



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products



The European voice of the
adhesive and sealant industry

Brussels, March 2017

A holistic approach to the evaluation of in-can preservatives

To the EU Commission and Member State Competent Authorities for Biocides (CA Meeting March 2017)

The undersigned associations, AISE, CEPE, EBPF, EDANA, EFCC, EPDLA, FECC and FEICA, along with their respective members, urge the European Commission and the Member State Competent Authorities to take a holistic approach to the evaluation of active substances needed for the manufacture of in-can preservatives (Product-Type 6 biocides - PT6) in order to ensure their future availability. It is proposed that Member States in charge of the assessment of PT6 active substance dossiers postpone the submission of their individual assessment reports by the deadline of December 31st, 2019 included in Annex III of Regulation (EU) 1062/2014.

Industries using preservatives in their products, which include a majority of SMEs, are currently faced with significant challenges for the preservation of those products linked to the technical and regulatory requirements of the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012), as well as to those resulting from other legislation such as the re-classification of individual biocidal active substances under Classification, Labelling and Packaging of substances and mixtures (Regulation (EU) 1272/2008, CLP).

In 2014, some of the undersigned downstream user associations discussed this topic at the 56th and 58th meetings of the Competent Authorities for the implementation of the Biocides Regulation considering the availability of in-can preservatives and the ongoing trend in their respective evaluation (CA-May14-Doc.4.4 and CA-Nov14-Doc.4.6). This demonstrated that downstream user industries face an increasingly challenging situation due to the developing uncertainty of the availability of critical active substances. Although many options appear to exist 'on paper' (i.e. list of PT 6 active substances undergoing evaluation) the choice is very limited in practice, because only a handful of substances provide the technical and compatible functions required to preserve the targeted products, while maintaining the products' performance.



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Most importantly, we fear that the limited number of active substances currently available will disappear following their evaluation through the active substance review programme of the BPR, without appropriate alternatives having been identified nor developed.

Downstream users and suppliers have invested a considerable amount of resources in innovation and Research and Development looking for alternatives. All results point to the same conclusion, namely, that industry is not able to move away from current substances.

The biocides industry faces high up-front costs from a lack of tiered data requirements, long development and review timeframes, the ongoing costs of a burdensome review programme in relation to the size of the overall market, the uncertainty of success through highly conservative risk-assessment models and the continued regulatory creep through continually developing guidance. This presents a significant barrier to the development and introduction of new active substances. This is evidenced by the relatively low number of new chemistries that have been brought to the market since the introduction of the biocides legislation. All factors together result in an increasing need to rely on existing preservative chemistries and solutions.

In-can preservatives remain fundamental for the effective and safe preservation of water-based products, because they control the presence of micro-organisms that may cause deterioration and spoilage thus ensuring products remain fit for purpose throughout their intended life. They provide improved protection of human health (by the elimination of human pathogens) and the environment (by reducing product losses and disposal, raw material and energy wastage, and by allowing the replacement of solvent-based with water-based products, so decreasing the volatile organic compound (VOC) emissions in the air). Biocides should be seen as necessary, desirable and part of the solution towards a sustainable EU manufacturing economy.

It is, therefore, essential to maintain a diverse portfolio of preservatives not only to maintain the multiple products' performance, but also to protect human health. A wide range is needed to avoid the development of potential tolerances and resistances. Our associations are concerned that the current review process does not appear to allow for long term planning as individual substances are reviewed and decisions taken on an individual level, with little consideration given to the wider potential consequences on the ability to maintain adequate preservation options.

As a consequence, we urge Member States and the European Commission to take a holistic approach to the evaluation of PT6 active substances under the BPR. In this regard, we propose that Member States in charge of the assessment of PT6 active substance dossiers postpone



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the submission of individual assessment reports by the deadline of December 31st, 2019 included in Annex III of Regulation (EU) 1062/2014, and do so concomitantly. This would then allow the European Chemicals Agency to provide their opinions on the approval of the various PT6 active substances to the Commission simultaneously, thus ensuring that decisions taken do not immeasurably and critically disrupt the market to the point where no appropriate in-can preservatives remain.

We look forward to discussing our proposal with the EU Commission and Member State Competent Authorities for biocides and trust the needs of the EU manufacturing industry will be duly considered in the active substance approval process.

*Altogether, the membership of the following associations comprises more than 2,300 companies across the respective sectors in Europe, the vast majority being SMEs:
AISE – International Association for Soaps, Detergents and Maintenance Products,
CEPE - the European Council of Paint, Printing Ink and Artists' Colours Industry,
EBPF – the European Biocidal Products Forum,
EDANA – International association for the nonwovens and related industries
EFCC – the European Federation for Construction Chemicals
EPDLA - the European Polymer Dispersion and Latex Association, and
FECC-European Association of Chemical Distributors
FEICA - the Association of the European Adhesive and Sealant Industry.*

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