Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission

COMMISSION IMPLEMENTING REGULATION (EU) No 380/2013

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amending Regulation (EU) No 1141/2010 as regards the submission of the supplementary complete dossier to the Authority, the other Member States and the Commission

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 19 thereof,

Whereas:

(1) Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances[(2)] provides for the supplementary summary dossier, as updated to take into account additional information requested by the rapporteur Member State, to be submitted by the applicant to the European Food Safety Authority (hereinafter 'the Authority'), the other Member States and, on request, to the Commission when the renewal assessment report is submitted to the Commission.

(2) The practice shows that the large majority of dossiers for the approval or renewal of the approval is evaluated by the Authority. To allow the Authority to give its conclusion on the entire risk assessment or on specific points, it is, however, necessary that the supplementary complete dossier is submitted to the Authority in addition to the supplementary summary dossier. The supplementary complete dossier should also be submitted to the Member States. The Commission should have the possibility to request the submission of the supplementary complete dossier.

(3) Regulation (EU) No 1141/2010 should therefore be amended accordingly.

(4) 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:

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 380/2013. 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 1

Amendment to Regulation (EU) No 1141/2010

In Article 14(6) of Regulation (EU) No 1141/2010, the following subparagraph is added:

In addition, the rapporteur Member State shall request the applicant to submit the supplementary complete dossier to the Authority, to the other Member States and, on request, to the Commission..

Article 2

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, 25 April 2013.

For the Commission

The President

José Manuel BARROSO