12 May 2020

Public consultation /the proposed restriction

undecafluorohexanoic acid (PFHxA), its salts and related substances

JBCE believes that the protection of human health and environment is successfully achieved by EU REACH Regulation (EC) No 1907/2006 by profound exposure and risk assessment of the uses and setting appropriate measures for protection from chemical substances which have been shown to be hazardous. As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the opportunity to contribute to the public consultation on restriction report of PFHxA, its salts and related substances (hereinafter collectively 'PFHxA', unless otherwise indicated).

(1) Careful review on uniform Restrictions on PFHxA is necessary in light of hazard and environmental risks.

JBCE refrains from discussing the detailed hazard properties of the substance group and would like to ask the fluorochemical industry to address the scientific discussions. JBCE has also recognized the following from the Restriction proposal as well as from previous REACH-related regulatory process:

a) According to the Restriction proposal, the substance group meets only persistence (P) as the regulatory requirements. The Dossier Submitter also confirms that PFHxA as such is neither CMR (page 31) nor Endocrine Disruptor (page 23).
b) In our view, risks are not adequately demonstrated in the Dossier and are based on speculations in many cases.
c) The substance group was proposed as an SVHC in 2018 but the proposal was withdrawn because of lack of unanimous agreement among the Member States on the hazard and risks of the substance in question. However, the content of the Restriction proposal is almost the same as that of the SVHC proposal at that time, and new knowledge has not been added.

On this basis, JBCE would like the Dossier Submitter to first conduct more detailed risk assessment and socio-economic impact assessment, and then to reconsider whether or not PFHxA, which have not qualified for listing as SVHC, need to be brought to a more stringent "restriction" than substances which qualified for SVHC listing.

(2) It is necessary to conduct the risk assessment of the articles containing PFHxA and socio-economic implications led by the Restriction.

In many cases, in the downstream sectors, substances which are not regulated by law are usually not controlled as strictly as regulated substances. So far, to our knowledge, PFHxA have not been subject to regulation on a global scale. As a consequence, in complex supply chains there is no knowledge on the impacts and socio-economic implications of the proposed restriction. First, article manufacturers have to start investigating whether or not PFHxA are used or contained in the production process of the articles, so that impacts and socio-economic implications by Restrictions can be considered in a more accurate manner.

In our view, it is desirable that the Dossier Submitter or ECHA will review whether the current proposed thresholds of 25 ppb / 1000 ppb for PFHxA in articles are realistic in line with the risks which could be caused by the hazard of the substance and by the use of the articles containing such substances. We assume that the Dossier Submitter merely followed the PFOA thresholds, without considering the hazard profile of PFHxA. There is no detailed rationale for the thresholds 25 ppb / 1000 ppb given in the Dossier. JBCE strongly believes that appropriate thresholds in any restrictions should be set established on risk assessment based on the science and socio-economic impact assessments under REACH. In this case as well, we also ask ECHA to assess hazard and potential risks based on the science, if proposing a restriction on PFHxA.

Generally speaking, it is our opinion that substances in articles, unlike substances and mixtures, have a significantly lower risk of release or exposure of substances under normal uses, unless release is intended. In addition, regulations on the waste management and occupational safety standards have already been established for in various industrial sectors such as for automobiles and electrical and electronic equipment. In case of concerns these options should be considered and adjusted first instead of proposing a general restriction.

(3) Analytical method for PFHxA is not established.

Adoption and implementation of any threshold should be linked to the availability of standardized and validated analytical methods, before a regulation comes into force. In theory, a similar analytical approach as used for PFOA could be used for PFHxA analysis. However, as of today, we are not aware that any EU-wide recommended analytical methods for PFOA, its salts and related substances has been adopted by ECHA in the form of the compendium on analytical methods to enforce restrictions[1]. It must be pointed out that lack of analytical methods for various matrices would make industry's compliance with the Restriction very difficult, especially because fluorochemicals are often used in complex articles (automobiles, electrical and electronic equipment (EEE), semi-conductor, etc.). This lacking would also make enforcement of the Restriction, including imported articles, very challenging.

[1] https://echa.europa.eu/documents/10162/13577/compendium_of_analytical_methods_en.pdf/3807683c-5340-4638-b5bc-5554635cdc8a

In any case, it is practically not possible for article manufacturers to control the content in the ppb level. As downstream users of chemical substances, article manufacturers rely on the information from upstream chemical manufacturers. But, in our view, even chemical manufacturers cannot easily manage their products on the ppb order. In the case of impurities or by-products arising from the manufacturing process, they may not be transmitted as confidential business information (CBI), or they may not be known to chemical manufacturers themselves unless precise detecting measurements are conducted.

(4) Assessment of alternatives are not given in the Restriction proposal.

Regarding the uses and applications, throughout the Dossier, the Dossier Submitter acknowledges that there are uncertainties in the analysis due to knowledge gaps regarding the tonnages of PFHxA affected by the proposed Restriction and the availability and/or functionality of alternatives. It is critical especially to several sectors, such as automotive, EEE, chemical and energy, as the Dossier Submitter did not seem to consider these sectors at all in the impact assessment and the assessment of alternatives to PFHxA related fluorochemicals (page 46). In many industrial sectors, PFHxA have hardly been noticed as substances to be regulated (PFHxA are not even SVHC), therefore there have been no impact assessment of the Restriction, feasibility assessment of substitution from PFHxA related fluorochemcals into other substances, or assessment of alternatives conducted on the industry side.

JBCE noticed that use of fluorochemicals and chrome plating were discussed in the Dossier (page 138 – 142, and page 154 – 160 in the Annex). The Dossier somewhat touched upon potential alternatives to PFHxA in those applications, but the conclusion of the assessment is unclear. It is also not clear what kind of benefits could be achieved by the alternatives, in terms of human health, the environment, safety and performance of products. The very likely possibility of moving to Regrettable Substitution must be avoided.

It is worth pointing out that REACH Regulation sets availability of alternatives as a condition of Restriction[2]. In our understanding, the PFOA Restriction has been realised, partially because the alternatives – PFHxA related fluorochemicals – have been identified and assessed. Since then, article manufacturers have been shifting from the PFOA related chemicals to the alternatives represented by PFHxA. One should ask why this Restriction proposal on PFHxA must come at this timing, without alternatives assessed or available.

(5) Sufficient time for the preparation in the downstream sector for restriction is necessary.

[2] Article 68 (1) of REACH Regulation: *When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio- economic impact of the restriction, including the availability of alternatives.*

The current proposal of "Restrictions begin 18 months after Official Journal published " for articles is not feasible in the industry. Firstly, even if PFHxA are contained in articles, it is difficult to investigate the entire long supply chain at this moment. In other words, in general, it is not possible to identify the parts or potential parts containing certain substances unless they are listed as SVHCs immediately.

Secondly an article can only be substituted after the upstream chemical manufacturers have completed its substitution with viable alternatives, based on the needs and standards applied in each sector. In particular, it is impossible for an article manufacturer alone to manage impurities of chemicals in the ppb level, which also applies to fluorinated chemical substances. It will become possible, only after the substitution at the very upstream chemical manufacturer in the global supply chain is completed and is expanded to the entire supply chain.

Thirdly, even if there is a potential alternative substance to PFHxA is identified, it is not always the case it will become a real and viable alternative. We have to prove whether it shows the same level of performance after design change. Many industrial sectors of course have to comply with chemical and environmental regulations, but also with sector-specific stringent product-related regulations as well as performance and safety standards. Special consideration is, for example, necessary for medical devices as well as monitoring, control and analytical devices, which contribute to human health and protection of the environment. If the preparation time for the compliance with new restrictions is too short, these devices with long design cycles cannot be placed on the EU market and consequently it would give negative influence on the production of pharmaceutical products or diagnostic in clinics.

As a general remark on such restrictions, it is JBCE’s opinion that any restriction should be introduced firstly to substances and mixtures based on the thorough hazard and risk assessment which must be based on the science, not mere speculation, and, in cases where restriction is found to comply with the restriction requirements under REACH Regulation, then to articles. Therefore, in case this Restriction on PFHxA were to be found appropriate and necessary based on scientific evidence rather than speculation, we still would like to propose a longer transition period or total exemptions with consideration of socio-economic aspects. It is important to set a derogation as long as there is no prospect of an alternative to PFHxA.

JBCE and its member support to promote for human health and environment in a realistic manner and on the basis of profound evaluation, and are willing to contribute to bring these ideas forward together with the European Institutions and other interested stakeholders.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organisation representing the interests of over 85 multinational companies of Japanese parentage active in Europe.
Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.
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