



Department
for Environment
Food & Rural Affairs

Seacole Building
2 Marsham Street
London
SW1P 4DF

Dr Thérèse Coffey MP
Minister of State

T 03459 335577
defra.helpline@defra.gov.uk
www.gov.uk/defra

Dr Michael Warhurst
Executive Director - CHEM Trust
34b York Way
London
N1 9AB

Our ref: PO2019/13002/BB

22 August 2019

Dear Dr Warhurst,

Thank you for your letter of 17 June to the Secretary of State about the recent Member State Committee meeting at the European Chemicals Agency (ECHA). I am replying as the Minister responsible for this policy area. I apologise for the delay in replying.

I can confirm that the Member State Committee took place between 24 and 27 June. It was unanimously agreed that HFPO-DA is a substance of very high concern due to its probable serious effects on human health and the environment. The UK Member made a statement to the minutes (Annex 1) which explains our views on this case. ECHA will publish a record of the meeting in due course.

As you know, there is increasing awareness at an international level of the poly and per-fluorinated alkyl substances (PFAS) group of chemicals, to which HFPO-DA belongs. At the June Environment Council, we adopted Council conclusions which call for an EU action plan in this area. UK Government scientists are working in national, European and international contexts to contribute and engage in a coordinated response that takes into account the size and complexity of this group of chemicals and leads to the most effective regulatory actions.

The UK has in place some of the highest environmental standards in the world. We are a member of international agreements, such as the Basel, Rotterdam and Stockholm conventions. When we leave the EU, we will continue to uphold our international commitments and the UK will continue to have ambitious and extensive environmental standards.

Yours sincerely,

Thérèse Coffey

DR THERESE COFFEY MP

UK statement for HFPO-DA for the minutes

We recognise the specific concern of the dossier submitter, clearly a substance which has only been used for a relatively short time but is detected widely should be a priority for regulatory evaluation. We also agree that the inherent properties described in the dossier such as very high persistence and mobility, high potential for continuing contamination and difficulty to treat or remove the substance from water resources in combination give rise to a high concern for this substance.

We highlight that there are a number of risk management options available to address this concern; In choosing to identify the substance as SVHC under Article 57(f), the question for MSC is whether the dossier provides sufficiently compelling 'scientific evidence of probable serious effects on human health or the environment which give rise to an equivalent level of concern (ELoC) to those of other substances listed in Article 57 (a) to (e)'. This wording suggests to us that a boundary exists in terms of the probability of effects being serious or less so and as such the UK believes that toxicity is a very relevant consideration – if a substance is not demonstrably toxic in a relevant hazard category or with a high potency then it is questionable whether it should be considered to pose a “very high” concern. In this case, we do not consider that there is clear evidence that HFPO-DA is significantly toxic in either aquatic or mammalian studies.

Uncertainty has been referred to a number of times to build the ELoC case. Uncertainty is inherent in all chemical assessments, otherwise it would not be possible to conclude whether the use of any chemical was acceptable, and is generally addressed through the use of elements such as assessment factors, or a clear policy agreement that a combination of properties leads to unacceptable uncertainty. We agree that for highly persistent substances, uncertainty is increased due to continuous and growing exposure over time. However, we are not convinced that a case has been made that the uncertainty associated with vPvB substances (addressed by their SVHC category) is analogous to that for chemicals such as HFPO-DA. The properties of vPvB substances can limit the ability of laboratory studies to identify relevant effects due to either slow uptake or adsorption to surfaces. The vPvB designation is therefore a surrogate for the likelihood of unpredictable toxic effects in the food chain. In contrast, the solubility of HFPO-DA means it is amenable to standard regulatory toxicity tests. Where substances such as these are demonstrated not to bioaccumulate significantly and their toxicity has low potency, unexpected effects in food chains would appear much less likely. We note that differing views have been expressed about what the concerns underlying vPvB concept itself are, so we suggest that further technical discussion on this is needed, for example at the PBT Expert Group.

In addition, we are not convinced that “unknown effects” should be included in reasoning to reach a conclusion that serious effects will be “probable”. If uncertainty exists, the concern could be addressed by other regulatory or policy action (such as voluntary measures, etc.) or by requesting additional regulatory studies. In this case we consider awaiting the results of the studies requested in the recent substance evaluation decision could remove some of the uncertainties used to build the case.