

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1295**of 16 September 2020****amending Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substances carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron-methyl, ipconazole and tembotrione in the list of candidates for substitution****(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 Articles 78(2) and 80(7) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2015/408 ⁽²⁾ established a list of active substances which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009 for being considered as candidates for substitution.
- (2) Implementing Regulation (EU) 2015/408 was based on a study taking stock of information for active substances approved before 31 January 2013. For the sake of consistency and equal treatment it is appropriate to update the list of substances candidates for substitution by including in it other substances, approved pursuant to the transitional rules under Article 80(1) of Regulation (EC) No 1107/2009, that meet the criteria set out by point 4 of Annex II to that Regulation.
- (3) Carbetamide, flurochloridone, halosulfuron-methyl and ipconazole were approved pursuant to Article 80(1) of Regulation (EC) No 1107/2009 but were not included in the list of candidates for substitution, because at that time they did not meet the criteria of point 4 of Annex II of that Regulation. In its recent opinions, the Committee for Risk Assessment of the European Chemicals Agency has concluded that these active substances should be classified as toxic for reproduction, Category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽³⁾. In light of this assessment, carbetamide, flurochloridone, halosulfuron-methyl and ipconazole ⁽⁴⁾ are considered to meet the criterion set out in the sixth indent of point 4 of Annex II to Regulation (EC) No 1107/2009.
- (4) Emamectin, gamma-cyhalothrin and tembotrione were not taken into consideration for the establishment of the list of candidates for substitution because they were not yet approved on 31 January 2013 which was the final date for the approval of substances considered in the study that was at the basis of Implementing Regulation (EU) 2015/408, and therefore omitted from the list established by that Implementing Regulation.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ 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).

⁽³⁾ 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).

⁽⁴⁾ Opinion proposing harmonised classification and labelling at EU level of: carbetamide (12 March 2015) <https://echa.europa.eu/documents/10162/b72929b7-77cc-148b-532c-4d5aab8661d4>, flurochloridone (3 November 2018) <https://echa.europa.eu/documents/10162/f186167a-b346-82dc-f237-fc8f580416b2>; halosulfuron-methyl (22 September 2017) <https://echa.europa.eu/documents/10162/4f58f826-4c3d-9388-7c59-a2b101f0d2c4> and of ipconazole (9 March 2018) <https://echa.europa.eu/documents/10162/bebd7903-5dc4-864a-da7a-7c3967da6e4d>.

- (5) Nevertheless, the European Food Safety Authority ('the Authority') had concluded, prior to the approval of the active substances emamectin ⁽⁵⁾ and tembotrione ⁽⁶⁾ that these substances satisfy the criterion set out in the first indent of point 4 of Annex II to Regulation (EC) No 1107/2009 because their respective acceptable daily intake and acceptable operator exposure level are significantly lower than the reference values of the majority of approved active substances.
- (6) The Authority has also concluded that gamma-cyhalothrin ⁽⁷⁾ satisfies the criterion set out in the first indent of point 4 of Annex II to Regulation (EC) No 1107/2009 because the acceptable operator exposure level and the acute reference dose for this substance are significantly lower than the reference values of the majority of approved active substances.
- (7) Implementing Regulation (EU) 2015/408 should therefore be amended accordingly to take due account of these assessments.
- (8) 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

The Annex to Implementing Regulation (EU) 2015/408 is amended as follows:

- (1) the name 'carbetamide' is inserted between the entry 'carbendazim' and the entry 'chlorotoluron';
- (2) the name 'emamectin' is inserted between the entry 'diquat' and the entry 'epoxiconazole';
- (3) the name 'flurochloridone' is inserted between the entry 'fluquinconazole' and the entry 'glufosinate';
- (4) the name 'gamma-cyhalothrin' is inserted between the entry 'fluquinconazole' and the entry 'glufosinate';
- (5) the name 'halosulfuron-methyl' is inserted between the entry 'glufosinate' and the entry 'haloxyfop-P';
- (6) the name 'ipconazole' is inserted between the entry 'imazosulfuron' and the entry 'isoproturon';
- (7) the name 'tembotrione' is inserted between the entry 'tebufenpyrad' and the entry 'tepraloxydim'.

Article 2

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, 16 September 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁵⁾ EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment of the active substance emamectin, *EFSA Journal* 2012;10(11):2955.

⁽⁶⁾ EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance tembotrione, *EFSA Journal* 2013;11(3):3131.

⁽⁷⁾ EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance gamma-cyhalothrin, *EFSA Journal* 2014;12(2):3560.