# Commission Implementing Regulation (EU) 2015/1165 of 15 July 2015 approving the active substance halauxifen-methyl, 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) 2015/1165

## of 15 July 2015

## approving the active substance halauxifen-methyl, 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, the United Kingdom received on 20 September 2012 an application from Dow AgroSciences Limited for the approval of the active substance halauxifen-methyl. In accordance with Article 9(3) of that Regulation, the United Kingdom, as rapporteur Member State, notified the Commission on 2 November 2012 of the admissibility of the application.

(2) On 20 December 2013 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the European Food Safety Authority (hereinafter 'the Authority'), assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(3) 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 October 2014.

(4) On 21 November 2014 the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance halauxifen-methyl can be expected to meet the approval criteria provided for in Article 4 of

**Changes to legislation:** *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/1165. 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*

Regulation (EC) No 1107/2009[(2)]. The Authority made its conclusion available to the public.

(5) On 20 March 2015 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for halauxifen-methyl and a draft Regulation providing that halauxifen-methyl is approved.

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

(7) 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. Those approval criteria are therefore deemed to be satisfied. It is therefore appropriate to approve halauxifen-methyl.

(8) 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, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011[(3)] should be amended accordingly.

(10) 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 halauxifen-methyl, 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*.

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

Done at Brussels, 15 July 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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ANNEX I

| **Common Name, Identification Numbers** | **IUPAC Name** | **Purity**[a] | **Date of approval** | **Expiration of approval** | **Specific provisions** |
|---|---|---|---|---|---|
| Halauxifen-methyl<br>CAS No: 943831-98-9<br>CIPAC No: 970.201 (halauxifen-methyl) 970 (halauxifen) | methyl 4-amino-3-chloro-6-(4-chloro-2-fluoro-3-methoxyphenyl)pyridine-2-carboxylate | ≥ 930 g/kg | 5 August 2015 | 5 August 2025 | 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 halauxifen-methyl, and in particular Appendices I and II thereof, shall be taken into account.<br>In this overall assessment Member States shall pay particular attention to:<br>— The risk to aquatic and non-target terrestrial plants.<br>Conditions of use shall include risk mitigation measures, where appropriate.<br>The applicant shall submit |

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

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|---|---|---|---|---|---|
| | | | | | confirmatory information as regards:<br>— The technical specification of the active substance as manufactured (based on commercial scale production).<br>The relevance of impurities present in the technical material should be confirmed,<br>— The compliance of the toxicity batches with the technical specification.<br>The applicant shall submit that information to the Commission, the Member States and the Authority by 5 February 2016. |

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