Enforcement of biocidal products with unstable active substances

Practical issue from BPRS transfers to CG for discussion

Context

There is currently discussions to BPRS (BPR Subgroup of the Forum for Exchange of Information on Enforcement) relating to the enforcement of biocidal products containing unstable active substances.

Background

The BPC GD on a procedure for granting shelf life for biocidal products (Document No. BPC-31-2019-13), clarifies that the concentration of the active substances in a product should not decrease by more than 10% of their initial value. If the degradation of the active substances exceeds 10%, the shelf life of the product can be based on risk assessment and efficacy. **If there is no risk, and the efficacy of the aged product is demonstrated, it is possible to extend the expiration date of the product beyond the 10% degradation rate of the active substances. This information is available in the PAR, not in the SPC.**

Therefore, for authorized products containing unstable active substances, there may be important difference between measured concentrations of active substances in the product and claims on the label.

Article 69(2) of the BPR lists required information to be present on the label of biocidal products, in particular:

- (a) the identity of every active substance and **its concentration in metric units**;
- (k) the formulation batch number or designation and **the expiry date relevant to normal conditions of storage**."

Biocidal products are placed on the market with specific concentrations reported on their labels. Consumers expect to purchase products with specific concentrations until the expiry dates. In case of unstable active substances, the concentrations decrease with time, maintaining however an acceptable efficacy. This can be seen as a consumer misleading and a non-compliance with Article 69 of the BPR.

During enforcement controls, information on the labels (and in some cases in the SPC) is checked. The measured concentration should thus be the same than the one indicated in the label and in the SPC. As the information regarding the acceptable active substance concentrations for which the efficacy is not altered, is only reported in the PAR, it is not easily accessible by the national enforcement bodies.

Question from BPRS to the CG

In this context, BPRS **investigates the possibility of adapting the labels and/or the SPC of biocidal** products containing unstable active substances, **in order to ease the work of enforcement bodies and better inform consumers** that the products are also efficient at a lower concentration levels.

To this, 3 options are proposed from BPRS to be considered by the CG:

1) To **indicate lower and upper limits for the active substance concentration** in the SPC and/or on the label of those products;

2) To **indicate a warning in the SPC regarding the potential variation of concentration** such as "the measured concentration may differ from the initial concentration, without altering the efficacy of the product"

3) To **indicate a shorter expiry date in the SPC**, in order to anticipate the concentration decreases.

Initiation of the commenting phase and discussion during CG 45 (Feb 2021)

An e-consultation was launched on 23/11/2020 until 14/12/2020 and written comments were received from 5 Member States.

The results of the e-consultation were further discussed during the CG45.

It was agreed by consensus that no change in the SPC information is foreseen in the case of biocidal products containing unstable active substances, since the information is publicly available in the PARs which are disseminated in the public ECHA website.

ECHA also underlined that enforcement controls can contact the authorisation holder to answer their questions.

On those basis, it is agreed that no change in the SPC information is foreseen in the case of biocidal products containing unstable active substance.