



JAPAN INDUSTRIAL VEHICLES ASSOCIATION

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Written comments on the Annex XV Restriction Report

Restrictions on the manufacture, market placement, and use of PFAS, jointly proposed by Germany, the Netherlands, Sweden, Norway, and Denmark, have been published in the Annex XV Restriction Report.

The Japan Industrial Vehicles Association (JIVA) submits the following comments in response:

I. Introduction

JIVA is established in 1948 and has been the leading organization of industrial truck manufacturers in Japan. The aim of JIVA is to contribute the sound development and progress of industrial trucks industry and the growth of national economy. We are working on a wide range of activities such as development of safety, environmental-friendly, and high productivity in intralogistics sector.

JIVA and its member companies fully support the EU's efforts to reduce the risks of hazardous substance via the REACH Regulation. We have been collecting chemical substance information through the supply chains since the REACH Regulation took effect, and for all products brought to market, we work to ensure compliance and closely monitor conditions to confirm that requirements are met. We select suppliers based on component quality standards, and our customers receive products confirmed to be safe and durable.

Nevertheless, we ask that you consider the following significant concerns of the PFAS restriction on proposal:

II. Concerns and requests regarding the proposed restrictions

1. Issues in gathering information

The proposed PFAS restrictions would apply restrictions to more than 10,000 organofluorine compounds (PFAS) due to the risks they pose, which are said to be equivalent to those of already regulated PFOS and PFOA substances, due to persistence in the environment. Compared to the 233



candidate substances currently subject to authorization (“CL substances” hereafter), the substances to which the proposed restrictions would apply include many chemical substances other than CL substances. This information is beyond the reach of supply chain investigations. Determining usage would pose significant difficulties.

Additionally, the absence in the proposal of a list of target substances complicates investigations.

2. Concerns regarding risk assessment

Article 68 (1) of the REACH Regulation refers to the scope of the restrictions, which regulates unacceptable risks to human health or the environment that need to be addressed by society as a whole. The proposed restriction lumps fluorine compounds together as "a universal PFASs". This means that a wide range of substances are covered, even those for which the hazard and risk assessment is not clear. Descriptions of alternative substances are also very broad and require time to review, although the list of apparent alternative substances is ultimately relatively narrow.

The restrictions proposed emphasize the persistent nature of PFAS and target a broad range of PFAS (universal PFAS) (Annex XV report, pp. 21–22). We believe that this approach is not consistent with the hazard and risk assessment approach of the REACH regulation. Regarding bioaccumulation potential, it is inconsistent and insufficient as a risk assessment to state that "there is a justified concern" (Annex XV Report p. 28) while stating that "large uncertainties remain for the majority of compounds due to lack of data. ". If concern is the sole reason for taking such action, we believe placing the substances on the CL as SVHCs in accordance with Article 59 should be considered as an initial measure.

3. Requests regarding proposed restrictions

(1) We believe it would be difficult to uniformly restrict PFAS in accordance with the REACH Regulation. A list of chemical substances subject to restrictions should be prepared for each substance or subgroup (such as OECD classification) to reduce the burden of information collection.

For each substance, in line with Article 68 of the REACH Regulation, data-based scientific evaluations are required to determine “unacceptable risk to human health or the environment.” We request that, instead of restricting fluorinated compounds as a single 'broad PFAS', substances for which an 'unacceptable risk' has been identified should be prioritized according to the magnitude of the risk and restricted.

(2) For exemption purposes, substance contents must be reported, as discussed in Paragraphs 4 and 7.



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While Annex E.4 appendix includes recommended analytical methods, it is unclear that these analytical methods are established as valid. It must be established that analyses performed by these methods are valid for determining and reporting substance content. This can be understood most clearly by adopting established analytical methods as EN standards. We request the standardization of these methods as EN standards. This would allow analysis by accredited laboratories.

(3) Regarding the transition period, the proposal provides for 18 months, while "C9-C14 PFCAs" and "PFHxA" are specified as "36 months". Since Paragraph 3 covers a much larger number of substances than those listed above, we anticipate that it will be very difficult to comply with the 18-month period. We request either a substance-by-substance restriction, or a subgroup with a similar level to the above-mentioned substances and a transition period of 36 months or longer.

(4) The concept of *essential use* mentioned in the Chemicals Strategy for Sustainability has not been defined. For this reason, the concept has not been considered in the proposal for the sake of establishing exemptions. We anticipate that this will cause confusion, as there will be a need to reconsider the uses and substances that should be exempted after an 'essential use' decision has been made, we request consideration to allow the submission of comments after essential use has been defined and exemptions clarified.

(5) We request a clear statement that certain substances are not subject to the proposal—specifically, PFOS, PFOA, and PFHxS, as regulated under POPs regulations; C9-C14 PFCAs, as already entered in Annex XVII of the REACH Regulation; and PFHxA and Bisphenol AF, for which legislative procedures are currently underway.

(6) The proposal indicates that the more rigorous restrictions apply in cases involving overlaps with other regulations, directives, or matters of restriction. However, we believe the broad scope of the restrictions makes it difficult to determine the actual meaning and practical interpretation of "stricter restrictions." We request that you specify in a restriction clause what takes precedence or establish guidelines.

Respectfully submitted,

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