Implementation of Article 4(2) of the POPs Regulation

I. Background

This document aims at providing an interpretation of Article 4(2) of Regulation (EU) 2019/1021 (the “POPs Regulation”), as questions have been raised following the adoption of Commission Delegated Regulation (EU) 2020/784 of 8 April 2020 amending Annex I to the POPs Regulation as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds.

II. Terminology used in this document

| Articles: as defined in the Article 3(3) of the REACH Regulation and Article 2(2) of the POPs Regulation, an article is an object, which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. They remain articles until they become waste, and can be constituents of other articles. Example: metal blades |
| Complex products: any object made up of more than one article and not constituting an article itself. Several articles can be joined or assembled together, and the more articles it is made of, the more complex a product becomes. They can also contain mixtures. Example: scissors |

This wording follows the terminology used in the judgment of the Court of Justice in Case C-106/14, and is equivalent to the use of ‘complex object’ by ECHA in its Guidance on requirements for substances in articles.

---

III. Exemptions from control measures under Article 4(2) of the POPs Regulation

Article 4(2) of the POPs Regulation, and in particular subparagraphs 1 and 2, defines certain exemptions from the measures to control the manufacturing, placing on the market and use of substances included in Annexes I or II to the POPs Regulation taken in accordance with Article 3 of that Regulation.

The first subparagraph states that an article containing a substance listed in Annex I or II to the POPs Regulation produced before or on the date of applicability of such listing is exempted from the restrictions laid down in Article 3 of that Regulation for a non-renewable six-months period counting from the first day of application of the POPs Regulation to that substance.

The second subparagraph states that the provisions laid down in Article 3 of the POPs Regulation do not apply to articles already in use at the date of the entry into application of the listing of the substance.

Consequently, articles containing the restricted substance can be placed on the market:

1) during six months from the date of applicability of the Regulation to the restricted substance, when the production of the article occurred before or on that date;
2) indefinitely, when the article was in use before or on the date of applicability of the Regulation to the restricted substance.

IV. The scope of the term ‘use’ under the POPs Regulation

a. General interpretation

Article 2 of the POPs Regulation refers to the REACH Regulation for the definition of ‘use’. Article 3(24) of REACH defines ‘use’ as “processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation”.

Strictly reading Article 4(2) of the POPs Regulation in conjunction with such a definition, it would be possible to conclude that an article containing a substance listed in Annex I or II to the POPs Regulation in use by the date of the listing can be placed on the market after the entry into application of the listing of that substance if it is being used for one or more of the activities included under the definition of ‘use’ in REACH.

However, according to settled case-law, when a provision of EU law is interpreted, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part.

In this case, the provisions of the POPs Regulation constitute an implementation in the Union of the Stockholm Convention on Persistent Organic Pollutants to which the Union is a party. The Stockholm Convention is hence an “integral part” of Union law. As international

---

3 Judgment in C-592/14, European Federation for Cosmetic Ingredients, ECLI:EU:C:2016:703, paragraph 31.
4 See e.g. Case 181/73 Haegemann v Belgian State, ECLI:EU:C:1974:41, para 5, Case Achtri, C-224/16, ECLI:EU:C:2017:880, para 50 and Case Western Sahara Campaign, C-266/16, ECLI:EU:C:2018:118, paras 45-46.
agreements binding on the Union are in principle situated above internal legislation and other legal acts of secondary law, acts of secondary law must as far as possible keep with the terms of the agreement (the duty of consistent interpretation)\(^5\).

Notes (ii) of Annexes A and B of the Stockholm Convention specifically exempt substances in articles produced and in articles already in use from the respective obligations under Article 3 of the Convention. The concepts of ‘article produced’ and ‘article in use’ therefore find their basis in the Stockholm Convention.

In this regard, and in order not to deprive the time-limited exemption in the first subparagraph of Article 4(2) of any meaningful effect, it needs to have some material scope and be differentiated from the unlimited exemption for ‘articles already in use’ in the second subparagraph of Article 4(2). Interpreting the ‘articles in use’ as also including articles produced and stored at the producer’s site would effectively deprive the first exemption of any useful meaning.

As far as objectives of the POPs Regulation are concerned, as these two provisions constitute exemptions from the general rule (control measures in Article 3) they must be interpreted restrictively. The objective of the POPs Regulation is to take further measures to protect human health and the environment from the continuous release of persistent organic pollutants into the environment. In this light, considering that ‘article in use’ includes also an article stored after production by the producer would broaden the scope of this unlimited exemption for articles and go against the objective of the protective measures pursued by Article 3.

Consequently, the term ‘articles in use’ should be understood as a special notion designed to denote the articles which are already in use as distinguished from ‘articles produced’, meaning those articles that are already outside the production process and fulfil the function for which they were produced.

It is suggested considering that an article is ‘in use’ when it is in possession of the final user (i.e. a consumer or professional user) or when it has started being processed into another product. Consequently, articles stored by EU producers, distributors, importers or retailers would not be considered ‘in use’.

More concretely:

- articles produced to be individually consumed should be considered ‘in use’ from the moment when they are in possession of the final user.

\[\text{Example: a plastic article with PFOA coating be considered ‘in use’ once it has been purchased in a store (physical sales) or after receipt of the parcel (remote sales).}\]

- articles produced to be assembled with other articles to produce complex products, or to produce new articles, should be considered ‘in use’ from the moment when they have been made part of the production process of such article or assembly;

---

b. Use of an exempted article in the production of a new article

The final use (function) of an exempted article may be to take part in the production of a new article, which itself complies with the definition of article in the REACH Regulation.

If the alteration of shape, surface or design leading to the production of the new article took place before the date when the POPs Regulation became applicable to that substance, the new article can benefit from the exemption from the control measures laid down in Article 4(2) first paragraph of the POPs Regulation (six-month exemption).

However, if the new article was produced after the date when the POPs Regulation became applicable to the substance using exempted articles, its placement on the market would require that the restricted substance be present in the new article in a concentration lower than those specified in accordance with Article 4(1)(b) of the POPs Regulation (UTC). This concentration should be measured taking into consideration the weight of the new article.

The reason for this is that the exemptions from the control measures should apply exclusively to those articles produced or in use before or on the date that the POPs Regulation becomes applicable to the restricted substance.

c. Use of an exempted article in the production of a complex product

The final use (function) of the exempted articles may be to take part in the production of a complex product, which is a mere assembly of articles and is not as such an article according to Article 3(3) of the REACH Regulation.

These complex products can be placed on the market for as long as their composing, exempted articles can:

1. if the composing, exempted articles were produced before or on the date the POPs Regulation became applicable to the substance but were not ‘in use’ by that date, the complex product will only be allowed to be placed on the market during the six month-period referred to in Article 4(2) first paragraph;
2. if the composing, exempted articles were ‘in use’ (i.e. part of the assembly process) before or on that same date, the complex product can be placed on the market without any time limit.

Example: metal blades are considered articles. When they are mechanically assembled, for example to create a pair of scissors, we can talk about the production of a complex product, formed by different articles: e.g. two metal blades, screws…

Complex product X (scissors) = Article A (metal blade) + Article B (metal blade) + Article F (screw)
The legal person responsible for this complex product (scissors) is also responsible for the compliance of the articles contained therein (metal blades, screws…).

V. Imports and exports of articles benefiting from the exemptions in Article 4(2)

In view of Notes (ii) to Annexes A and B to the Stockholm Convention, the Commission considers that the exemptions in Article 4(2) are limited to the territory of the signing party, and that this should be interpreted as not allowing import and export of articles produced or articles in use containing restricted substances.

Although the provisions of the first and second subparagraphs of Article 4(2) of the POPs Regulation do not specifically refer to the articles produced in the Union or the articles in use in the Union, in our view, they should be interpreted in line with the Stockholm Convention and refer to the articles produced in the Union and articles in use in the Union containing restricted substances.

In this light, point 8 of the last column of Commission Delegated Regulation 2020/784 does not seem to add anything to the general exemptions foreseen in Article 4 of the POPs Regulation. The Commission also considers that it would be challenging to consider the Commission empowered to limit or prevent the application of the general exemption of Article 4(2) through changes in the Annexes.

With regard to exports, the POPs Regulation only indicates that they are regulated by Regulation (EU) No 649/2012 (the PIC Regulation) and therefore need not be further addressed in the POPs Regulation. Consistency between the listings in both Regulations must be ensured in order to properly implement the provisions under the Stockholm Convention.

VI. Documentation

Companies are advised to keep relevant documentation at hand proving that the article was already produced (for the exception of Article 4(2) first subparagraph) or in use (in the case of complex products, that it was assembled) before the applicability of the POPs Regulation to the substance.