

COMMISSION IMPLEMENTING REGULATION (EU) 2022/43**of 13 January 2022****renewing the approval of the active substance flumioxazin 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 Annexes to Commission Implementing Regulation (EU) No 540/2011 and to Implementing Regulation (EU) 2015/408****(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 20(1) in conjunction with Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2002/81/EC ⁽²⁾ included flumioxazin 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 flumioxazin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2022.
- (4) An application for the renewal of the approval of the active substance flumioxazin was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 4 March 2013.
- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 5 June 2014, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether flumioxazin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a review report and a draft Regulation regarding flumioxazin to the Standing Committee on Plants, Animals, Food and Feed on 3 December 2014.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2002/81/EC of 10 October 2002 amending Council Directive 91/414/EEC to include flumioxazine as active substance (OJ L 276, 12.10.2002, p. 28).

⁽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⁾ Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

⁽⁶⁾ EFSA Journal 2014;12(6):3736. Available online: www.efsa.europa.eu

- (9) On request of the Commission, in accordance with Article 4(7) and point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 respectively, the Authority adopted on 15 December 2016 a Scientific Report on the evaluation of data concerning the necessity of flumioxazin as a herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods ⁽⁷⁾ and on 31 August 2018, it adopted a Conclusion on the peer review of the pesticide risk assessment in light of negligible exposure ⁽⁸⁾.
- (10) On 15 March 2019 the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) adopted an opinion recommending to classify flumioxazin as toxic for reproduction category 2. Following discussion with the Member States in the Standing Committee on Plants, Animals, Food and Feed in July 2019, the Commission mandated the Authority to update its Conclusion on flumioxazin with regard to endocrine disrupting properties according to the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽⁹⁾.
- (11) On 29 September 2020, the Authority published an updated conclusion ⁽¹⁰⁾ with regard to the endocrine disrupting properties considering the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605. The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 17(1) of Regulation (EU) No 1141/2010, on the review report. The applicant submitted its comments, which have been carefully examined.
- (12) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance flumioxazin that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (13) Commission Implementing Regulation (EU) 2015/408 ⁽¹¹⁾ listed flumioxazin as a candidate for substitution based on the former harmonised classification of the substance as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽¹²⁾.
- (14) In the light of the updated classification of flumioxazin as toxic for reproduction category 2 under Commission Delegated Regulation (EU) 2021/849 ⁽¹³⁾, it does no longer fulfil the criteria to be considered a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Accordingly, flumioxazin should be deleted from the Annex to Implementing Regulation (EU) 2015/408.
- (15) It is therefore appropriate to renew the approval of flumioxazin.

⁽⁷⁾ EFSA (European Food Safety Authority), 2017. Scientific report on the evaluation of data concerning the necessity of flumioxazin as a herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA Journal 2017;15(1):4688, 33 pp.

⁽⁸⁾ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the active substance flumioxazin in light of negligible exposure data submitted. EFSA Journal 2018;16(9):5415, 16 pp.

⁽⁹⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

⁽¹⁰⁾ EFSA Journal 2020;18(9):6246. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6246>

⁽¹¹⁾ Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12.3.2015, p. 18).

⁽¹²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽¹³⁾ Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 188, 28.5.2021, p. 27).

- (16) The risk assessment for the renewal of the approval of the active substance flumioxazin is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing flumioxazin may be authorised. It is therefore appropriate not to maintain the restriction to use flumioxazin as a herbicide.
- (17) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6, point (f), thereof and in the light of current scientific and technical knowledge, it is, however, necessary to provide for certain conditions.
- (18) In order to increase the confidence in the conclusion that flumioxazin does not have endocrine disrupting properties, the applicant should provide an updated assessment, in accordance with point 2.2(b) of Annex II to Regulation (EC) No 1107/2009 concerning the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to that Regulation.
- (19) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (20) Commission Implementing Regulation (EU) 2021/745 ⁽⁴⁾ extended the approval period of flumioxazin to 30 June 2022 in order to allow the renewal process to be completed before the expiry of that approval period. However, given that a decision to renew the approval has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.
- (21) 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

Renewal of the approval of the active substance

The approval of the active substance flumioxazin is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

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

Article 3

Amendment to Implementing Regulation (EU) 2015/408

The entry for flumioxazine is deleted from the Annex to Implementing Regulation (EU) 2015/408.

⁽⁴⁾ Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, bentiavalicarb, bifentazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxylglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 160, 7.5.2021, p. 89).

*Article 4***Entry into force and date of application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 March 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Flumioxazin CAS No 103361-09-7 CIPAC No 578	N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxa-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboximide	≥ 960 g/kg	1 March 2022	28 February 2037	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on flumioxazin, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material that is authorised for use in plant protection products; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of non-target plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine disrupting properties in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽²⁾ by 1 March 2024.</p>

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0605&from=EN>

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 39 on flumioxazine is deleted;
 (2) in Part B, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'149	Flumioxazin CAS No 103361-09-7 CIPAC No 578	N-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2H-1,4-benzoxa-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboximide	≥ 960 g/kg	1 March 2022	28 February 2037	<p>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on flumioxazin, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the specification of the technical material that is authorised for use in plant protection products; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of non-target plants. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine disrupting properties in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 ⁽²⁾ by 1 March 2024.'</p>

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

⁽²⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0605&from=EN>