DG Environment - Department of Product Policy and Chemicals

Risk Management Option Analysis Conclusion Document

Substance Name: Perfluamine

EC Number: 206-420-2

CAS Number: 338-83-0

Authority: Belgium (Federal Public Service Health, Food Chain Safety and Environment, DG Environment – REACH)

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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

Data consulted on 03 June 2024.

Table 1: Completed or ongoing processes

EC/List No	Other REACH related work	RMOA	Evaluation			Authorisation		Restriction	CLH	Actions not under REACH/ CLP
			CCH[2]	TPE[6]	SEV[3]	Candidate List	Annex XIV	Annex XVII	Annex VI (CLP)	
206-420-2			X	X	X					

A targeted compliance check is in the follow-up phase, in which the following studies are requested (no deadline specified):

- Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD TG 211) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance.

- Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the FZ-7941 (cell crude of FC-3283) composition of the registered substance.

A testing proposal is ongoing, information was requested, and an update of the registration dossier is expected by 21 January 2026. The following studies are requested in the testing proposal:

- *In vivo* mammalian alkaline comet assay (test method: OECD TG 489) combined with *in vivo* mammalian erythrocyte micronucleus test (test method: OECD TG 474) in rats, or if justified, in mice, oral route (triggered by Annex I, Section 0.5 in conjunction with Annex IX, Section 8.4., column 2).

- Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) by oral route, in rats (with specifications in the Decision).

- Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) by oral route, in a second species (rabbit).

Perfluamine was included in the Community Rolling Action Plan (CoRAP) for Substance Evaluation (SEv; evaluation year: 2020). The requested study was received, and the SEv conclusion document is being finalized. No further information will currently be requested via SEv.

[2] ECHA dissemination website – Perfluamine – Dossier Evaluation Status
https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status/-/dislist/substance/100.005.837
[3] ECHA dissemination website – Perfluamine – Substance Evaluation – CoRAP
https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b8a7e5

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.

Table 2: Conclusion of RMOA

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	
No action needed at this time	

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

The substance evaluation performed by BE CA confirmed the concern for vPvB, for which further regulatory risk management is appropriate.

3.1 Harmonised classification and labelling

The SEv did not reveal any further concern related to human health or to the environment, other than the concern for bioaccumulation in aquatic species for which a study was requested and submitted by the Registrant(s).

A targeted compliance check and a testing proposal are ongoing (see section 1), from which other concerns could possibly arise.

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

Perfluamine meets the Annex XIII criteria for very persistent and very bioaccumulative. BE CA therefore submitted an Annex XV dossier for the identification of the substance as SVHC in August 2024. The public consultation on the proposal is currently ongoing. Identification of Perfluamine as SVHC according to Article 57 (e) of REACH will consequently lead to placing it on the Candidate List. This will create legal certainty and oblige the Registrant(s) to review their risk management measures and provide advice on safe use to downstream users. Furthermore, the authorization process provides an incentive for substitution to safer alternatives.

3.3 Restriction under REACH

Restriction can be introduced when there is an unacceptable risk to human health and/or the environment, arising from the manufacture, placing on the market (including imports) or the use of the substances, which needs to be addressed on a community-wide basis. A restriction may apply to any substance on its own, in a mixture or in an article. Restriction procedure also takes into account the socio-economic impact of the restriction, including the availability of alternatives. If it can be demonstrated that there is a community-wide risk, which is not adequately controlled for certain uses of substances, a restriction process according to REACH Articles 69(1) and 69(4) should be started.

Measured data on discharges, or monitoring data on actual environmental concentrations, are currently not available for Perfluamine, or are very limited. Consequently, it is not possible to demonstrate whether there is a community-wide risk and to quantify the risk in an accurate manner. Information on potential alternatives is not available either. It is however expected that Perfluamine as a perfluorinated compound will fall into the scope of the (planned) universal PFAS restriction. Therefore, the scope of that restriction will determine whether any other follow-up RMM is needed.

3.4 Other Union-wide regulatory measures

Not applicable.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Not applicable.

5. NO ACTION NEEDED AT THIS TIME

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Table 3: Tentative plan for follow-up actions

Follow-up action	Date for follow-up	Actor
Annex XV dossier for SVHC identification	August 2024	Belgium