

Response to the EA Evaluation Reports on AGC Chemicals Europe, Ltd. substances.

General text:

The UK Environment Agency (EA) have published environmental risk evaluation reports on a number of per- and polyfluoroalkyl substances (PFAS).^[1] Four of the evaluation reports published relate to substances used by AGC Chemicals Europe, Ltd. (AGCCE). AGCCE can confirm that we are in full compliance with UK and EU regulations, and we work closely with the UK EA to ensure the regular assessment of the substances we use, setting the highest standards for ourselves as a member of the local community. Our mission is to contribute to a safe, secure, comfortable, and environmentally friendly world with chemical technology.^[2]

We were actively engaged with the Environment Agency's (EA) Chemical Assessment Unit (CAU) (part of the Chief Scientist's Group) during the preparation of the reports.

The EA has made several recommendations to improve the risk assessments on the four substances and, although this is not part of an enforcement process, we are fully committed to addressing the points. Furthermore, the EA evaluation has been conducted using processes adopted in the UK REACH Regulation. As a company that is actively engaged in both UK and EU REACH, including acting as the sole registrant for one of the substances, the recommendations, where appropriate, will be applied at our next update of the UK and EU REACH dossiers. The updates will be done in 2024 for the substances where AGC Chemicals Europe, Ltd. is the lead registrant. Our comments on the specific technical recommendations relating to the four substances used by AGC Chemicals Europe, Ltd. are included in the following sections.

We understand that some stakeholders have concerns relating to the use and emission of perfluorinated industrial chemicals, including those used by AGC Chemicals Europe, Ltd. We would like to confirm that, even though we believe that the emissions of the evaluated substances from our fluoropolymer manufacturing facility at Thornton-Cleveleys do not present a significant environmental risk, we are committed to achieving further reductions in the emissions. As part of our Responsible Manufacturing approach, we are continually developing and investing in our manufacturing processes to reduce our emissions further by implementing additional abatement technologies. We have also committed to Responsible Manufacturing Principles as a member of a Fluoropolymer Product Group^[3] of PlasticsEurope. The Responsible Manufacturing initiative aims to continuously improve and/or develop "the best available techniques in the manufacturing process, management of environmental

[1] <https://www.gov.uk/government/publications/environmental-risk-evaluation-reports-per-and-polyfluoroalkyl-substances-pfas>

[2] See the AGC Chemicals Division vision "Chemistry for a Blue Planet"; <https://www.agc-chemicals.com/na/en/company/vision/index.html>.

[3] <https://fluoropolymers.plasticseurope.org/>

emissions, development of R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids, and/or the increase of recyclability and reuse of its products in line with the objectives of circular economy". We have also been directly involved in the creation of, and are signatories to, the industry Manufacturing Programme for European Manufacturing sites. ^[4] This is voluntary commitment aimed at reducing PFAS emissions, and it sets specific targets for all signatories to reach by the end of the year, and the end of 2030.

In response to the recommendations published in the environmental risk evaluation report on Perfluoro(2-ethoxy-2-fluoroethoxy)-acetic acid, ammonium salt (EEA-NH₄) (CAS no. 908020-52-0)^[5]:

1. The determination of vapour pressure is a required REACH endpoint. We will further strengthen the assessment of vapour pressure of EEA-NH₄ using QPRF according to the EA recommendations. This reassessment will be included in the next update of the REACH dossier.
2. The results of further studies on micelle formation, water solubility and the log Pow of EEA-NH₄ were shared with the EA CAU in February 2022 and their impact on the findings for hazard and risk characterisation will be assessed. These study results will be included in the next update of the REACH dossier.
3. A new study on the water solubility of EEA-NH₄ has provided a reliable experimental value. This will be included at the next update of the REACH dossier. Further modelling will not be required.
4. The further study on the partition coefficient of EEA-NH₄ provided a reliable experimental value as noted in point 2 and will be included in the next update of the REACH dossier. Further modelling will not be required.
5. The robust study summaries for the available aquatic toxicity studies on EEA-NH₄ in the REACH dossier will be updated to include the additional information.
6. The robust study summary for the algal toxicity study on EEA-NH₄ in the REACH dossier will be updated to include the additional information.
7. The robust study summary for the ASRIT study on EEA-NH₄ in the REACH dossier will be updated to include the additional information.
8. AGC Chemicals Europe, Ltd.'s is considering how to address the significance of exposure of air breathing organisms to EEA-NH₄ in the context of the PBT assessment of the molecule.
9. Additional studies to assess the toxicity of EEA-NH₄ in two representative invertebrate marine species have been completed. The results of these studies will be used to refine the calculation of the RCRs of EEA-NH₄ for the marine compartment and will be included in the

[4] [Microsoft Word - FPG Manufacturing Programme for European Manufacturing sites - September 2023 - Final \(fluoropolymers.eu\)](#)

[5] [Environmental risk evaluation report: Perfluoro\(2-ethoxy-2-fluoroethoxy\)-acetic acid, ammonium salt \[EEA-NH₄\] \(CAS no. 908020-52-0\) \(publishing.service.gov.uk\)](#)

next update of the REACH dossier.

We are aware that the EA has performed analysis of various tissues from fish caught in the River Wyre and Morecambe Bay as part of their annual marine survey^[6]. AGC Chemicals Europe, Ltd. provided the EA with an EEA-NH₄ analytical standard so that the substance could be included in the analysis. Although the results are not yet published, the EA has already shared the results for EEA-NH₄ with AGC Chemicals Europe, Ltd. For the fish collected from 52 locations around the River Wyre and Morecambe Bay, no EEA-NH₄ was detected in any of the tissue samples analysed (to a limit of detection of between 0.06 and 0.12 µg/kg (equivalent to parts per billion)).

10. AGC Chemicals Europe, Ltd. will address the issue of the need for the mandatory classification and labelling of EEA-NH₄ for reproductive toxicity under the UK CLP Regulation once the UK REACH dossier has been updated.

In response to the recommendations published in the environmental risk evaluation report on Trideca-1,1,1,2,2,3,3,4,4,5,5,6,6-fluorohexane (1H-PFHx, AC-2000, C6H) (CAS no. 355-37-3)^[7]:

1. Due to the high vapour pressure of 1H-PFHx and its low solubility in water, it has not been possible to perform a reliable study on the impact of pH variability or potential colloid formation on the level of water solubility.
2. The report titled "ASAHIKLIN AC-2000: Determination of Hydrolysis as a Function of pH" was shared with the EA CAU. The report concluded:
"The hydrolysis test could not be performed reliably due to issues caused by the volatility of the test item. Based on the functional groups within the chemical structure of the test item, it was considered that hydrolysis at environmentally relevant pH and temperatures would be negligible".
3. The predicted aquatic toxicity values on 1H-PFHx generated by the EA suggest that the study data are valid. AGC Chemicals Europe, Ltd. will include this additional supportive assessment at the next dossier update.
4. For highly volatile substances, with low solubility in water, AGC Chemicals Europe, Ltd. has not deemed an Aquatic Chronic 4 classification as appropriate due to the short residence time in water; we will review this at the next dossier update.
5. 1H-PFHx has a long atmospheric half-life.
6. The exposure assessment for 1H-PFHx will be updated, and if necessary, further refined to demonstrate that the RCR is below 1 for all relevant compartments.
7. AGC Chemicals Europe, Ltd. is implementing further emission control technology to further reduce emissions. Currently, AC-2000 is recycled in the process with a recycling efficiency

[6] EA Morecambe bay investigation – fish tissue analysis 2023 – not yet published.

[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1146176/5_Environmental_risk_evaluation_report_Trideca-1_1_1_2_2_3_3_4_4_5_5_6_6-fluorohexane.pdf

of more than 99.7 %. We have committed to further reduce the AC-2000 emissions from ETFE plant to both air and water.

In response to the recommendations published in the environmental risk evaluation report on 1,1,1,2,2,3,3-Heptafluoro-3-[(trifluorovinyl)oxy]propane (PPVE) (CAS no. 1623-05-8)^[8]:

1. AGC Chemicals Europe, Ltd. is not the Lead Registrant (LR) for this substance and does not have access to the full reports, only to the study summaries as part of our EU and UK REACH registrations. AGC Chemicals Europe, Ltd. will discuss these recommendations with the LR.
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8. For highly volatile substances, with low solubility in water, AGC Chemicals Europe, Ltd. has not deemed an Aquatic Chronic 4 classification as appropriate due to the short residence time in water. We will review this at the next dossier update.

[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1146179/6_Environmental_risk_evaluation_report_1_1_1_2_2_3_3-Heptafluoro-3-trifluorovinyl_oxy_propane.pdf

In response to the recommendations published in the environmental risk evaluation report on 3,3,4,4,5,5,6,6,6-Nonafluorohexene (Perfluorobutylethylene, PFBE, C4 Olefin) (CAS no. 19430-93-4)^[9]:

1. For highly volatile substances, with low solubility in water, AGC Chemicals Europe, Ltd. has not deemed an Aquatic Chronic 4 classification as appropriate due to the short residence time in water. We will review this at the next dossier update. This conclusion is consistent with the view of the Fluoromonomers Consortium^[10], that commissioned an evaluation of the ecotoxicological studies on PFBE. The Fluoromonomers Consortium concluded that "PFBE meets the 'rapidly degradable' criteria set for non-classification as Chronic Category 4 due to its ultimate environmental fate"^[11].
2. The Fluoromonomers Consortium commissioned an expert report on the degradation, fate, and behaviour of PFBE in the environment^[12]. This report highlights that standard EUSES modelling does not consider degradation in the atmospheric compartment, so this property was estimated using the US EPA model (Q)SAR AOPWIN. This model was run using all the available physicochemical inputs that were relevant for the model. The output was a conservative estimate of the atmospheric half-life (DT₅₀) of 6.4 hours. There is no indication of potential transformation products included in the report. AGC Chemicals Europe, Ltd. will consider if an investigation into transformation products is warranted and if so, will include this information in the next dossier update.
3. AGC Chemicals Europe, Ltd. is implementing further emission control technology to further reduce emissions. These technologies are also expected to reduce the PFBE emissions.

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[9] [Environmental risk evaluation report: 3,3,4,4,5,5,6,6,6-Nonafluorohexene \[Perfluorobutylethylene: PFBE\] \(publishing.service.gov.uk\)](#)

[10] The Fluoromonomers Consortium is the SIEF that manages the EU REACH registration of PFBE; AGC Chemicals Europe, Ltd. is the Lead Registrant for PFBE.

[11] "Evaluation of Ecotoxicological Studies in Support of PFBE", Project No.: FMC.001a, Blue Frog Scientific, May 2013.

[12] "PFBE: REACH Annex IX Waivers for the Degradation and Fate and Behaviour in the Environment", Project No.: FMC.001b, Many 2013.