



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10574/2021
[...] (2021) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen and repealing Implementing Regulation (EU) 2018/185

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance penflufen and repealing Implementing Regulation (EU) 2018/185

(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/EEC¹, and in particular Article 21(3), second alternative in conjunction with Article 6 thereof, and Article 78(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 1031/2013² approved the active substance penflufen and added it to Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011³, subject to certain conditions, requiring, in particular, the submission of confirmatory information in accordance with Article 6 of Regulation (EC) No 1107/2009.
- (2) Commission Implementing Regulation (EU) 2018/185⁴ amended the conditions of approval of the active substance penflufen and addressed part of the confirmatory information required by Implementing Regulation (EU) No 1031/2013.
- (3) Implementing Regulation (EU) No 1031/2013 also provides for the submission of further confirmatory information as regards the relevance of the metabolite M01 (penflufen-3-hydroxy-butyl) for groundwater if penflufen is classified, under Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁵, as ‘carcinogen category 2’ within 6 months from the notification of the classification decision concerning that substance.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Implementing Regulation (EU) No 1031/2013 of 24 October 2013 approving the active substance penflufen, 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 (OJ L 283, 25.10.2013, p. 17).

³ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁴ 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 (OJ L 34, 8.2.2018, p. 13).

⁵ 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) On 15 October 2018, the European Chemical Agency's Committee for Risk Assessment adopted an opinion⁶ in which it concluded that penflufen should be classified as 'carcinogen category 2'. Following that opinion, and since Member States agreed with such a classification, penflufen was included in the list of harmonised classification and labelling of hazardous substances provided for in Annex VI to Regulation (EC) No 1272/2008.
- (5) On 15 March 2019, the applicant informed Poland, the rapporteur Member State, that it would not submit the required confirmatory information, which was only relevant for the representative use to treat seed potato tubers before or during planting.
- (6) Since the information required in accordance with Article 6(f) of Regulation (EC) No 1107/2009 has not been provided, the Commission informed the Member States, the Authority and the producer of the active substance penflufen that a Regulation will be proposed to withdraw the approval or to amend the conditions of approval of penflufen.
- (7) On 19 February 2021 the applicant was given the possibility to submit comments and any relevant information to the Commission. The applicant submitted its comments confirming that it would not submit the confirmatory information requested.
- (8) The Commission has concluded that the available data is not sufficient to determine the relevance of the metabolite M01 (penflufen-3-hydroxy-butyl), which is predicted to occur above 0.1 µg/L in all relevant groundwater scenarios when seed potato tubers treated with penflufen are planted, as the information required in Implementing Regulation (EU) No 1031/2013 has not been provided.
- (9) Therefore, it is necessary and appropriate to restrict the approval of penflufen and prohibit the treatment of seed potato tubers before or during planting, while it is possible to maintain the use of penflufen to treat cereal seeds, since safe uses have been demonstrated.
- (10) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (11) For the sake of clarity, and since the amendments made by this Regulation make Implementing Regulation (EU) 2018/185 redundant, it is also appropriate to repeal Regulation (EU) 2018/185.
- (12) Member States should be provided with sufficient time to amend or withdraw authorisations for plant protection products containing penflufen which are not complying with the restricted conditions of approval.
- (13) For plant protection products containing penflufen, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months after the entry into force of this Regulation.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁶ Opinion of 15 October 2018 concerning 5-fluoro-1,3-dimethyl-N-[2-(4-methylpentan-2-yl)phenyl]-1Hpyrazole-4-carboxamide;2'-[(RS)-1,3-dimethylbutyl]-5-fluoro-1,3-dimethylpyrazole-4-carboxanilide; penflufen (CLH-O-0000001412-86-233/F)

HAS ADOPTED THIS REGULATION:

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

Repeal of Implementing Regulation (EU) 2018/185

Implementing Regulation (EU) 2018/185 is repealed.

Article 3

Transitional measures

Member States shall, where necessary, amend or withdraw existing authorisations for plant protection products containing penflufen as active substance by [*Publications office please insert date 3 months after date of entry into force*].

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on [*Publications office please insert date 6 months after date of entry into force*] at the latest.

Article 5

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,

For the Commission

The President

Ursula VON DER LEYEN