COMMISSION IMPLEMENTING REGULATION (EU) 2015/1730

of 28 September 2015

approving hydrogen peroxide as an existing active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6

(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 Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes hydrogen peroxide.

(2) Hydrogen peroxide has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ([3]) for use in product-type 1, human hygiene biocidal products, product-type 2, private area and public health area disinfectants and other biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, product-type 5, drinking water disinfectants, and product-type 6, in-can preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 2, 3, 4, 5 and 6, as defined in Annex V to Regulation (EU) No 528/2012.

(3) Finland was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 2 August 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([4]).

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 2 February 2015 by the Biocidal Product Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 1, 2, 3, 4, 5 and 6 and containing hydrogen peroxide may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.

(6) It is therefore appropriate to approve hydrogen peroxide for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6 subject to compliance with certain specifications and conditions.

(7) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing hydrogen peroxide in materials and articles intended to come into contact directly or indirectly with food within the meaning of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([5]). 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.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([4]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(8) Regulation (EU) No 98/2013 of the European Parliament and of the Council [1] on the marketing and use of explosive precursors applies to hydrogen peroxide.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(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

Hydrogen peroxide is approved as an active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6, 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, 28 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

[1] Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors (OJ L 39, 9.2.2013, p. 1).

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Date of approval	Expiry date of approval	Product type	Specific conditions
Hydrogen peroxide	IUPAC Name: Hydrogen peroxide EC No: 231-765-0 CAS No: 7722-84-1	The active substance as manufactured is an aqueous solution containing 350 - < 700 g/kg (35 - < 70 % by weight) hydrogen peroxide. The theoretical (calculated) dry weight specification: minimum purity of hydrogen peroxide is 995 g/kg (99,5 % by weight).	1 February 2017	31 January 2027	1	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. The authorisations of biocidal products are subject to the following conditions: (1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established for the handling of concentrated products.
					2	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. The authorisations of biocidal products are subject to the following conditions: (1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
					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. The authorisations of biocidal products are subject to the following conditions: (1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
					4	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. The authorisations of biocidal products are subject to the following conditions: (1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
						(3) Products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of hydrogen peroxide into food or it has been established pursuant to that Regulation that such limits are not necessary.
					5	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. The authorisations of biocidal products are subject to the following conditions: (1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.
					6	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.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type	Specific conditions
						The authorisations of biocidal products are subject to the following conditions: (1) Authorisations of biocidal products shall be without prejudice to Regulation (EU) No 98/2013 on the marketing and use of explosive precursors. (2) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 16(2) of Directive 98/8/EC. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.