Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1313

of 1 August 2016

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

(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 first alternative of Article 21(3) thereof,

Whereas:

(1) The active substance was included in Annex I to Council Directive 91/414/EEC[(2)] by Commission Directive 2001/99/EC[(3)].

(2) Active substances included in Annex I of 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) The approval of the active substance glyphosate, as set out in the Annex to Implementing Regulation (EU) No 540/2011 expires 6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency by the Commission or 31 December 2017, whichever is the earlier.

(4) On 30 October 2015[(5)] the European Food Safety Authority (hereinafter 'the Authority') communicated to the Commission its statement on the toxicological assessment of POE-tallowamine (CAS No 61791-26-2), a substance frequently used as a co-formulant in plant protection products containing glyphosate. It concluded that compared to glyphosate, a significant toxicity of POE-tallowamine was observed on all endpoints investigated. Additional concerns were highlighted as regards the potential of POE-tallowamine to negatively affect human health when used in plant protection products containing glyphosate. The Authority also considered that a likely explanation for the medical data in humans for plant protection products containing glyphosate is that the toxicity is mostly driven by the POE-tallowamine component of the formulation.

(5) In accordance with Directive 2009/128/EC of the European Parliament and of the Council[(6)] in conjunction with Article 55 of Regulation (EC) No 1107/2009, Member States should encourage the development and implementation of integrated pest

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2016/1313. 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*

management and of alternative approaches or techniques in order to reduce their dependency on the use of pesticides. As plant protection products containing glyphosate are widely used for non-agricultural applications, Member States should ensure that the use of plant protection products containing glyphosate is minimised or prohibited in areas such as public parks and gardens, sports and recreation grounds, school grounds and children's playgrounds and in the close vicinity of healthcare facilities.

(6) Plant protection products containing glyphosate are also used for pre-harvest applications. In certain situations pre-harvest uses to check or prevent undesired growth of weeds are in line with good agricultural practices. Nevertheless it appears that plant protection products containing glyphosate are also used with the intention to control the time point of harvest or to optimise the threshing, although these uses may not be considered within good agricultural practices. Such uses may therefore not be compliant with the provisions of Article 55 of Regulation (EC) No 1107/2009. Member States should therefore pay particular attention to compliance of pre-harvest uses with good agricultural practices when authorising plant protection products.

(7) The Commission invited the notifiers to submit their comments.

(8) In the light of current scientific and technical knowledge it is appropriate to amend the conditions of use of the active substance in particular by excluding the co-formulant POE-tallowamine (CAS No 61791-26-2) from the use in plant protection products containing glyphosate.

(9) Implementing Regulation (EU) No 540/2011 should be amended accordingly.

(10) In accordance with Article 27(2) of Regulation (EC) No 1107/2009, a list of co-formulants not accepted for inclusion in plant protection products shall be established. The Commission, the Authority and Member States have started work in view of establishing that list. In carrying out that work, the Commission will pay particular attention to potentially harmful co-formulants used in plant protection products containing glyphosate. The list of unacceptable co-formulants will be established in future in a separate act, in accordance with the procedural requirements set out in Article 27(2) of Regulation (EC) No 1107/2009.

(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:

Article 1

In the seventh column, ‘specific provisions’, of entry 25 on glyphosate in Part A of the Annex to Implementing Regulation (EU) No 540/2011, the text is replaced by the following:

Only uses as herbicide may be authorised.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on glyphosate, and in particular Appendices I and II thereof, as amended in the Standing Committee on Plants, Animals, Food