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

of **XXX**

**amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the
conditions of approval of the active substance sulfoxaflor**

(Text with EEA relevance)

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

of **XXX**

amending Implementing Regulations (EU) No 2015/1295 and No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor

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

Whereas:

- (1) Commission Implementing Regulation (EU) No 2015/1295² provides for the approval of the active substance sulfoxaflor and the resulting insertion of sulfoxaflor in the Annex to Commission Implementing Regulation (EU) No 540/2011³.
- (2) Implementing Regulation (EU) No 2015/1295 also provides for the submission of further confirmatory information on the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust, the risk to honey bees foraging for nectar or pollen in succeeding crops and flowering weeds, the risk to pollinators other than honey bees and the risk to bee brood.
- (3) The applicant submitted the required confirmatory information within the period provided for in Implementing Regulation (EU) No 2015/1295.
- (4) As agreed between Ireland and the Czech Republic, the rapporteur and the co-rapporteur Member State, the Czech Republic assessed the confirmatory information submitted by the applicant. The Czech Republic 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 12 March 2018.
- (5) The Member States, the applicant and the Authority were consulted and asked to provide comments on the assessment of the confirmatory information by the co-rapporteur Member State.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, 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 199, 29.7.2015, 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).

- (6) The Authority published a technical report⁴ summarising the outcome of this consultation for sulfoxaflor on 20 September 2018.
- (7) As divergent opinions were expressed during the consultation on the addendum to the draft assessment report, the Commission consulted the Authority and requested it to provide a conclusion on all points where there were divergent opinions.
- (8) The Authority published its conclusion on the risk assessment on 28 March 2019⁵. The Commission further consulted the Authority in relation to the risk to bees. The Commission asked the Authority, particular, to complete the assessment of the spray drift reducing measures necessary to protect bumblebees and solitary bees in field margins from exposure to sulfoxaflor and of the risk to bees from puddle water.
- (9) The Authority published its updated conclusion on 30 March 2020⁶.
- (10) In its updated conclusion, the Authority considered that in the light of the outcome of the evaluation of the confirmatory information provided by the applicant, the risk to bees for uses in permanent greenhouses was acceptable. However, the assessment of the risk to bumble bees and solitary bees from outdoor uses could not be finalised. Therefore, the Authority could not conclude that there is a low risk to bumble bees and solitary bees from outdoor uses.
- (11) The draft assessment report, the addendum and the updated 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 28 January 2022. At the same time, the review report for sulfoxaflor was updated.
- (12) The applicant was given the possibility to submit comments on the updated review report.
- (13) However, despite the arguments put forward by the applicant, the Commission has concluded that a risk to bees from outdoor uses of sulfoxaflor cannot be excluded. Consequently, 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 sulfoxaflor to uses in permanent greenhouses only.
- (14) Implementing Regulations (EU) No 2015/1295 and (EU) No 540/2011 should therefore be amended accordingly.
- (15) Member States should be allowed sufficient time to withdraw or amend authorisations for plant protection products containing sulfoxaflor that do not comply with the restricted conditions of approval.
- (16) For plant protection products containing sulfoxaflor, where Member States grant a grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should be as short as possible and expire no later than 12 months after the entry into force of this Regulation.

⁴ EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for sulfoxaflor in light of confirmatory data. EFSA supporting publication 2018:EN-1474. 73 pp.

⁵ EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment for the active substance sulfoxaflor in light of confirmatory data submitted. EFSA Journal 2019;17(3):5633, 14 pp.

⁶ EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment for the active substance sulfoxaflor in light of confirmatory data submitted. EFSA Journal 2020;18(3):6056, 15 pp.

- (17) In light of all the available pertinent information, it is considered inappropriate to maintain the approval of the active substance for outdoor use at this time. However, this Regulation does not prevent the applicant from submitting additional information to amend the conditions of approval, as provided in Articles 7 and 14 of Regulation (EC) No 1107/2009, and that information will be reviewed within a reasonable period of time as provided for in that Regulation.
- (18) 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 2015/1295

Annex I to Implementing Regulation (EU) No 2015/1295 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 sulfoxaflor 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 expire by... [*Office of Publications please 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

Ursula VON DER LEYEN