EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10311/2016 rev. 0
[…](2016) 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 buprofezin

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2011/6/EU[2] included buprofezin as active substance in Annex I to Council Directive 91/414/EEC[3], under the condition that the Member States concerned ensure that the notifier, at whose request buprofezin was included in that Annex, provides further confirmatory information as regards the processing and conversion factors for consumer risk assessment.

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[4].

(3) On 30 January 2013, the applicant submitted additional information concerning the processing and conversion factors to the rapporteur Member State United Kingdom within the time period provided for its submission.

(4) The United Kingdom assessed the additional information submitted by the applicant. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', on 9 September 2014.

(5) The Commission consulted the Authority which presented its conclusion on the risk assessment of buprofezin on 28 July 2015[5]. The draft assessment report, the addendum and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and

---

1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2011/6/EU of 20 January 2011 amending Council Directive 91/414/EEC to include buprofezin as active substance (OJ L 18, 21.1.2011, p. 38).

3 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

4 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).

5 Conclusion on the peer review of the pesticide risk assessment for the active substance buprofezin in light of confirmatory data. EFSA Journal 2015; 13(8): 4207, 24 pp. doi: 10.2903/j.efsa.2015/4207.

finalised on 24 January 2017 in the format of the Commission review report for buprofezin.

(6) The Commission invited the applicant to submit its comments on the review report for buprofezin.

(7) The Commission has considered that the additional information provided showed that under high temperature processing conditions buprofezin is degraded into several metabolites, including aniline. Aniline is a carcinogen for which a genotoxic mechanism cannot be excluded and therefore no threshold for acceptable exposure can be assumed.

(8) The Commission has concluded that the further confirmatory information required has not been fully provided and that exposure of consumers to aniline via consumption of processed crops cannot be excluded except by imposing further restrictions. In particular, the use of buprofezin should be limited to non-edible crops only.

(9) It is confirmed that the active substance buprofezin is to be deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of consumers to aniline, it is, however, appropriate to amend the conditions of use of this active substance.

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

(11) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing buprofezin.

(12) For plant protection products containing buprofezin, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on *[Office of Publications please insert date 15 months from the date of entry into force]*.

(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
Amendment to Implementing Regulation (EC) No 540/2011

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

Article 2
Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary amend or withdraw existing authorisations for plant protection products containing buprofezin as active substance by [*Office of Publications please insert date 3 months from the date of entry into force*] at the latest.

Article 3
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 by *[Office of Publications please insert date 15 months from the date of entry into force]* at the latest.

Article 4
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
Jean-Claude JUNCKER