



**22ND MEETING OF THE COMPETENT AUTHORITIES FOR REGULATION (EU)
2019/1021 ON PERSISTENT ORGANIC POLLUTANTS**

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(Item 5 of the agenda)

Implementation of Article 4(2) of the POPs Regulation

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Background

The delegated act listing PFOA, its salts and PFOA-related compounds in Annex I to the POPs Regulation introduces an exemption for “articles already in use in the Union before 4 July 2020”. It also refers to the provisions of Article 4(2), third and fourth subparagraphs, of the POPs Regulation. The same exemption is foreseen for other entries in Annex I to the POPs Regulation.

The Commission and ECHA received many questions on the interpretation of this provision in relation with PFOA. This document aims at providing a preliminary evaluation of the relations between the delegated act listing PFOA in Annex I to the POPs Regulation and its Article 4(2).

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-month 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.

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

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 is 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 part¹. It seems rational, based on this, that the notion of ‘use’ under the POPs Regulation should include all those activities under the definition in Article 3(24) of REACH insofar they are aligned with the general objective of the POPs Regulation.

It is also important to recall that the use of an article containing the restricted substance for the ‘production of an[other] article’ would imply that, in order for this new article to be legally placed on the market, the restricted substance should be present in the new article in a concentration lower than those specified in the delegated act in accordance with Article 4(1) of the POPs Regulation. The concentration should be measured taking into consideration the weight of the final article.

The reason for this is that the exemption 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 substance. However, the use of these articles for the ‘production of an article’ as laid down in Article 3(24) of the REACH Regulation would necessarily imply that the outcome is a new article, which would logically have not been produced nor in use by the deadlines laid down in Article 4(2) of the POPs Regulation.

¹ Judgment in C-592/14, European Federation for Cosmetic Ingredients, ECL1:EU:C:2016:703, paragraph 31.

The answer to what constitutes the production of an article using an already existing article should consider the judgment of the Court of Justice in Case C-106/14²:

‘[...] the question whether a complex product itself may be classified as an article therefore turns solely on a determination according to the criteria laid down in Article 3(3) of that regulation.

It is therefore only if the production of an object using a combination of more than one article gives that object a special shape, surface or design which is more decisive for its function than its chemical composition that that object may be classified as an article. Accordingly, unlike a simple assembly process, that production process must alter the shape, surface or design of the articles used as components’.

Thereby, the production of an article from another article could only occur in a case where the complex product obtained complies with the definition of article under REACH and where its components have seen their shape, surface or design altered.

The operator placing on the market a complex object incorporating an article subject to an exemption should be responsible for providing evidence that such complex product does not constitute an article or, otherwise, that the new article contains the restricted substance in a concentration lower than that specified in accordance with Article 4(1) of the POPs Regulation.

Companies are also 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 before the applicability of the POPs Regulation to the substance.

Finally, it should also be noted that the PFOA entry in Annex I to the POPs Regulation only exempts the use of articles already in use in the Union. Consequently, articles in use outside the EU/EEA cannot benefit from those exemptions. This is aligned with the text of the Stockholm Convention, which states that these derogations apply provided that ‘a Party has notified the Secretariat that a particular type of article remains in use within that Party’.

The relation between ‘production’ and ‘use’ under the POPs Regulation

In certain circumstances, both the first and second subparagraph of Article 4(2) of the POPs Regulation might be applicable to the same article. That would be the case when an article containing a restricted substance has been produced before the entry into application of the Regulation to that substance and is also being used before that date.

Practically, most of the articles produced can be considered in use soon after they are produced, as they will be subject to *utilisation* as laid down in Article 3(24) of the REACH Regulation. This implies that, for those articles, the exemption from the control measures would be of indefinite duration and not limited to the six-month period of the first subparagraph.

² Judgment in C-106/14, ECLI:EU:C:2015:576.