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VCI

VCI Comments to the Annex XV report on the proposed restriction of

Undecafluorohexanoic acid (PFHxA), its salts and related substances

Germany has submitted a REACH report to restrict the manufacture, use or placing on the market of undecafluorohexanoic acid (PFHxA), its salts and related substances.

The German chemical industry supports the restriction of substances in accordance with the REACH Regulation, if they pose a risk to human health or the environment that is not adequately controlled and if such restrictions are science-based and proportionate.

We take this opportunity to give comments on general aspects of the Annex XV report. Detailed information on the scope of the restriction, substance-specific aspects and the uses of PFHxA related substances is provided by the respective sector industries.

Clear evidence of an unacceptable risk is lacking

The adoption of restriction measures shall comply with the rules laid down in Articles 67 - 73 of the REACH Regulation and follow a proper and proportionate application of chemicals legislation. Any restriction in accordance with REACH shall be based on substance-specific risk assessments. In order to initiate the REACH restriction process, an unacceptable risk to human health or the environment must be demonstrated by a dossier.

The dossier submitters argumentation is based on the extreme persistence of PFHxA, its mobility in the aquatic environment and a possible future risk. PFHxA does not fulfil the current PBT nor vPvB criteria according to REACH Annex XIII.

Evidence on hazard and exposure substantiating an unacceptable risk is a mandatory pre-condition for a restriction under REACH. Therefore, the proposed restriction of PFHxA cannot be considered to be in compliance with the REACH requirements on hazard and risk assessment.

In our view, the evidence of an unacceptable risk to human health or the environment required for a REACH restriction is not sufficiently substantiated in the currently proposed restriction of PFHxA. Quite the contrary, in its Annex XV report the dossier submitter states:

“To date no indications of serious human health risks are documented. Human exposure to PFHxA is limited and the studies available suggest a considerable gap between effect levels and measured exposure levels and the current state of research suggests that human exposure to PFHxA is unlikely to increase to levels that cause risks to the human health. […] It may thus be possible that serious health concerns related to PFHxA-exposure may be documented in the future. […] Considering the absence of clear evidence regarding human health impacts from exposure to PFHxA,

the Dossier Submitter concludes that there are currently no impacts to be expected. However, with a rising environmental concentration of PFHxA this may change in the future." [Chapter 2.5.2 Human health impacts]

"Environmental risks from the emission of PFHxA cannot be quantified with sufficient certainty. […] Information on current spatial effects from releases is uncertain and future effects are impossible to predict. […] A derivation of an acceptable amount of release into the environment is also not possible. Any releases that occur contribute to the environmental stock over time, which would eventually exceed any effect threshold in the future." [Chapter 2.5.3 Environmental impacts]

Furthermore, the parameter "Mobility" has been proposed by the German authorities, but it cannot be considered an official evaluation criterion under REACH. Thus, authorities should not give the impression that it is a generally accepted criterion.

Detailed substance identification and clarity on substances falling within the scope is required

Art. 67(1) of REACH states that "a substance on its own, in a mixture or in an article" may be subject to a restriction. Substance(s) must be identified under the terms of Annex XV, which states that "the proposal shall include the identity of the substance […]". As per Annex XV, thus, each substance or group subject to restriction must be adequately defined (by Chemical name, CAS/EC number, etc.).

The restriction proposal covers undecafluorohexanoic acid (PFHxA), its salts and related substances (substances which, based upon their structural formulae, have the potential to degrade or be transformed to PFHxA).

A grouping of substances may be possible under certain, closely defined conditions. In the Annex XV Report the dossier submitter gives a justification for grouping and states:

"Besides such PFHxA-related substances, for which their degradation to PFHxA has already been shown in different studies, other substances (for examples see chapter B.1.1 and Appendix B.4.1) show similarities in their molecular structures compared to PFHxA and related substances for which degradation to PFHxA was shown. This similarity and the nature of the chemical binding of the perfluorinated alkyl moiety to other parts of the molecules lead to the hypothesis, supported by modelling evidence, that formation of PFHxA as result of degradation is very likely, but has simply not yet been investigated in detail." [Chapter 1.3.2 Justification for grouping]

We question whether a grouping of related substances based on a hypothesis, meets the REACH requirements and demand further substantiation.

According to the information note provided by ECHA for the public consultation, forty six substances registered under REACH (in 75 registrations) are within the scope of the proposal. ECHA has also compiled a further indicative list of substances covered by the scope of the restriction proposal.

For the sake of clarity, an exhaustive list of well-defined substances, with their respective CAS numbers, falling within the scope, should be published as an amendment to a possible future restriction entry in Annex XVII of the REACH Regulation. In addition, prior risk assessment related to each of the substances in scope would be required.

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The VCI represents the politico-economic interests of around 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. In 2019 the German chemical industry realised sales of ca. 196 billion euros and employed 464,800 staff.