Commission Implementing Regulation (EU) No 94/2014 of 31 January 2014 approving iodine, including polyvinylpyrrolidone iodine, as an existing active substance for use in biocidal products for product-types 1, 3, 4 and 22 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 94/2014

of 31 January 2014

approving iodine, including polyvinylpyrrolidone iodine, as an existing active substance for use in biocidal products for product-types 1, 3, 4 and 22

(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 iodine.

(2) Iodine has been evaluated in accordance with Article 11(2) of Directive 98/8/EC for use in product-type 1, human hygiene biocidal products, product-type 3, veterinary hygiene biocidal products, product-type 4, food and feed area disinfectants, and product-type 22, embalming and taxidermist fluids, as defined in Annex V to that Directive, which correspond respectively to product-types 1, 3, 4 and 22 as defined in Annex V to Regulation (EU) No 528/2012.

(3) The data submitted for the purpose of the evaluation allowed conclusions to be also drawn on polyvinylpyrrolidone iodine.

(4) Sweden was designated as Rapporteur Member State and submitted the competent authority report, together with recommendations, to the Commission on 20 April 2011 in accordance with Article 14(4) and (6) of Regulation (EC) No 1451/2007.

(5) The competent authority report was 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 13 December 2013, in an assessment report.

(6) It appears from that report that biocidal products used for product-types 1, 3, 4 and 22 and containing iodine may be expected to satisfy the requirements laid down in

Article 5 of Directive 98/8/EC, provided that the conditions specified in the Annex to this Regulation are satisfied.

(7) It is therefore appropriate to approve iodine, including polyvinylpyrrolidone iodine, for use in biocidal products for product-type 1, 3, 4 and 22.

(8) 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.

(9) The evaluation did not address the incorporation of biocidal products containing iodine 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.

(10) 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.

(11) 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

Iodine, including polyvinylpyrrolidone iodine, shall be approved as an active substance for use in biocidal products for product-types 1, 3, 4 and 22, 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, 31 January 2014.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 94/2014. (See end of Document for details)*

ANNEX

Common Name	**IUPAC Name Identification Numbers**	**Minimum degree of purity of the active substance**[a]	**Date of approval**	**Expiry date of approval**	**Product type**	**Specific conditions**[b]
Iodine (including polyvinylpyrrolidone iodine)	IUPAC Name: Iodine EC No: 231-442-4 CAS No: 7553-56-2 IUPAC Name: Polyvinylpyrrolidone iodine EC No: n.a., CAS No: 25655-41-8	995 g/kg of iodine For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 95 g/kg	1 September 2015	31 August 2025	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.
					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,

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 94/2014. (See end of Document for details)*

						but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 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 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 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 products that may lead to residues in food or feed,