



Brussels, **XXX**
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[...] (2017) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance dithianon

(Text with EEA relevance)

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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/EEC¹, and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) The active substance dithianon was included in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market by Commission Directive 2011/41/EU², under the condition that the Member States concerned ensure that the applicant, at whose request dithianon was included in that Annex, provides further confirmatory information as regards the storage stability and the nature of residues in processed products, the aquatic and groundwater exposure assessment for phthalic acid and the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011³.
- (3) In May 2013, the applicant submitted additional information concerning the requested confirmatory data to the rapporteur Member State Greece within the time period provided for its submission.
- (4) Greece assessed the additional information submitted by the applicant. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority ('the Authority'), on 5 December 2013.
- (5) The submitted information was considered as adequate by the rapporteur Member State to address all the issues in the confirmatory information request. However, some Member States disagreed and considered the information was sufficient regarding the

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Implementing Directive 2011/41/EU of 11 April 2011 amending Council Directive 91/414/EEC to include dithianon as active substance and amending Commission Decision 2008/934/EC (OJ L 97, 12.4.2011, p. 38).

³ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

aquatic and groundwater exposure assessment for phthalic acid and the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol, but not for the storage stability and the nature of residues in processed products.

- (6) The Commission therefore consulted the Authority on the outstanding issue of the storage stability and the nature of residues in processed products. The Authority presented its conclusion on the risk assessment of dithianon on 27 October 2015⁴. The draft assessment report, the addendum and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 22 March 2018 in the format of the Commission review report for dithianon.
- (7) The Commission invited the applicant to submit its comments on the review report for dithianon. The applicant submitted its comments which have been carefully examined.
- (8) The Commission has come to the conclusion that the additional information provided showed that an exposure of consumers to potentially toxicologically relevant metabolites through the consumption of pome fruit and grapes processed commodities cannot be excluded. Furthermore, data on the storage stability of dithianon residues in grape wine is lacking.
- (9) The Commission has concluded that the confirmatory information required has not been fully provided and that the review of the submitted additional information failed to establish that exposure to certain potentially toxicologically relevant metabolites from the representative uses of the dithianon on wine grapes and pome fruit, consistent with good plant protection practice, have no harmful effects. An exposure of consumers to potentially toxicologically relevant metabolites of dithianon via consumption of pome fruit and grapes processed commodities cannot be excluded except by imposing further restrictions. In particular, the use of dithianon should be limited to non-edible crops only.
- (10) It is confirmed that the active substance dithianon is deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of consumers to the potentially toxicologically relevant metabolites of dithianon, it is however appropriate to amend the conditions of use of this active substance.
- (11) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (12) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing dithianon.
- (13) For plant protection products containing dithianon, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on *[Office of Publications please insert date 15 months from the date of entry into force]*.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ Conclusion on the peer review of the pesticide risk assessment for the active substance dithianon in light of confirmatory data submitted. EFSA Journal 2015;13(11):4278. doi: 10.2903/j.efsa.2015.4278.

HAS ADOPTED THIS REGULATION:

Article 1
Amendment to Implementing Regulation (EC) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2
Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing dithianon as active substance by [*Office of Publications please insert date 6 months from the date of entry into force*] at the latest.

Article 3
Grace period

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 [*Office of Publications please insert date 15 months from the date of entry into force*] at the latest.

Article 4
Entry into force

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,

For the Commission
The President
Jean-Claude JUNCKER