EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10657/2017 rev. 1
[…](2018) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulations (EU) No 22/2013 and 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.

---

1 OJ L 309, 24.11.2009, p. 1.

2 Commission Implementing Regulation (EU) No 22/2013 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 of confirmatory data for cyflumetofen in light of confirmatory data. EFSA supporting publication 2016:EN-997. 25 pp.

(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 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 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 XX XXXX 2019 in the format of the Commission review report for cyflumetofen.

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

(9) The Commission has conlcuded that the additional information provided is not sufficient to exclude the genotoxic potential of metabolie B3 and that the conditions of approval set out in the Annex to Commission Implementing Regulation (EU) No 540/2011[6] 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.

---

5 EFSA Journal 2016;14(12):4635, available online: www.efsa.europa.eu

6 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).

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 [*Office of Publications please insert date 6 months after date of entry into force*] 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 *[insert date 12 months from the date of entry into force]* 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,

For the Commission
The President
Jean-Claude JUNCKER