06. September 2021

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 the SEAC draft opinion on the REACH restriction proposal to PFHxA, its salts and related substances (hereinafter collectively 'PFHxA', unless otherwise indicated).

Specific information requests

1. Reporting requirements

In line with the proposal by the Dossier Submitter, SEAC currently suggests reporting requirements for the proposed uses to be derogated in PPEs, high visibility clothing, medical devices and their impregnation agents, epilames in watches, filtration and separation media, and fire-fighting foams (for class B fires in tanks >400m2 and their bunded areas). For more details, please refer to paragraphs 9 and 11 of the conditions of the restriction as proposed by SEAC in the SEAC draft opinion.

SEAC would like to receive feedback from stakeholders concerning the availability of information as required in paragraphs 9 and 11 to the actors indicated. In particular, if any issues in collecting this information is expected, a detailed explanation (including examples) should be provided.

We would like to address that the required information is difficult to collect in the long and complex supply chain, because of no harmonised and validated analytical methods. (See our following comments about analytical methods in General concerns other than specific questions)

Any reporting requirements should be efficient and accurate as possible. It should require minimum burdens on the industry. For example, it could occur that a natural and legal person placing a mixture on the market and a natural and legal person placing an article on the market exist in the same supply chain which benefits from one of the specified derogations. In this case, there is a risk of double counting of the quantity of PFHxA, its salts and related substances for one use (= used in mixtures which will be incorporated in an article). This situation will lead to overestimation of the total volume of this substance. To avoid a potential double counting and overestimation, the industry needs to have clear guidance on whom, within the supply chain for a specific derogation, is obliged to fulfil the legal requirement.

2. Concentration limits for PFHxA, its salts and related substances in fluoropolymers

i. possible difficulties of complying with different concentration limits for different sectors where fluoropolymers are used, as suggested by the Dossier Submitter

We are concerned that having multiple thresholds for different types of fluoropolymers and/or for limited applications or uses will make it very complicated, if not impossible, for the industry to assess its wide range of products or applications for compliance. This complexity would also make enforcement very difficult, and such multiple thresholds would be almost unenforceable. Fluoropolymers are in general further processed by mid-stream manufacturers (such as mechanical parts, sealants, etc.) before reaching the OEMs and at the industrial installations, and the supply chain is usually long and different in each sector.

In order to avoid such extreme complexity and difficulties, we therefore welcome and support SEAC's proposal that would include only two thresholds: one for PFHxA and its salts, and one for PFHxA-related substances, both numbers being applicable to all fluoropolymers regardless of their applications. JBCE understands that raw material suppliers and midstream suppliers in the supply chains propose certain thresholds of impurities in fluoropolymers in their responses to the public consultation. Given our assumption that these material suppliers and mixture/article manufacturers

know their chemistry, technologies and/or products very well, JBCE endorses proposals made by relevant industry stakeholders, such as PlasticsEurope Fluoropolymers Product Group (FPG), but also recognises that even higher thresholds might be necessary, depending on types of fluoropolymers and end applications of these.

We however also would like to point out that there are **no harmonised and validated analytical methods** for PFHxA, its salts and related substances in various matrices (other than water) which can easily be used by operators and enforcement authorities. The Dossier Submitter as well as RAC and SEAC state that a lack of standard methods for the substances in the restriction should not be considered a hindrance to the enforceability or monitorability of the restriction as the situation mirrors the same circumstances as for the previously adopted PFAS restrictions. In this regard, we would like to remind SEAC that industry still struggles with analysis of PFOA (C8) in various industrial products such as rubber and multi-layered coatings. We would welcome further efforts by ECHA to establish the validated analytical methods for PFOA in various matrices first during the transitional period.

3. Coating of electronic devices

PFHxA-related substances are known for excellent properties such as low refractive index, low dielectric constant and dielectric loss tangent, and oil repellency which cannot be achieved with other materials. Besides these, PFHxA-related substances also have excellent properties such as electrical insulation, heat resistance, chemical resistance, weatherability, water repellency and release properties, and they are used where multiple of these properties are required simultaneously. The most important property of PFHxA-related substances is the ability to provide these various properties in a single material, and it is not known to us that any other substance other than PFHxA-related substances can achieve this property. This is the reason why we think that it is difficult to replace PFHxA-related substances.

PFHxA-related substances for EEE are mainly used in “functional coating” applications so that EEE components and materials work properly for a long period of time, as well as in additive applications so that lubricants (e.g. grease) stay in the fine moving parts of precision instruments. Here "functional coating" means a coating applied to an article for the functions such as low refractive index, low dielectric constant and dielectric loss tangent, oil repellency, electrical insulation, heat resistance, chemical resistance, weatherability, water repellency, release properties and so on.

"Functional coating" includes, for example, "conformal coating" used to protect electronic materials. We use the term "functional coating" because the required functions are not only to protect the objects.

The PFHxA-related substances used in these applications do not volatilise at room temperature because of their very low vapour pressure. They are to remain in the coating and lubricant to provide the required functionality during the product life of the EEE to which they are applied, and their performance is verified before they are applied. In the design of materials for PFHxA-related substances, "wear resistance", "heat resistance", etc. are taken into consideration in order to ensure performance under more severe conditions than the rated operating conditions. Therefore, PFHxA-related substances are not expected to be released from EEE into the atmosphere and/or transferred to other substances during the use of the product under rated environmental conditions.

5. Medical devices

Restriction for in vitro diagnostic medical devices should be carefully introduced:
Medical devices include all devices listed in the European Medical Device Nomenclature (EMDN), not only those defined in the Medical Device Regulation (MDR: Regulation (EU) 2017/745). In the current pandemic, all these medical devices should be available to provide best diagnosis and treatment for all patients.

Especially the restriction for in vitro diagnostic medical devices should be carefully introduced since PFHxA may be used in these devices. Firstly, PFHxA is used in electric/electronic components and mechanical components in medical devices defined in MDR. It is very likely that these applications also apply to in vitro diagnostic medical devices which fall within the scope of the In Vitro Diagnostic Medical Devices Regulation (IVDR: Regulation (EU) 2017/746). Secondly, due to its water and oil repellent properties, PFHxA is also likely to be used in microscope slides and pipettes for general laboratory use as well as in vitro diagnosis use. However, it is currently quite difficult to confirm the use of the substances covered by the proposed restriction in these articles through the supply chains. The reason is - as described below – these substances have neither been regulated nor are listed as SVHCs, so their presence and concentration in articles are not subject to communication in the complex supply chains so far.

In the current pandemic, it is important to keep in vitro diagnostic medical devices largely available for the diagnosis of patients. Therefore, we suggest to carefully introduce the restriction to these devices only after no negative impact on society is ensured. Concretely we suggest to cover these devices by

derogation and to make annual reporting obligatory to enable quantitative risk assessment and to identify the necessary controls at least for a couple of years.

8. Technical textiles: textiles used in engine bays

The derogation should be extended to all high-performance technical textiles. In this regard, high-performance materials are defined by the introduction of multiple technical functions, such as the combination of repellency against water, oil, stain, gasoline and/or IPA. This distinction is critical as it emphasises the combination of technical functions and benefits delivered by the short-chain fluorinated polymers, which cannot be achieved through other treatment systems. In addition, an extension of the derogation to all means of transport (e.g., cars, electric vehicles, commercial vehicles, motor-cycles, aircraft, trains) and mobile machinery/equipment (e.g., hydraulic excavators, fork-lifts, road maintenance equipment, harvesters, gardening tools), since these mobile machineries applies the same or similar techniques and technologies as the automotive industry. This derogation should also apply to non-woven used for the same applications.

Regarding technical textiles, we would like to draw SEAC's attention, for SEAC's information, to the Opinion (CCMI/105-EESC-2012-1966) of the European Economic and Social Committee on Growth Driver Technical Textiles (https://www.eesc.europa.eu/en/our-work/opinions-information-reports/opinions/technical-textiles), in which the concept of 'technical textile' is discussed.

9. Filtration and separation media

d) The elements that a suitable wording for the derogation should contain.

JBCE welcomes the derogation proposal and would like to highlight that the derogation aims to cover filtration and separation media which require a combination of water and oil repellency at industrial sites. This combination of properties, which can only be achieved by chemistry based on PFHxA related substances (short-chain fluorinated polymers), provide critical benefits including optimal pressure drop, barrier properties against airborne harmful pollutants and microbiological contaminants, high dust holding capacity, durability and the required level of glue-repellency.

General concerns (other than the specific questions)

(1) 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. PFHxA is not added in the Candidate List of SVHC, nor classified as hazardous under CLP Regulation. As a consequence, in complex supply chains there is no enough knowledge on the amount and usage of PFHxA in article at the moment in order to analyze the accurate impacts and socio-economic implications of the proposed restriction. 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 (re: SCIP database).

(2) Transitional period

The original proposal of the Restrictions would begin 18 months after Official Journal published and in previous submission, we stated that it is not feasible for articles. Therefore, we welcome SEAC's proposal to extend the transitional period to 36 months after Entry-into-Force, and in JBCE's view 36 months is the minimum. For some article longer transitional period is necessary.

Firstly, it is difficult to investigate PFHxA contained in mixtures and articles in the entire long supply chain at this moment. Therefore, the socio-economic impact by the restriction cannot be assessed correctly. It is well possible that some usage turns out to be affected by the restriction.

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. Therefore, special consideration is necessary for some sectors.

For example, the electric displays have been imported to EU countries as various products such as TVs, personal computers (PCs), mobile phones, smartphones, tablets, monitors for automotive (e.g. navigation system), and other industrial monitors including medical equipment. These are widely used as not only main display itself, but also as a part of device or main parts. Surfactants as PFHxA-related substances are widely being used as a part compositions of display materials, such as surface layers and retardation layers of polarizing films, protective layers, functional layers of touch panels, protective layers on the outer surface of liquid crystal cells, and colour photoresists for colour filters of displays.

These are used for the various purposes such as photoresist and interlayer insulation layer of Thin Field Transistor (TFT) substrates. Not only due to their functionality, but also their brighter and lower energy consumption which highly contribute to the more precise medical imaging diagnostic or saving energy consumption (result in energy and resource efficiency), it is presumed that there are being used for the most of industrial displays.

On the other hand, due to the variety of the usages and specific physical/chemical properties, it takes time to investigate for alternatives by material manufacturers, and by the downstream sectors.

The display industry uses TFTs, which are made of the same production process and materials as semiconductors. (And PFHxA related substances are also used for the components other than TFTs). This industry is the long supply chain and has an obligation to supply repairing parts which is same as semiconductors.

The image sensor, which is one of the products of semiconductors, has a structure that the color photoresist remains within the device as a functional film. Its configuration and production process are similar to those of color displays composed by TFT substrates and color filters. As an additional similar point, they are both incorporated into various devices like medical and automotive applications with obligation to supply for repair parts even after EoS (End of Sales).

Therefore, we believe enough transition period is needed as semiconductors which is a similar industrial and supplying structure.

Fourthly, restriction to laboratory devices should be carefully introduced. As mentioned above, due to its water and oil repellent properties, PFHxA is also likely to be used in microscope slides and pipettes for laboratory use. Such laboratory devices contribute scientific research and development which lead innovations. However, it is currently difficult to confirm the use of PFHxA in these articles through the supply chains. Therefore, the restriction to laboratory devices should be introduced in a way further scientific research and development are possible.
Last but not the least, medical devices including in vitro diagnostic medical devices as well as monitoring, control and analytical devices have longer lifetimes and longer design cycles, and consequently they need longer transition period. In fact, from this reason, RoHS Directive gives longer transition period for these devices compare to C2C electric and electronic devices. These devices contribute to the society through, for example, diagnostic (ex. PCR test), measurement of hazardous chemicals, environmental monitoring (ex. air pollution, water quality), safety monitoring (ex. fire warning, product safety and reliability) and innovation (ex. development of new pharmaceutical products). If the transition period is too short, these devices cannot be placed on the EU market and consequently it would give negative influence on the society.

(3) Analytical methods

From analytical point of view, it is not possible to perfectly implement this restriction:
PFHxA in an article can be identified and quantified by using LCMS or LCMSMS after solvent extraction process. Since no standard for PFHxA is currently available, it is common practice to refer to the PFOS standard CEN/TS 15968:2010[1]. However, this standard is applicable only for limited cases and it is not applicable to all articles. For example, many side-chain polymers are difficult to extract because coating surface are water and oil repellent and therefore often insoluble in methanol or water/methanol solvents. In particular, the presence of cross-linked groups makes extraction much more difficult, as they may be further polymerised during processing or be more strongly bonded by reaction with the substrate. Apart from this, it is only possible to identify and quantify PFHxA in an article if the structure of the related substances and side-chain fluorinated polymers is known.

[1] CEN/TS 15968:2010: Determination of extractable perfluorooctanesulphonate (PFOS) in coated and impregnated solid articles, liquids and fire fighting forms – Method for sampling, extraction and analysis by LC-qMS or LC-tandem/MS

Therefore, even with reference to the existing standards, the restriction cannot be fully implemented because only limited cases of analytical methods have been established so far and because the structure of all PFHxA-related substances cannot be determined.
In particular, the presence of cross-linked groups makes extraction much more difficult, as they may be further polymerised during processing, react with the substrate, or be more strongly bonded by reaction with the substrate.

(4) Spare part exemption

We strongly believe that spare parts for EEE placed on the market before the implementation of the restriction should be excluded without expiry date. If spare parts are not exempted, the lifetime of EEE might be shorten. Consequently, the volume of waste of EEE will rapidly increase, which is undesirable from the viewpoint of circular economy.

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.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 90 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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