COMMISSION IMPLEMENTING REGULATION (EU) 2019/716

of 30 April 2019

amending Implementing Regulations (EU) No 22/2013 and (EU) No 540/2011 as regards the conditions of approval of the active substance cyflumetofen

(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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 22/2013 ([2]) provides for the approval of the active substance cyflumetofen and the resulting insertion of cyflumetofen in the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]). Implementing Regulation (EU) No 22/2013 also provides for the submission of further confirmatory information on the mutagenic potential of metabolite B3 and the dietary exposure thereof and on the risk from cyflumetofen to aquatic vertebrates.

(2) The applicant submitted additional information with a view to rule out the mutagenic potential of metabolite B3 and to confirm an acceptable risk for aquatic vertebrates.

(3) The Netherlands 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 6 October 2015.

(4) The Member States, the applicant and the Authority were consulted and asked to provide comments on the assessment of the rapporteur Member State. The Authority published a Technical Report ([4]) summarising the outcome of this consultation for cyflumetofen on 25 February 2016.

(5) The Commission further consulted the Authority in relation to the assessment of metabolite B3. The Authority published its Conclusion ([5]) on the assessment of the additional information on 5 December 2016.

(6) The Authority considered that according to the additional information provided by the applicant, an acceptable risk to aquatic vertebrates is confirmed on a life-cycle basis. Point (c) in the Annex to Implementing Regulation (EU) No 22/2013 should hence be considered addressed. However, concerning metabolite B3, a genotoxic potential could not be excluded from the additional data submitted in accordance with points (a) and (b) of the Annex to Implementing Regulation (EU) No 22/2013.

(7) 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 2019 in the format of the Commission review report for cyflumetofen.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) No 22/2013 of 15 January 2013 approving the active substance cyflumetofen, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 11, 16.1.2013, p. 8).

([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).

([4]) EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for cyflumetofen in light of confirmatory data. EFSA supporting publication 2016:EN-997. 25 pp.

([5]) EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment for the active substance cyflumetofen in light of confirmatory data. EFSA Journal 2016;14(12):4635, 20 pp. doi:10.2903/j.efsa.2016.4635.

(8) The applicant was given the possibility to submit comments on the updated review report.

(9) The Commission has concluded that the additional information provided is not sufficient to exclude the genotoxic potential of metabolite B3 and that the conditions of approval set out in the Annex to Implementing Regulation (EU) No 540/2011 should be restricted to ensure that the use of products containing cyflumetofen is acceptable, in particular concerning the exposure of groundwater to metabolite B3.

(10) Therefore in accordance with Article 21(3) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof, it is necessary and appropriate to restrict the approval of cyflumetofen.

(11) Implementing Regulations (EU) No 22/2013 and (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 cyflumetofen which are not complying with the restricted conditions of approval.

(13) For plant protection products containing cyflumetofen, 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 12 months after the entry into force of this Regulation.

(14) 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 22/2013

Annex I to Implementing Regulation (EU) No 22/2013 is amended in accordance with Annex I to this Regulation.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

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

Article 3

Transitional measures

Member States shall, where necessary, withdraw or amend authorisations for plant protection products containing cyflumetofen as active substance by 30 November 2019 at the latest.

Article 4

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 30 May 2020 at the latest.

Article 5

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, 30 April 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

In Annex I to Implementing Regulation (EU) No 22/2013, the column 'Specific provisions' is replaced by the following:

'Plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B3 in groundwater is expected to be below 0,1 μg/L.

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 cyflumetofen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account.

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

— the protection of operators and workers;

— the protection of groundwater, in particular for metabolite B3, when the substance is applied in regions with vulnerable soils and/or climatic conditions;

— the protection of drinking water;

— the risk to aquatic organisms.

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

ANNEX II

The column 'Specific provisions' of row 31, cyflumetofen, in Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'Plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B3 in groundwater is expected to be below 0,1 μg/L.

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 cyflumetofen, and in particular Appendices I and II thereto, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 November 2012 shall be taken into account.

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

— the protection of operators and workers;

— the protection of groundwater, in particular for metabolite B3, when the substance is applied in regions with vulnerable soils and/or climatic conditions;

— the protection of drinking water;

— the risk to aquatic organisms.

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