



Brussels, **XXX**
SANTE/10154/2020 Rev 1
[...](2019) **XXX** draft

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

of **XXX**

concerning the non-renewal of the approval of the active substance bromoxynil, 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

(Text with EEA relevance)

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(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 Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2004/58/EC² included bromoxynil as an active substance in Annex I to Council Directive 91/414/EEC³.
- (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 540/2011⁴.
- (3) The approval of the active substance bromoxynil, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2020.
- (4) An application for the renewal of the approval of the active substance bromoxynil was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012⁵ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Directive 2004/58/EC of 23 April 2004 amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham as active substances (OJ L 120, 24.4.2004, p. 26).

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 Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (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 21 March 2016.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 10 April 2017, the Authority communicated to the Commission its conclusion⁶ on whether bromoxynil can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The conclusion of the Authority indicates that, during the peer review, experts from Member States and the Authority suggested that bromoxynil, currently subject to harmonised classification and labelling in accordance with Regulation (EC) No 1272/2008⁷ as toxic for reproduction category 2, should be classified as toxic for reproduction category 1B in accordance with the criteria laid down in that Regulation. The Commission therefore requested the Authority to consider whether negligible exposure in accordance with Point 3.6.4 of Annex II to Regulation (EC) No 1107/2009 could be demonstrated. On 8 November 2018, the Authority communicated to the Commission its conclusion⁸ that, for the representative uses considered, non-dietary exposure to bromoxynil cannot be considered negligible. In that conclusion the Authority identified a risk to child residents from the representative uses of bromoxynil even when taking into account available mitigation measures.
- (10) In its conclusion from 2017, the Authority also identified a high risk to wild mammals from dietary exposure to bromoxynil. Furthermore, the Authority concluded that the consumer risk assessment for products of animal origin and the risk assessment for aquatic organisms could not be finalised.
- (11) In its Scientific Report⁹ the Authority concluded that although for some uses of bromoxynil and in some Member States there may be an insufficient number of chemical alternatives available, a wide range of preventive and curative non-chemical methods are available, and that a combination of chemical and non-chemical methods appears often possible. Given the above-mentioned concerns, in particular the risk to child residents, and the existence of alternatives, which would allow the application of the principles of integrated pest management, as provided for in Article 55 of Regulation (EC) No 1107/2009, the conditions for the application of the derogation in Article 4(7) of Regulation (EC) No 1107/2009, which are cumulative, are not fulfilled.

⁶ EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance bromoxynil (variant evaluated bromoxynil octanoate). EFSA Journal 2017;15(6):4790, 24 pp. <https://doi.org/10.2903/j.efsa.2017.4790>.

⁷ 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).

⁸ EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment for the active substance bromoxynil in light of negligible exposure data submitted. EFSA Journal 2018;16(12):5490, 15 pp. <https://doi.org/10.2903/j.efsa.2018.5490>.

⁹ EFSA (European Food Safety Authority), 2018. Scientific report on evaluation of data concerning the necessity of bromoxynil as herbicide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA Journal 2018;16(8):5391, 80 pp. <https://doi.org/10.2903/j.efsa.2018.5391>

- (12) The Commission invited the applicant to submit its comments on the conclusions of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (13) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.
- (14) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance bromoxynil in accordance with Article 20(1)(b) of that Regulation.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Member States should be given sufficient time to withdraw authorisations for plant protection products containing bromoxynil.
- (17) For plant protection products containing bromoxynil where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months from the date of entry into force of this Regulation.
- (18) This Regulation does not prevent the submission of a further application for the approval of bromoxynil pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (19) 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

Non-renewal of the approval of the active substance

The approval of the active substance bromoxynil is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 85 on bromoxynil, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing bromoxynil as an active substance by ... [*Office of Publications please insert date 6 months from the date of entry into force*].

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*].

Article 5
Entry into force

This Regulation shall enter into force on the third 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