Commission Implementing Regulation (EU) No 201/2013 of 8 March 2013 amending Implementing Regulations (EU) No 788/2011 and (EU) No 540/2011 as regards an extension of the uses for which the active substance fluazifop-P is approved (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 201/2013

of 8 March 2013

amending Implementing Regulations (EU) No 788/2011 and (EU) No 540/2011 as regards an extension of the uses for which the active substance fluazifop-P is approved

(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) By Commission Implementing Regulation (EU) No 788/2011 of 5 August 2011 approving the active substance fluazifop-P, 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 and Commission Decision 2008/934/EC[(2)] the active substance fluazifop-P was approved. The approval included the special provision 'only uses as herbicide for orchards (basal application) with one application every year may be authorised'.

(2) On 29 June 2011 Syngenta Crop Protection AG, at whose request fluazifop-P had been approved, submitted an application for an amendment to the conditions of approval of the active substance fluazifop-P to allow uses as a herbicide to be authorised without restriction. That application was accompanied by information relating to the requested extension of uses. It was submitted to France, which had been designated rapporteur Member State by Commission Regulation (EC) No 1490/2002[(3)].

(3) France assessed the information submitted by the applicant and prepared an addendum to the draft assessment report. It submitted that addendum to the Commission, with a copy to the European Food Safety Authority, hereinafter 'the Authority', on 2 April 2012.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 201/2013. 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) The Authority circulated the addendum to the applicant and the Member States, with the exception of the rapporteur Member State, and made it available to the public, allowing a period of 60 days for the submission of written comments.

(5) The Authority organised an expert consultation as regards mammalian toxicology.

(6) Taking into account the addendum to the draft assessment report, the Authority adopted its conclusion on fluazifop-P on 18 October 2012[4], as regards its unrestricted use as a herbicide. It communicated that conclusion to the applicant, the Member States and the Commission and made it available to the public. The draft assessment report, the addendum thereto and that conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 1 February 2013 in the format of the Commission review report for fluazifop-P. The applicant was given the possibility to submit comments on the review report.

(7) It has appeared from the information submitted by the applicant that allowing uses as a herbicide to be authorised without restriction does not cause any risks in addition to those already taken into account in Implementing Regulation (EU) No 788/2011 and in the Commission review report on which that Implementing Regulation was based.

(8) On the basis of the review report, as finalised on 1 February 2013 and of the conclusion by the Authority adopted on 18 October 2012, it is appropriate to extend the approval of fluazifop-P to cover uses as a herbicide without restriction.

(9) In order to take into account the remaining uncertainty on the calculation of the degradation half time of the metabolite Compound X[5] Member States should pay particular attention to consumer safety as regards the occurrence in groundwater of that metabolite.

(10) Implementing Regulations (EU) No 788/2011 and Commission Implementing Regulation (EU) No 540/2011[6] should therefore be amended accordingly.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) No 788/2011

Annex I to Implementing Regulation (EU) No 788/2011 is amended in accordance with Annex I to this Regulation.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 201/2013. 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 2

Amendment 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, 8 March 2013.

For the Commission

The President

José Manuel BARROSO