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COMMISSION REGULATION (EU) …/…

of XXX

modifying Annex III of Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 27(2) and Article 44 thereof,

Whereas:

(1) Co-formulants are identified as unacceptable co-formulants if it is established that their residues, consequent to applications under realistic conditions of plant protection practices have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment. Co-formulants are to be identified as unacceptable co-formulants if it is established that their uses, consequent to applications under realistic conditions of plant protection practices have a harmful effect on human or animal health or an unacceptable effect on plant, plant products or the environment. These unacceptable co-formulants should be listed in Annex III to Regulation (EC) 1107/2009 (hereafter 'the ~~Annex~~ Regulation').

(2) Commission Implementing Regulation [*Office of Publications please insert reference to the published regulation*][2] setting rules according to Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market clarifies the procedure and the criteria to identify unacceptable co-formulants and how to populate Annex III of the Regulation.

(3) Some Member States and Norway have notified several substances and preparations to the Commission before the entry into force of the Co-formulant Regulation. These substances are deemed to be notified according to article 1 of the Co-formulant Regulation. According to article 9 of the Co-formulant Regulation and especially its second paragraph, the European Commission shall adopt a regulation whether co-formulants listed in Part A of Annex II of the Co-formulant Regulation should be listed in Annex III of Regulation (EC) 1107/2009.

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1 OJ L […], […], p […]

2 OJ L [*Office of Publications please insert reference to the published regulation*]

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(4) Buiten reikwijdte verzoek

[redacted]

[redacted] title

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Buiten reikwijdte verzoek

(19) During the renewal of glyphosate, a concern was identified regarding the toxicity of polyethoxylated tallow amines (hereafter 'POE-tallowamine'). The European Food Safety Authority (hereinafter 'Authority') concluded that 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. As a consequence the use of POE tallowamines (CAS No 61791-26-2) in plant protection products containing the substance glyphosate should be restricted. As no new information has been made available so far for this compoound, the restriction of use of POE tallowamines in plant protection products should be also added in the Annex.

From Buiten reikwijdte verzoek

[redacted]

(21) Article 29 of the Regulation provides that a plant protection product shall only be authorised if complying with specific requirements. Authorised products shall not contain unacceptable co-formulants listed up in Annex III. Member States shall not granted authorisations for plant protection products for which a dossier was submitted or assessed according to Article 33 or Article 43 after the entry into force of this Regulation.

(22) Article 44 of the Regulation provides that Member States shall withdraw the existing authorisations at any time, when the requirements of Article 29 of the Regulation are no longer satisfied. Member States should be provided with time to examine the formulation of the products currently authorised in their national territory and to withdraw or amend authorisations for plant protection products containing an unacceptable co-formulant or not complying with the specific provisions set in Annex.

(23) For plant protection products containing an unacceptable co-formulant or not complying with the specific provisions, where Member States grant any period of grace in accordance with Article 46 of the Regulation ~~(EC) No 1107/2009~~, this period should be as short as possible and should expire at the latest one year after the withdrawal of the authorisations.

(24) 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

Annex III to Regulation (EC) No 1107/2009 is amended in accordance with the Annex to this Regulation.

Article 2

For all the co-formulants listed in Annex I except for POE-tallow amines (CAS No 61791-26-2), Member States shall amend or withdraw authorisations for plant protection products containing co-formulants listed in Annex or not complying with the provisions set in Annex, by [*Office of Publications please insert date 3 years after entry into force of this Regulation*].

Met opmerkingen 3.1.2.8 **:** 3.1.5 wants a shorter transitional period

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Member States shall amend or withdraw authorisations for plant protection products containing POE-tallow amines in accordance with 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.

Article 44(1) and article 33 shall apply.

Met opmerkingen [3.1.2.8]: To be discussed Different options available

Article 3

Any grace period granted by Member States shall be as short as possible in accordance with Article 46 of Regulation (EC) No 1107/2009.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Met opmerkingen [3.1.2.9]: Need for provisions for pending authorisations, in conjunction with article 2 paragraph 1

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,