

COMMISSION IMPLEMENTING REGULATION (EU) No 116/2014

of 6 February 2014

concerning the non-approval of the active substance potassium iodide, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 13(2) thereof,

Whereas:

- (1) In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC ⁽²⁾ is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For potassium iodide the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Decision 2005/751/EC ⁽³⁾.
- (2) In accordance with Article 6(2) of Directive 91/414/EEC the Netherlands received on 6 September 2004 an application from Koppert Beheer BV for the inclusion of the active substance potassium iodide in Annex I to Directive 91/414/EEC. Decision 2005/751/EC confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- (3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the

applicant. The designated rapporteur Member State submitted a draft assessment report on 27 July 2007. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 ⁽⁴⁾ additional information was requested from the applicant. The applicant informed on 30 May 2011 that no additional information was available.

- (4) The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance potassium iodide ⁽⁵⁾ on 22 October 2012. The Authority identified several data gaps that would have required further contributions from the applicant. By letter of 27 September 2013 Koppert BV withdrew its application for the approval of potassium iodide.
- (5) In accordance with Article 8(1)(b) of Directive 91/414/EEC, Member States were given the possibility to grant provisional authorisations for plant protection products containing potassium iodide for an initial period of 3 years. Commission Decision 2010/457/EU ⁽⁶⁾ allowed Member States to extend provisional authorisations for potassium iodide for a period ending on 31 August 2012 at the latest. Commission Implementing Decision 2012/363/EU ⁽⁷⁾ allowed Member States to extend provisional authorisations for potassium iodide for a period ending on 31 July 2014 at the latest.
- (6) Due to the withdrawal of the application, potassium iodide should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽³⁾ Commission Decision 2005/751/EC of 21 October 2005 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of ascorbic acid, potassium iodide and potassium thiocyanate in Annex I to Council Directive 91/414/EEC (OJ L 282, 26.10.2005, p. 18).

⁽⁴⁾ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive (OJ L 53, 26.2.2011, p. 51).

⁽⁵⁾ EFSA Journal 2013;11(6):2923. Available online: www.efsa.europa.eu

⁽⁶⁾ Commission Decision 2010/457/EU of 17 August 2010 allowing Member States to extend provisional authorisations granted for the new active substances *Candida oleophila* strain O, potassium iodide and potassium thiocyanate (OJ L 218, 19.8.2010, p. 24).

⁽⁷⁾ Commission Implementing Decision 2012/363/EU of 4 July 2012 allowing Member States to extend provisional authorisations granted for the new active substances bixafen, *Candida oleophila* strain O, fluopyram, halosulfuron, potassium iodide and potassium thiocyanate and spirotetramat (OJ L 176, 6.7.2012, p. 70).

(7) Existing provisional authorisations should, consequently, be withdrawn and no new authorisations be granted.

HAS ADOPTED THIS REGULATION:

Article 1

Non-approval of active substance

(8) Member States should be provided with time to withdraw authorisations for plant protection products containing potassium iodide.

The active substance potassium iodide is not approved.

Article 2

Transitional measures

(9) For plant protection products containing potassium iodide, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months after the entry into force of this Regulation.

Member States shall withdraw existing authorisations for plant protection products containing potassium iodide as active substance by 27 August 2014 at the latest.

Article 3

Grace period

(10) This Regulation does not prejudice the submission of a further application for potassium iodide pursuant to Article 7 of Regulation (EC) No 1107/2009.

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 27 August 2015 at the latest.

Article 4

Entry into force

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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, 6 February 2014.

For the Commission

The President

José Manuel BARROSO
