Commission Implementing Regulation (EU) No 1035/2013 of 24 October 2013 approving benzoic acid as an existing active substance for use in biocidal products for product-types 3 and 4 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1035/2013

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approving benzoic acid as an existing active substance for use in biocidal products for product-types 3 and 4

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[(1)], and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Regulation (EC) No 1451/2007[(2)] establishes a list of active substances to be assessed, with a view to their possible inclusion in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council[(3)]. That list includes benzoic acid.

(2) Benzoic acid has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 3, veterinary hygiene biocidal products, and product-type 4, food and feed area disinfectants, as defined in Annex V to that Directive, which correspond respectively to product-types 3 and 4 as defined in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as Rapporteur Member State and submitted the competent authority reports, together with recommendations, to the Commission on 3 February 2011 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(4) The competent authority reports were reviewed by the Member States and the Commission. In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the findings of the review were incorporated, within the Standing Committee on Biocidal Products on 27 September 2013, in two assessment reports.

(5) It appears from those reports that biocidal products used for product-types 3 and 4 and containing benzoic acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC.

(6) It is therefore appropriate to approve benzoic acid for use in biocidal products for product-types 3 and 4.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 1035/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) Since the evaluations did not address nanomaterials, the approvals should not cover such materials pursuant to Article 4(4) of Regulation (EU) No 528/2012.

(8) For the use in product-type 4, the evaluation did not adress the incorporation of biocidal products containing benzoic acid in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[(4)]. Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of Regulation (EC) No 1935/2004. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit Member States, interested parties, and the Commission where appropriate, to prepare themselves to meet the new requirements entailed.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Benzoic acid shall be approved as an active substance for use in biocidal products for product-types 3 and 4, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 October 2013.

For the Commission

The President

José Manuel BARROSO

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ANNEX

Common Name	**IUPAC NameIdentification Numbers**	**Minimum degree of purity of the active substance**[a]	**Date of approval**	**Expiry date of approval**	**Product type**	**Specific conditions**[b]
Benzoic acid	IUPAC Name: Benzoic acid EC No: 200-618-2 CAS No: 65-85-0	990 g/kg	1 July 2015	30 June 2025	3	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: (1) For industrial or professional users, safe operational procedures and appropriate organizational measures shall

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							be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
						(2)	For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No

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						470/2009 of the European Parliament and of the Council[c] or Regulation (EC) No 396/2005 of the European Parliament and of the Council[d] shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
					4	The product assessment shall pay particular attention to the exposures, the risks