24 September 2023

EDA'S INPUT TO THE PUBLIC CONSULTATION ON UNIVERSAL PFAS RESTRICTION PROPOSAL

Reference: ECHA Public Consultation on the Annex XV restriction report of 22 March 2023 for Per- and polyfluoroalkyl substances (PFASs)[1]

In the context of REACH Regulation, defence exemptions according to Article 2(3)[2] and specific derogations/extended transitional periods for defence uses are two different approaches that can be used to address the specificities of defence sector under the REACH restriction regime.

In order to avoid misconception on defence exemptions, which could be seen as the only means to deal with REACH issues related to defence, and to underline that defence exemptions are clearly seen as last resort solution, the European Defence Agency (EDA) has identified the need to highlight some key messages.

Based on the below key messages and considering the specificities and potential impacts on the defence sector and the operability of Member States' armed forces, in particular in view of the long life cycle of military equipment and the wide and numerous critical uses of PFAS substances in EU defence equipment, **it is crucial that the universal PFAS restriction proposal includes sufficient transition periods for research, testing and implementation of viable alternatives for defence uses at EU level, as well as relevant derogations where necessary.**

[1] Available at https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term.
[2] In accordance with Article 2(3) of the REACH Regulation, Member States may allow for exemptions from the REACH Regulation in specific cases for certain substances on their own, in a mixture or in an article, where necessary in the interests of defence.

1. **Defence exemptions are only valid to the extent of the jurisdiction of the Member State granting them.**

   - Granting of a defence exemption is a sovereign national responsibility, and a Member State can only provide a defence exemption to the extent of its own jurisdiction. In addition, the REACH defence exemption process is often no option, or very difficult to manage, in cases in which defence industries in more than one Member State are involved in a transnational supply chain. Therefore, **applying this approach to the universal PFAS restriction will impact the development of a level playing field and thus could negatively influence the European Defence Technological and Industrial Base (EDTIB)**.

   - On the other hand, an extended transitional period included in the restriction proposal (in the specific Annex XVII entry) provides all stakeholders at EU level with more time to comply with the restriction and to find suitable alternatives, during which they can continue to use the substance within the limits described in the restriction.

2. **Member States frequently foresee a conservative use of national defence exemptions from health and environmental regulations.**

   - It is important to recall the principles of the REACH defence exemptions agreed by the EDA participating Member States (pMS), and more specifically the EDA REACH Code of Conduct on REACH Defence Exemptions, adopted by EDA pMS[3]. According to this Code of Conduct, pMS agreed that the granting of defence exemptions should be considered **only after the following alternative methods have been examined**:
     - **complying** with the requirements of the REACH Regulation;
     - **substitution** of hazardous substance(s) with more benign alternatives.

   - In addition to possible delays in the defence exemption process, the unpredictability of its outcome creates **significant uncertainties and risks for the defence industry** (and consequently for the ministries of defence), as the lack of visibility is not in phase with the defence equipment development cycle.

[3] All EDA participating Member States, except Poland, as well as Norway have decided to subscribe to and therefore participate in the implementation of the Code of Conduct on REACH defence exemptions.

3. Defence exemptions do not ensure the availability on the market of a dual-use substance.

- REACH defence exemptions allow for some flexibility in the use of a restricted substances, where necessary in the interests of defence. However, **defence exemptions are not panacea**, as they constitute a temporary solution that do not ensure that the substance at stake will remain available.
- Indeed, a major limitation of the REACH defence exemption is that it cannot be used to support the continued use of a dual use substance outside the defence domain, i.e., for civil applications. Civil markets often include sectors with lower performance requirements and hence better substitution prospects. If a dual-use substance is withdrawn from the civil market due to REACH constraints (e.g., restriction or authorisation etc.), it may become commercially unavailable or very expensive for military customers even if its uses continue to be legally allowed for the defence sector due to a defence exemption.
- Therefore, **common REACH compliant solutions should be sought for issues having an impact on both the civil and military sectors** (e.g., specific restriction derogations for both military and civil uses).

4. Applications for defence exemptions entail an administrative burden for the applicants and the Member States.

- When granting exemptions from obligations deriving from REACH in the interests of defence, EDA pMS agreed to do so on the basis of:
    - a national procedure that provides, as far as possible, for the highest safety and traceability standards, mirroring those imposed by REACH and
    - the Framework for Applying for a defence exemption from a requirement of REACH, annexed to the EDA Code of Conduct on REACH Defence Exemptions.
- This Framework provides guidance on what defence exemptions dossiers/applications should contain as a minimum for the most likely cases of exemption. In the context of an exemption dossier from the REACH restriction process, it should contain, at least[4], the following three types of information:
    - Basic application information

[4] The subscribing Member States can include additional technical requirements to meet national procedures as required.

- Defence Exemption justification
- Health and environmental risk assessment, including:
  - a Chemical Safety Assessment (limited to the relevant uses/exposure routes),
  - an extended safety datasheet, and
  - an analysis of risks associated with alternatives.

- These requirements entail an administrative burden for the applicants and the Member States granting the defence exemptions.
- In the case of relevant defence derogations in the restriction proposal, it is expected that the administrative burden will be reduced for the applicants and the specific Member States.

5. The POPs Regulation does not provide for a defence exemption mechanism for defence/military uses of PFAS substances that might be included in its Annex I at a later stage.

- Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs Regulation) is the main EU instrument implementing the Stockholm Convention and the UNECE POPs Protocol. The main objective of the Stockholm Convention, and thus the POPs Regulation, is to eliminate the production and use of intentionally produced POPs and encourage their substitution.
- It is important to underline the interaction between REACH and POPs Regulations when it comes to PFAS substances, especially because there is no defence exemption mechanism in the POPs Regulation.
- As described in detail in 2020 EDA Study on the Impact of (other than REACH/CLP) European Chemical/Waste Regulations on the Defence Sector[5] (section 2.2), new PFAS substances are likely to be listed in the Annexes to the Stockholm Convention and the POPs Regulation as it was done for other PFAS substances as PFOS[6] and PFOA[7].
- Although **there is no exemption mechanism specific to defence or military equipment**, specific derogations for defence/military uses may be provided in the Annexes to the Convention and in the POPs Regulation. One way to have specific derogations/exemptions for defence uses included directly in the Annexes of the POPs Regulation is to have these defence

[5] Available on EDA Website.
[6] PFOS: Perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride
[7] PFOA: Perfluorooctanoic acid, its salts and PFOA-related compounds

derogations included in the REACH Annex XVII entries related to the same chemicals, as has been the case for decaBDE in civil and military aircrafts.

- The general rule in case a new POP is already restricted under REACH, is that the entry in REACH Annex XVII is deleted. For example, and as described in detail in the 2020 EDA Study, PFOS and PFOA were included respectively in REACH Annex XVII in 2009 and 2017 and then in Annex I to POPs Regulation in 2010 and 2019. After inclusions in Annex I to the POPs Regulation, the entries in REACH Annex XVII were deleted. In the end, **Annex I to the POPs Regulation contains exemptions previously included in the REACH restriction.**

- As there are no more possibilities for specific derogations once amendments to the Stockholm Convention have been adopted, **it is critical to manage potential impacts of the inclusion of a substance in the Stockholm Convention as early as possible in the REACH regulatory process** to ensure that appropriate specific derogations can be proposed and negotiated in the Stockholm Convention.