

COMMISSION IMPLEMENTING REGULATION (EU) 2018/690**of 7 May 2018****amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fenazaquin****(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)(c) thereof,

Whereas:

- (1) Commission Implementing Directive 2011/39/EU ⁽²⁾ included fenazaquin as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (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 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance fenazaquin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, was restricted to the uses as acaricide on ornamentals in greenhouses.
- (4) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 19 September 2011 Gowan Comércio Internacional e Serviços Limitada, the producer of the active substance, submitted an application to the designated rapporteur Member State, Greece, seeking an amendment to the conditions of approval of fenazaquin in order to lift the restriction and allow uses on grapes, citrus, pome fruit and stone fruit. The application was found to be admissible by the rapporteur Member State.
- (5) The rapporteur Member State prepared an addendum to the draft assessment report and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 14 February 2012.
- (6) The Authority circulated the addendum to the draft assessment report to the applicant and to the Member States for comments and made it available to the public in accordance with Article 12(1) of Regulation (EC) No 1107/2009.
- (7) On 19 March 2013 the Authority communicated to the Commission its conclusion ⁽⁵⁾ on whether the new uses of the active substance fenazaquin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission referred the amended draft review report to the applicant for comments on 17 September 2013 and to the Standing Committee on the Food Chain and Animal Health on 2 October 2013. The Standing Committee could not conclude whether it was appropriate to modify the conditions of approval of fenazaquin, as requested by the applicant.

⁽¹⁾ 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 (OJ L 309, 24.11.2009, p. 1).

⁽²⁾ Commission Implementing Directive 2011/39/EU of 11 April 2011 amending Council Directive 91/414/EEC to include fenazaquin as active substance and amending Commission Decision 2008/934/EC (OJ L 97, 12.4.2011, p. 30).

⁽³⁾ 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).

⁽⁴⁾ 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).

⁽⁵⁾ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance fenazaquin. *EFSA Journal* 2013;11(4):3166. [80 pp.] doi:10.2903/j.efsa.2013.3166.

- (8) Following further examination of the dossier, the Commission produced a draft addendum to the original review report and a draft Regulation on fenazaquin. The Commission presented the draft addendum and draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 13 December 2017.
- (9) The Commission invited the applicant to submit its comments on the draft addendum of the review report for fenazaquin. The applicant submitted its comments which have been carefully examined.
- (10) It has not been demonstrated that it may be expected that plant protection products containing fenazaquin satisfy in general the requirements laid down in Article 4 of Regulation (EC) No 1107/2009 unless the currently provided restriction for the use in greenhouse only is kept. It is, therefore, appropriate to maintain the restriction for the use in greenhouses only, as defined in Article 3(27) of Regulation (EC) No 1107/2009.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that, when the plant protection product is used on the edible crop, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to maintain the restriction for the use of fenazaquin on ornamentals only.
- (12) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in light of current scientific and technical knowledge, it is necessary and appropriate to amend the conditions of approval of the active substance fenazaquin while keeping it subject to certain conditions and restrictions. Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) No 540/2011

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

Article 2

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, 7 May 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The text of the column 'Specific provisions' of row 342, fenazaquin, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'PART A

Only uses as acaricide in greenhouses may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenazaquin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011, and of the addendum to the review report on fenazaquin, and in particular Appendices I and II thereto, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 22 March 2018, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- (a) the protection of aquatic organisms;
- (b) the protection of operators, also ensuring that the conditions of the use include the application of adequate personal protective equipment;
- (c) the protection of bees;
- (d) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses;
- (e) the risk to consumers, in particular from the residues generated during processing;
- (f) the conditions of use to avoid exposure to residues of fenazaquin with respect to crops for human and animal consumption.

Conditions of use shall include risk mitigation measures, where appropriate.'
