

30 July 2020

## **JBCE input /PFAS Call for evidence**

As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the openness for stakeholders to provide information to the five European countries (Netherlands, Germany, Denmark, Sweden and Norway)'s initiative, the Call for Evidence regarding per- and polyfluoroalkyl substances ('PFAS').

### **“Persistence alone” and Article 68 of REACH Regulation**

JBCE has grave concern with the idea of basing a potential REACH restriction only on the persistence. JBCE understand that this 'persistence alone' approach has been proposed by some Member States as well as academia<sup>1</sup>, but notes that this argument does not consider the full picture of risk assessment which is required by the EU REACH Regulation.

Let's take polytetrafluoroethylene (PTFE) as an example. PTFE is durable, as are many types of glass or ceramics. PTFE is similarly considered to be persistent, insoluble and inert, as are glasses, ceramics and metals that must be refined from ores. The processes involved in manufacturing glasses, ceramics and many metals are as “chemical” as the one for PTFE. If we follow the “persistence only” argument, theoretically speaking, the EU would have to consider restricting glasses, ceramics and metals for all uses except for 'essential uses', while these are widely used by consumers - in other words, the general public is being exposed to such persistent materials – how would the EU mitigate the risk? One should ask what the difference is between PTFE and glasses, ceramics or refined metals such as aluminium, while all are obtained by human manufacturing processes. Why should a gasket made of PTFE be banned, while porcelain coffee cups are allowed?

In the Call for Evidence, the five EEA Member States argue that *the consequences of this persistence include that the presence of these substances in the environment is practically irreversible, and pose an unacceptable risk to the environment and humans*. But persistence by itself does not pose a hazard *per se*. Persistent substances can only be a concern if they also entail some hazard. If they entail a hazard, their potentially increasing presence in the environment from use and/or emissions could be a reason for concern, but only then, not in

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<sup>1</sup> Cousins, Ian T., et al. "Why is high persistence alone a major cause of concern?." *Environmental Science: Processes & Impacts* 21.5 (2019): 781-792.

the absence of a hazard. As we understand the REACH Regulation, 'persistence' itself is not considered as a hazard under REACH Regulation. Instead, it is a factor to be considered in the risk assessment of a chemical substance together with bioaccumulation and/or toxicity. This is evident from the Preamble, paragraph 76 of REACH Regulation. Thus, persistence by itself cannot be an intrinsic property that has an adverse effect on human health or the environment in the absence of any other property that constitutes a hazard.

This logic leads us to question the legality and proportionality of a REACH restriction based on persistence alone. According to Chapter 2 of REACH Regulation, for a restriction to be adopted, not only must a hazard be identified, but the resulting risk must be assessed and found to be 'unacceptable' to human health or the environment and the proposed restriction found to be the most appropriate measure to manage the identified risk.

It should be recognised that, for substances like PFAS, the intrinsic property of persistence confers the desirable properties of high durability and unique functionality to products made and treated with this chemistry. Persistent substances and materials provide health, safety, environmental and energy savings benefits. If you look at fluoropolymers, these are critical components in numerous technologies, industrial processes and daily applications, for instance, automotive, aerospace, chemicals & power, electronics, food & pharma, textiles & architecture, medical applications, analytical applications and renewable energy. Likewise, fluorotelomer-based products can be used for treatment of textiles, non-wovens and surfaces, which are components of personal protective garment & equipment and textile & non-woven in medical sector, and for filtration and coating in industrial applications. This property results in significant maintenance and durability of materials, contributing to waste reduction in line with the EU's objectives for a circular economy, and in protection of human health, for example. In our view, less durability would lead to frequent maintenance and/or replacement of materials, as well as to potential increase of waste. Prohibiting substances on the basis of persistence alone runs completely counter to the goal of a sustainable Circular Economy.

It is worth noting that the increased focus on persistence is likely to lead to restrictions of potential alternatives as they would require similar properties in order to fulfil the abovementioned critical functions in industrial applications. In addition, we are concerned that this kind of restriction would discourage researchers and companies to develop materials and business for sustainable future, and, as a result, limit future innovation for betterment of the society in the EU.

JBCE believes that, if a restriction on the basis on persistence alone were to be established, this precedent would severely hamper and possibly prevent any future innovation in chemical industry, in particular innovation aimed at durable materials. We therefore would like to encourage the relevant authorities in the EU to reconsider the future direction of the EU chemicals strategy. Do we really want products that inevitably break and fail after a short time and are impossible to recycle because they chemically degrade?

## **Mobility**

JBCE understands that so-called ‘mobility’ of substances is an additional concern expressed by the 5 EEA Member States.

The criterion of ‘mobility’ is not defined in the REACH Regulation nor is it identified as a hazard. There are debates surrounding this concept among regulators, academia and relevant stakeholders and are no agreement or consensus on the methodology, if or how to apply this concept – is it a screening criterion or regulatory? It is worrying that such a nebulous criterion is being proposed as a basis for a REACH restriction. Therefore, JBCE would like to encourage the relevant stakeholders (in the chemicals industry) as well as the competent authorities to consider what kind of roles ‘mobility’ should play in the EU chemicals policy, if at all, and under which regulatory instrument. If mobility were to be considered under REACH, the concept and agreed criteria would have to be introduced into the main body of the REACH regulation, similar to bioaccumulation.

## **Grouping**

Fluorochemicals are being regulated by the grouping, as has been done for PFOA and PFOS. The Call for Evidence however targets a far larger group of chemicals (thousands of substances), in our view, without scientific hazard and risk assessment of each substance.

We understand that the initiators of this Call for Evidence would like to prioritise efficiency of regulatory actions, rather than taking time-consuming but science-based hazard and risk assessment approach. We agree that efficiency is important in general, especially when a large trade and political union is governed. However, it must be pointed out that still this ‘mega’ grouping, including hydrofluorocarbons (HFC) and olefins (HFO), small molecules and huge polymers is over-simplified. This broad approach short cuts science and indeed all reason, treating completely dissimilar substances alike.

HFC and HFO are not generally considered as PFAS, and most of them are not classified as ‘persistent’. Globally, these substances are being phased down per a schedule established by the Kigali Amendment to the Montreal Protocol. Some examples of the phase down mechanisms in different countries are the EU F-Gas Regulation and the Japan Ozone Layer Protection Act. In the EU, HFCs are strictly regulated under F-Gas Regulation in light of the EU’s climate goals. The Regulation is under review towards the amendment in a few years. It is worrying that trying to box F-Gases in this general restriction plan would create a double-regulation and unnecessary uncertainty and confusion in the EU market, as well as could result in a ban of all viable refrigerants in the market. If risk management of HFCs and HFOs is necessary in terms of the chemicals policy, usual REACH procedures (registration, substance evaluation and dossier evaluation) should be sufficient<sup>2</sup>. Therefore, JBCE strongly recommends that F-Gases be out of the scope of the Call for Evidence and the PFAS action plan.

Further, in view of the enormous breadth of substances for which a restriction is contemplated, beyond the chemical persistence of the parts of the molecule that contain –

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<sup>2</sup> Certain refrigerants have been evaluated under Dossier and Substance Evaluations.

CF<sub>2</sub>- or -CF<sub>3</sub>, these substances have almost no unifying shared properties. Some are toxic, others are not toxic at all. Some are gasses, others are liquids and still others are solids. Some are water soluble, others are fat soluble and still others are completely insoluble. Some are chemically reactive, others are chemically inert. Some are volatile, others are not. How can such diverse properties possibly be adequately covered by a single risk assessment? Is this exceedingly broad Call for Evidence really serious or is it merely a “fishing expedition for the next thing to ban”?

JBCE would also like to emphasise the importance of availability of analytical methods. Generally, under the chemical substance legislation, analytical methods are key for enforcement. For that, it would be necessary to establish the analytical method for PFAS and certified references. How could that be possible for a category that includes several thousands of compounds? In the case of detecting the PFAS as impurities, it is not possible to identify the type of PFAS contained. Currently, neither analytical methods nor the certified references for all kinds of PFAS are available. In fact, we can identify and determine the concentration only for very limited kind of PFAS.

Under the REACH Regulation, the registration of a substance is not the final goal. Registration is intended to be the starting point towards further evaluation of the substance, hazard and risk assessment using on the scientific information obtained by the registration, and determination of sound and reasonable management of the chemical compounds, with consideration of socio-economic impacts. This grouping of PFAS proposes to skip all of these steps and simply jump to a conclusion on the basis of mere suppositions, without considering the information gathered in the registrations. JBCE is concerned that such sound principles for chemical management are already being abandoned only 10 years since the start of REACH registrations and only 2 years since completion of phase-in. JBCE therefore would like to strongly encourage the relevant EU stakeholders to consider whether there is really a need to completely abandon REACH's science and fact-based approach, replacing it with broad, rapid and sweeping actions based on suppositions and which group dissimilar substances together, in contradiction to the facts collected in the REACH registration process.

### **Essential uses**

The term ‘essential uses’ is increasingly being heard in relation to PFAS, and the Call for Evidence initiators intend to propose a REACH restriction to the group of PFASs, with aiming for all uses except ‘essential uses’. It must however be noted that there is no definition of ‘essential uses’ in anywhere in the REACH Regulation. There are various views and opinions proposed by NGOs and academia, but JBCE members are of the opinion that inclusion of ‘essentiality’ into the REACH restriction regime must require a legal and political consideration, which results in the amendment of REACH Regulation, i.e. amendment of the conditions for REACH restriction (Article 68).

Some say that ‘essentiality’ is already proposed and established by Montreal Protocol. JBCE also recognise that the Parliament passed a resolution calling for an action plan to phase out all non-essential uses of PFASs as part of the upcoming EU chemicals strategy for

sustainability with the definition provided in the Montreal Protocol. However, it must be pointed out that the purposes of Montreal Protocol and REACH Regulation are different - climate action and management of chemicals -, and an easy and simple application of a concept from one regime to the different regime could incur unexpected inconvenience and disturbance to the future development of chemistry. (The substances targeted by the Montreal Protocol also only had a limited range of uses and the risk was well-defined.)

According to the Montreal Protocol, the essentiality is recognised only if it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. It might be easy to identify the purpose of protection of human lives, however 'functioning of society' can depend on what kind of society the EU would like to be. For example, we understand that fluoroelastomers (e.g. for o-rings and sealing) and fluoroplastics (e.g. for wire and cable) are required to automobiles functioning to comply with the emission regulation as well as running safe on the road. How would the essentiality be applied to this case? Would the road safety be considered as 'protection of human safety', or a critical part of the functioning of society?

We would emphasize that a discussion of "essential uses" is inappropriate because there is no identified hazard or risk of PFAS as a group, since the persistence does not pose a hazard or risk *per se*. An essential use discussion should take place only for those PFAS that are identified as posing an actual risk to human health or the environment based on the sound science, not just hypothetical conjectures.

### **Precautionary principle**

We note that the restrictions or bans solely on the basis of persistence cannot be justified under the REACH regulation as it stands today. If the initiators of this Call for Evidence believe that their concern and action might be justified by the 'precautionary principle', we would like to remind the initiators of how the 'precautionary principle' is applied in EU legislation and jurisprudence.

The precautionary principle is indeed a basis of the EU legal framework, as a preventive function to protect the environment<sup>3</sup>. The European Commission issued the Communication from the Commission on the precautionary principle (2.2.2000 COM(2000) 1)<sup>4</sup>:

*Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:*

- **proportional** to the chosen level of protection,
- **non-discriminatory** in their application,
- **consistent** with similar measures already taken,

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<sup>3</sup> Article 191 of the Treaty on the Functioning of the European Union

<sup>4</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52000DC0001>

- **based on an examination of the potential benefits and costs** of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis),
- **subject to review**, in the light of new scientific data, and
- **capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.**

In order for any action such as the substance bans under consideration to be proportional to the chosen level of protection, first a negative effect must be identified. Case law (for example 174/82, T13/99, C-192/01, C-236/01, C-333/08) makes it abundantly clear that it is not sufficient to merely suggest a hypothetical risk. For such a broad range of substances and extremely diverse properties under consideration for PFAS ban, the risk postulated by the Member States proposing their ban can only be purely hypothetical.

For the action to be non-discriminatory, the action (substance ban) would have to be applied to all substances exhibiting the same property, namely persistence. Thus, if PFAS were to be banned merely on the basis of persistence, then all other persistent substances, including ceramics, glass and various metals, would also need to be banned. In the absence of bans of other persistent substances and materials, substance bans solely for PFAS could not possibly be consistent.

In our view, any justification for a substance ban based on the precautionary principle – in this case persistence alone without any identified hazard – must stem from a thorough assessment of potential benefits and costs of such a ban, as well as the scientific evidence for the risk assessment. Moreover, it must be subject to review, in light of new scientific information. Lip service to precautionary principle itself does not exempt regulators from looking into available scientific information; this is clear by certain Court Judgements and Regulatory Decisions<sup>5</sup>. It is doubtful that an approach based on persistence alone in the absence of any common hazards and which addresses such a huge and varied group of substances with completely diverse properties, without reviewing available scientific evidence, could possibly be justified under precautionary principle as implemented in EU Law.

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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<sup>5</sup> For example, Commission vs Kingdom of the Netherlands (C-41/02) / Council Decision 2009/121/EC