COMMISSION IMPLEMENTING REGULATION (EU) 2019/1138

of 3 July 2019


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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 florpypyrxiufen-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 florpypyrxiufen-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.

(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 florpypyrxiufen-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 florpypyrxiufen-benzyl and the draft of this Regulation providing that florpypyrxiufen-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 florpypyrxiufen-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).

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.

It is therefore appropriate to approve floratexifen-benzyl.

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.


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 floratexifen-benzyl, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

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

### ANNEX I

<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (1)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227</td>
<td>benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate</td>
<td>≥ 920 g/kg The impurity toluene shall not exceed 3 g/kg in the technical material.</td>
<td>24 July 2019</td>
<td>24 July 2029</td>
<td>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 nozzles, where appropriate. 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 activity 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 by 24 July 2021.</td>
</tr>
</tbody>
</table>

(1) Further details on identity and specification of active substance are provided in the review report.
In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

<table>
<thead>
<tr>
<th>No</th>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity ((^*))</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>'139</td>
<td>Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227</td>
<td>benzyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)-5-fluoropyridine-2-carboxylate</td>
<td>(\geq 920) g/kg The impurity toluene shall not exceed 3 g/kg in the technical material.</td>
<td>24 July 2019</td>
<td>24 July 2029</td>
<td>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 nozzles, where appropriate. 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 activity 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 by 24 July 2021.</td>
</tr>
</tbody>
</table>

\(^*\) Further details on identity and specification of active substance are provided in the review report.'