on the use and exposure of PFBS and PFBS-related substances is needed before a restriction dossier may be submitted.

A global regulation of PFBS and related substances under the Stockholm convention could also be appropriate due to the long-range transport properties of PFBS and related substances

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for intention	Actor
SVHC Annex XV dossier	To be decided	Norway
Annex XV restriction dossier	To be decided	Norway