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EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex III to Regulation (EC) 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products

(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 78(2) thereof,

Whereas:

(1) Co-formulants are described in Article 2(3)(c) of Regulation (EC) No 1107/2009 as substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners nor synergists.

(2) Co-formulants are unacceptable in plant protection products if their residues, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or on groundwater or an unacceptable effect on the environment. Co-formulants are also unacceptable in plant protection products if their use, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, have a harmful effect on human or animal health or have an unacceptable effect on plants, plant protection products or the environment. Such unacceptable co-formulants are to be listed in Annex III to Regulation (EC) No 1107/2009.

(3) Co-formulants are substances or preparations used together with active substances in plant protection products and are thus equally spread in the environment. Therefore, the criteria concerning human health, the environment, ecotoxicity and groundwater, provided for by points 3.6, 3.7, 3.8 and 3.10 of Annex II to Regulation (EC) No 1107/2009, should also be relevant to identify unacceptable co-formulants.

(4) The list of unacceptable co-formulants thus should include substances with a harmonised classification as carcinogens, category 1A or 1B, as cell mutagens, category 1A or 1B, or as toxic to reproduction, category 1A or 1B, in accordance with Annex VI to Regulation (EC) No 1272/2008[2].

[1] OJ L 309, 24.11.2009, p. 1.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(5) The list of unacceptable co-formulants should further include substances identified as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with points (d) and (e) of Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3].

(6) The list of unacceptable co-formulants should also include substances of very high concern due to endocrine disrupting properties in accordance with point (f) of Article 57 of Regulation (EC) No 1907/2006 or substances identified as endocrine disruptors under Regulation (EC) No 528/2012[4] concerning the making available on the market and use of biocidal products or substances identified as persistent organic pollutants (POP) under Regulation (EC) No 850/2004[5].

(7) Regulation (EC) No 1907/2006 sets out restrictions for certain dangerous substances in its Annex XVII. Where the use of those substances is subject to restrictions as co-formulants in plant protection products, they should be added to that list of co-formulants in Annex III to Regulation (EC) No 1107/2009.

(8) Member States have identified unacceptable co-formulants for plant protection products under Council Directive 91/414/EEC[6] and under Article 81 of Regulation (EC) No 1107/2009. Such co-formulants have been notified by Austria, Belgium, France, Germany, Italy, Lithuania, Spain and Norway. Amongst those co-formulants, those with a harmonised classification as carcinogens, category 1A or 1B, as cell mutagens, category 1A or 1B, or as toxic to reproduction, category 1A or 1B, in accordance with Annex VI to Regulation (EC) No 1272/2008, those identified as PBT or vPvB according to points (d) and (e) of Article 57 of Regulation (EC) No 1907/2006, those identified as substances of very high concern due to endocrine disrupting properties in accordance with point (f) of Article 57 of Regulation (EC) No 1907/2006, and those identified as POP under Regulation (EC) No 850/2004 should be listed in Annex III to Regulation (EC) No 1107/2009.

(9) The use of POE tallowamines (CAS No 61791-26-2) in plant protection products containing glyphosate was prohibited by Commission Implementing Regulation (EU) 2016/1313[7], as concerns were identified in relation to the toxicity of POE tallowamines and their potential to negatively affect human health. Given that those concerns are due to the intrinsic properties of the substances concerned and are thus not limited to formulated products containing glyphosate but are equally valid for formulated products containing other active substances, POE tallowamines should also be added to that list of co-formulants in Annex III to Regulation (EC) No 1107/2009.

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3 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

4 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

5 Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7).

6 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).

7 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 (OJ L 208, 2.8.2016, p. 1).

(10) The use of PHMB (1600; 1.8), CAS number 27083-27-8 and 32289-58-0, and PHMB (1415; 4.7), CAS number 32289-58-0 and 1802181-67-4, as in-can preservatives in plant protection products would lead to unacceptable effects on human health and in the environment. Commission Implementing Decisions (EU) 2016/109[8] and 2018/619[9] did not approve them as existing active substances for use in biocidal products for product-type 6 (in-can preservatives), amongst other product types due to unacceptable risks for human health and the environment. Therefore PHMB (1600; 1.8) and PHMB (1415; 4.7) should also be added to Annex III to Regulation (EC) No 1107/2009.

(11) Co-formulants to be listed in Annex III to Regulation (EC) No 1107/2009 may also be contained in adjuvants placed on the market. As detailed rules for the authorisation of adjuvants, in accordance with Article 58(2) of Regulation (EC) No 1107/2009, have not yet been established, Member States may continue to apply national provisions as regards adjuvants in accordance with Article 81(3) of that Regulation. As Regulation (EC) No 1107/2009 aims to prevent the placing on the market or use of adjuvants containing prohibited co-formulants, it is necessary to ensure that also adjuvants, to be mixed with plant protection products, do not contain any of those unacceptable co-formulants.

(12) Member States should be provided with sufficient time to review the composition of the plant protection products and adjuvants currently authorised in their territory, in order to assess whether they contain co-formulants listed in Annex III to Regulation (EC) No 1107/2009 and to withdraw or amend authorisations for plant protection products and adjuvants containing those co-formulants.

(13) For plant protection products or adjuvants containing a co-formulant listed in Annex III to Regulation (EC) No 1107/2009, where Member States grant any grace period in accordance with Article 46 of that Regulation or in accordance with national provisions for authorisation of adjuvants, respectively, that period should expire for the sale and distribution at the latest 3 months and for the disposal, storage and use additional 9 months after the amendment or withdrawal of the authorisations.

(14) Co-formulants to be listed in Annex III to Regulation (EC) No 1107/2009 may be present as unintentional impurities in other co-formulants, which as such are acceptable for use in plant protection products or adjuvants. Therefore, the individual concentration of the unacceptable co-formulants in the finished plant protection product or adjuvant should be less than 0,01 % weight by weight (w/w) in order to be considered as acceptable unintentional impurity, unless a different limit is provided due to technical limitations of relevant analytical methods.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

[8] Commission Implementing Decision (EU) 2016/109 of 27 January 2016 not to approve PHMB (1600; 1.8) as an existing active substance for use in biocidal products for product-types 1, 6 and 9 (OJ L 21, 28.1.2016, p. 84).

[9] Commission Implementing Decision (EU) 2018/619 of 20 April 2018 not approving PHMB (1415; 4.7) as an existing active substance for use in biocidal products of product-types 1, 5 and 6 (OJ L 102, 23.4.2018, p. 21).

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

Member States which have granted authorisations for plant protection products containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation, shall amend or withdraw those authorisations as soon as possible but no later than *[Office of Publications please insert date corresponding to 2 years from the date of the Entry into Force]*.

Article 3

Member States shall not authorise the placing on the market or use of adjuvants containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation.

Member States which have authorised adjuvants containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009, as amended by this Regulation, shall amend or withdraw those authorisations as soon as possible and no later than *[Office of Publications please insert date corresponding to 2 years from the date of the Entry into Force]*.

Article 4

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 or national provisions for authorisation of adjuvants shall be as short as possible and shall expire for sale and distribution at the latest 3 months and for disposal, storage and use additional 9 months after the date of withdrawal or amendment of the authorisation referred to in Articles 2 and 3.

Article 5

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
Ursula VON DER LEYEN

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