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Contribution of the State Government of Baden-Württemberg to the Consultation on the PFAS restriction proposal under the REACH regulation

On 7 February 2023, the European Chemicals Agency (ECHA) published a proposal to **restrict more than 10,000 perfluorinated and polyfluorinated alkyl substances (PFAS)** under the REACH regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

An EU public consultation is being held during the period 22.03.2023 – 25.09.2023 on the PFAS restriction proposal under the REACH regulation. The State Government of Baden-Württemberg is contributing to the consultation with the following considerations:

Starting point

PFAS are either inherently persistent or degrade to become persistent PFAS (e.g. PFCAs, TFA, etc.). PFAS remain in the environment for decades and can have an impact on humans and the environment.

Some studies have linked certain PFAS to adverse health effects such as liver damage, thyroid disorders, fertility problems and cancer. There is still limited knowledge on the impact that PFAS have in the food chain and in drinking water. It is not possible to classify PFAS as carcinogenic across the board, partly because there is insufficient data available for some PFAS. However, when levels of PFAS (more precisely perfluorooctanoic acid, PFOA, and perfluorooctane sulfonate, PFOS) are elevated in the blood, it is possible to observe effects such as altered cholesterol levels and reduced vaccination titres. Another health risk associated with PFAS is that their presence can lead to a reduced immune response.

In the past, the approach of placing restrictions on individual substances or substance subgroups belonging to the PFAS group of substances has, in the view of the Member States, not proven to be effective in adequately addressing the risk posed by the PFAS group of substances. This is because a restricted substance can be replaced by

another substance from the PFAS group, which in turn exhibits equally problematic properties (keyword: regrettable substitution).

For certain applications and production processes, such as various medical products and pharmaceuticals, lithium-ion batteries, fuel cells, electrolysers or microchip production, there are, to the knowledge of the State Government, no suitable alternatives for the production of PFAS-free products or for PFAS-free processes available on an industrial scale. In many fields, industry does not believe that it will be possible to replace certain substances from the PFAS group with alternatives either now or in the long term.

The use of PFAS should be banned in areas where PFAS endanger humans and the environment and can be replaced by other substances. In areas where PFAS cannot be replaced by other substances and a severe restriction would compromise patient care and hinder progress in future technologies and the energy transition, we advocate for a differentiated regulatory framework.

Using medical technology as an example, it is clear that without PFAS, functional properties will be lost unless alternative materials or treatment methods are developed. Although the current draft of the restriction proposal provides, among other things, for transitional arrangements with long deadlines for medical technology, these are, in the view of the sectors concerned, not sufficient in cases where production has to be altered and new products have to be certified. Furthermore, there is a risk that, due to the deadlines set, manufacturers of basic materials may withdraw from the market prematurely, thereby jeopardising the continued availability of PFAS in the required quality, including for the production of medicinal products. There are indications that some manufacturers are already withdrawing from the market.

As part of the certification process for medical devices, risk management is conducted to ensure that the risks posed by medical devices are known, managed and deemed acceptable in relation to the benefits. This risk assessment is a prerequisite for placing any medical product on the market.

According to the medical industry, there is a danger that the currently planned restriction on PFAS could result in an end to the European production of urgently needed medical devices, such as endoscopes and implants.

It is essential to ensure that the discharge of PFAS into the environment is prevented or minimised during the manufacture, use and disposal of these products.

Given this context, the following points must be taken into account going forward in this process:

- A restriction on the use of PFAS should adequately regulate the risks to human health and the environment, thereby ensuring a ***high level of protection for humans and the environment***. In particular, it should guarantee that the ***discharge of PFAS into the environment is avoided or minimised***.

- Based on a **differentiated approach**, the benefits for people, society and the environment should be assessed in relation to the risks for the respective applications, and a **regulatory approach that differentiates** between the applications should be proposed accordingly.
  This should ensure that **appropriate alternatives are available** for **applications important to society**, such as medical devices and pharmaceuticals, renewable energies, the automotive industry, mechanical engineering and plant construction, or microelectronics production. It should also mean that the **transitional provisions** and **adequate exemptions** are designed appropriately.

- One thing is certain: Substitutes for PFAS – where available – cannot be named or listed for all areas of application relevant to society. Even if intensive research is conducted on alternatives for specific applications, an assessment must be made as to whether a changeover is feasible within the defined transitional periods or whether, if necessary, a **transitional period needs to be extended further** for particularly relevant uses or whether general **exemptions** should be granted. Adequate exemptions and transitional provisions should be considered for society-relevant applications where no alternatives exist, and particularly for **closed loop systems** where it has been demonstrated that environmental exposure can be excluded.

- All products eventually become waste. Efforts should therefore be made to ensure that **disposal technologies** are available and used for substances that have been approved for applications. In addition, **production** can result in emissions being released into the environment. To prevent this from happening, **closed production systems** must be in place or be implemented.

- In addition, the **interfaces** to already existing restrictions as per the REACH regulation, as well as other provisions, such as the **F-Gases** regulation, must be clarified and adequately regulated.

- The regulations must be **implementable and enforceable**, in particular to prevent non-compliant imports from outside the EU. To achieve this, the following provisions are required:
    - The restriction proposal submitted under the REACH regulation seeks to restrict the entire group of substances. However, for this purpose, a substance definition has been put forward which is unclear even to experts and which, according to the documents submitted, appears to be ambiguous in some cases. What is needed is a **clear and unambiguous substance definition**.
    - Furthermore, coordinated or standardised **analytical methods** are not available for all proposed limit values. Therefore, it is necessary to establish appropriate **uniform and enforceable standards**.

- In complex products and multi-stage process and supply chains, complete identification, assessment and communication of each individual instance is particularly challenging and complex. It may not be possible to properly evaluate essential applications in time; therefore, adequate **exemptions** should be provided.

- To ensure that the current situation regarding the availability of alternatives is taken into account, a **review clause** should be introduced for the Commission at the end of the defined transitional periods, with the obligation to provide the relevant information for the economic sectors concerned at that time. This clause must be drafted in such a way as to minimise red tape, ensuring that

SMEs in particular are not disproportionately burdened and offering a straightforward means of verification.

- During the ongoing process accompanying the current restriction proposal, **workable solutions** must be developed which, on the one hand, are capable of preventing or minimising the discharge of PFAS into the environment and, on the other hand, provide a practicable way of enabling the safe use of PFAS in society-relevant applications. This is particularly important while **no substitute substances** are available for society-relevant products and applications. The **transitional periods and adequate exceptions** must pay due consideration to these concerns.

To conclude:

In summary, the State Government advocates a differentiated regulatory framework. For society-relevant applications where there are no alternatives to the use of PFAS, there must be appropriate transitional provisions and adequate exemptions. In addition, there must be intensified research into alternative materials.