Commission Implementing Regulation (EU) 2018/185 of 7 February 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/185

of 7 February 2018

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen

(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)(c) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 1031/2013[(2)] approved the active substance penflufen and included it in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011[(3)]. The approval was restricted to uses to treat seed potato tubers before or during planting limited to one sowing of seeds treated with penflufen every third year in the same field.

(2) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 13 May 2014 the producer of the active substance Bayer CropScience AG submitted an application to the designated rapporteur Member State, the United Kingdom, seeking an amendment to the conditions of approval of penflufen in order to allow its use on other seeds. Uses on barley and wheat were described in the dossier. In accordance with Article 9(3) of that Regulation, United Kingdom notified the applicant, the other Member States, the European Food Safety Authority ('the Authority') and the Commission on 16 June 2014 that the application was admissible.

(3) The designated rapporteur Member State assessed the new use of the active substance penflufen in relation to potential effects on human and animal health and the environment in accordance with the provisions of Article 4 of Regulation (EC) No 1107/2009, and submitted a draft assessment report to the Commission and to the Authority on 5 August 2015. In accordance with Article 12(3) of that Regulation additional information was requested from the applicant. The United Kingdom evaluated the additional information and submitted an updated draft assessment report to the Commission and to the Authority on 8 July 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/185. 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*

(4) On 3 November 2016 the Authority communicated to the Commission its conclusion[4] on whether the new uses of the active substance penflufen can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft addendum to the review report for penflufen and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 23 January 2017.

(5) The applicant was invited to submit comments on the addendum to the review report.

(6) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance that, when the plant protection product is used to treat seeds or other propagating materials which are sown or planted, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to withdraw the restriction for the use of penflufen for seed potato tubers only and allow its use also for other seeds or other propagating materials.

(7) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in light of current scientific and technical knowledge, it is necessary and appropriate to amend the conditions of approval while keeping certain conditions and restrictions and to require the applicant to provide confirmatory information provided in the first approval.

(8) Implementing Regulation (EU) No 1031/2013 required the applicant to submit confirmatory information regarding the long-term risk to birds within two years after the entry into force of that Regulation. As the applicant submitted that data as part of the dossier seeking the amendment of the conditions of approval of the active substance penflufen the requirement is considered as fulfilled. Member States should take advantage of these new pieces of information and check the national authorisations for products containing penflufen, where relevant.

(9) Implementing Regulation (EU) No 1031/2013 also required that information regarding the specification of the technical material as commercially manufactured to be submitted to the Commission. As that data were evaluated by the United Kingdom as part of the procedure to amend the conditions of approval of the active substance penflufen the requirement is considered as fulfilled.

(10) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(11) 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:

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/185. 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 1

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

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, 7 February 2018.

For the Commission

The President

Jean-Claude JUNCKER