Commission Implementing Regulation (EU) 2019/1138 of 3 July 2019 approving the active substance florpyrauxifen-benzyl 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1138

of 3 July 2019

approving the active substance florpyrauxifen-benzyl 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)

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 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Italy received on 24 March 2016 an application from Dow AgroSciences for the approval of the active substance florpyrauxifen-benzyl.

(2) In accordance with Article 9(3) of that Regulation, Italy, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 17 June 2016 of the admissibility of the application.

(3) On 28 April 2017 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether the active substance florpyrauxifen-benzyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report in May 2018.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1138. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(5) On 5 July 2018, the Authority communicated to the applicant, the Member States and the Commission its conclusion[(2)] on whether the active substance florpyrauxifen-benzyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 22 March 2019 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for florpyrauxifen-benzyl and the draft of this Regulation providing that florpyrauxifen-benzyl is approved.

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

(8) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[(3)], the Commission considers that florpyrauxifen-benzyl does not have endocrine disrupting properties based on the available scientific information summarised in the conclusion of the Authority. However, in order to increase the confidence in this conclusion, the applicant should provide an updated assessment, in accordance with point 2(2)(b) of Annex II to Regulation (EC) No 1107/2009, of 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 and in accordance with the guidance for the identification of endocrine disruptors[(4)].

(9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(10) It is therefore appropriate to approve florpyrauxifen-benzyl.

(11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions. It is, in particular, appropriate to require further confirmatory information.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011[(5)] should be amended accordingly.

(13) 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

Approval of active substance

The active substance florpyrauxifen-benzyl, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1138. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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

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, 3 July 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1138. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227	benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate	≥ 920 g/kg The impurity toluene shall not exceed 3 g/kg in the technical material.	24 July 2019	24 July 2029	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 22 March 2019, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of aquatic and terrestrial non-target plants. Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction

a Further details on identity and specification of active substance are provided in the review report.