

## E-consultation: IGS case type 1, special case “modular system” (*in situ*-reaction system, industrial washing machine)

### Introduction:

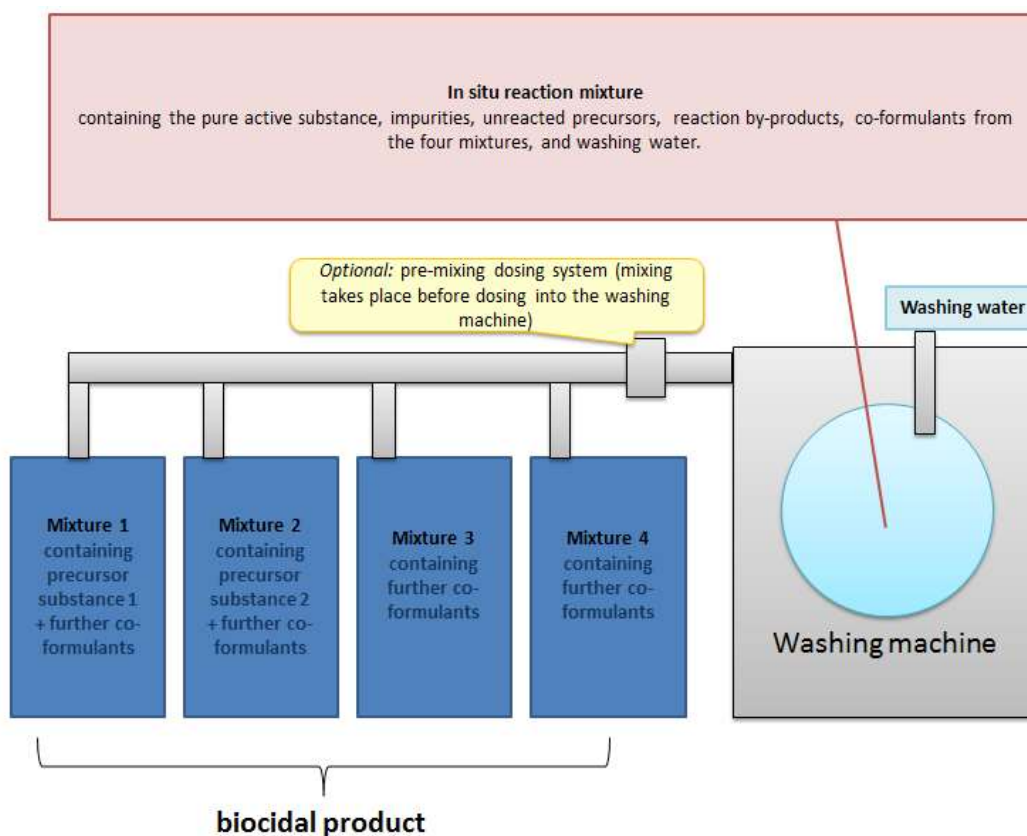
For *in-situ* dossiers, there are two main documents for guidance:

- CA-Jul19-Doc 4.1-Final
- Recommendation of the BPC Working Groups: In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors (currently under revision).

In the course of evaluation of *in-situ* b.p. dossiers, the need for clarification of a special case was identified.

### IGS case type 1, special case “modular system”:

Four containers with mixtures are connected to a dosing system of an industrial washing machine. Mixtures 1-4 are sold separately to the user, in the form of a modular system. The dosing during washing is automated and uses all four mixtures. Only mixture 1 and mixture 2 contain precursor substances. (Note: the product is a disinfectant in PT 2). The system can be depicted as follows:



The washing machine acts like a mixing vessel and not as an in-situ generating device like e.g. an electrolysis system. Therefore, the example corresponds to IGS case type 1<sup>1</sup>.

**It is questioned whether a single product or a biocidal product family is on hand.**

**Conclusion:**

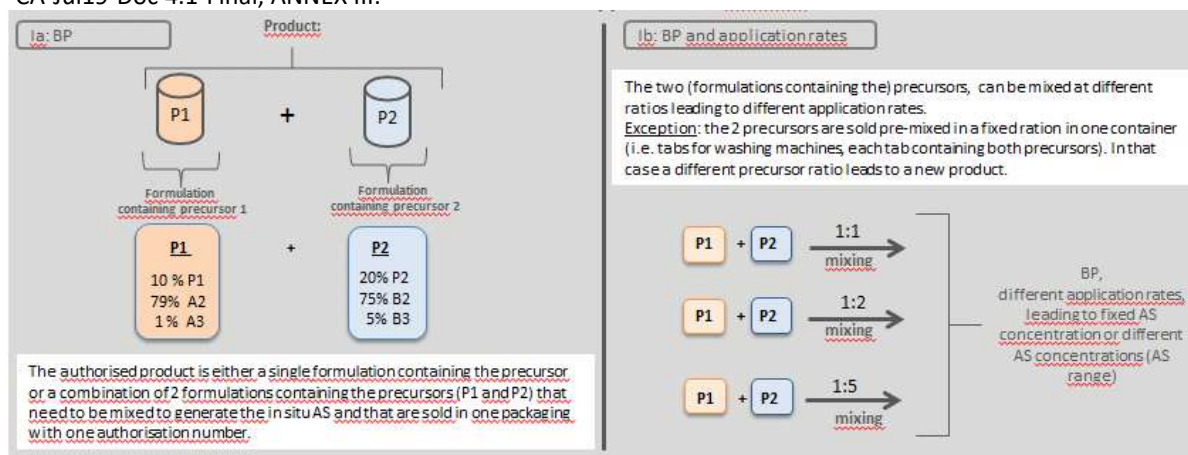
Annex III, 1a of CA-Jul19-Doc 4.1-Final<sup>2</sup> defines the precursor mixtures (in separate containers) as one biocidal product, if they are sold within the same outer packaging. The packaging has one authorisation number.

In line with Annex III, 1b of CA-Jul19-Doc 4.1-Final<sup>2</sup>, the automated dosing corresponds to different application rates leading to fixed AS concentration. There is no family on hand, as there are no ranges in the formulations containing the precursor.

Even if in this special case the single precursor mixtures are not sold together in the same outer packaging, as demanded in Annex III, 1a of CA-Jul19-Doc 4.1-Final<sup>2</sup>, they are sold together as modular system and only can be used together, which justifies drawing an analogy with the illustration of Annex III to the CA document mentioned above. The SPC should refer to the same authorisation number for the modules which are part of the biocidal product, and the SPC has to contain a restriction that the mixtures shall only be used together with the other mixtures that are part of the product.

<sup>1</sup> CA-Jul19-Doc 4.1-Final defines case type 1 as follows: Case-type 1: the in situ biocidal products involve an IGS only based on the mixing of two or more [formulations containing the] precursors without using a device

<sup>2</sup> CA-Jul19-Doc 4.1-Final, ANNEX III:



**It is questioned whether the mixtures 3 and 4 should be part of the biocidal product.**

Mixtures 1 and 2 contain the precursor substances and are therefore part of the biocidal product.

Generally, in line with the definition in CA-Jul19-Doc 4.1-Final, paragraph 8a) (“*the formulation containing the precursor will be authorised as biocidal product*”), that amounts to considering whether mixtures 3 and 4 consist, contain or generate one or more of the active substance(s) in the washing mixture. If the answers to those questions is negative, mixtures 3 and 4 cannot be considered as being part of the biocidal product as these cannot be considered precursors.

However, in this special case of a modular system, the precursors formulations which are relevant for reaction are split into modules and only mixed on-site. It is questionable, if the modules “mixture 3” and “mixture 4” are part of the biocidal product or not. According to the legal interpretation, a precursor can be a substance or a mixture. In exceptional cases, the precursor mixture may be done only at the site of use. If mixtures 3 and 4 are part of a precursor formulation through mixing at the site of use, this is still in line with the definition of CA-Jul19-Doc 4.1-Final, paragraph 8a).

#### **Conclusion:**

The mixtures without precursor (mixture 3 and 4) are considered as part of the biocidal product in case they are **relevant for the *in situ*-reaction** (generation of the *in situ* active substance; e.g. pH regulators which are not precursors, complexing agents, solubilisers, etc.), as they have influence on the composition of the *in situ* reaction mixture and on the formation of the pure active substance.

In case mixture 3 and 4 are **not relevant for the *in situ*-reaction** (e.g. optical brighteners, perfumes), they are not part of the biocidal product. However, scientific evidence has to be shown to prove that. Also a mere modulator of water hardness is not considered to be part of the biocidal product.

#### **Disclaimer:**

This document is agreed as **specific conclusion** as basis for further evaluation of a **current case**. It can be used as a starting point for decision making for future cases.

The Revision Task Group for the “*Recommendation of the BPC Working Groups: In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors*” is invited to explore what would be the best way to integrate the CG agreement into the revised recommendations.