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PESTICIDE 5
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PHYTOSAN 6
SAN 66**

COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 3 February 2026

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: D(2026) 105865

Subject: COMMISSION REGULATION (EU) .../... of XXX amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council by adding twelve co-formulants which are not accepted for inclusion in plant protection products

Delegations will find attached document D(2026) 105865.

Encl.: D(2026) 105865



Brussels, **XXX**
PLAN/2024/1813
(POOL/E4/2024/1813/1813-EN.docx)
D105865/05
[...] (2025) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council by adding twelve co-formulants which are not accepted for inclusion in plant protection products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council by adding twelve 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/EEC¹, and in particular Article 27(2) and 78(2) thereof,

Whereas:

- (1) Co-formulants are described in point (c) of Article 2(3) 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 or synergists.
- (2) In accordance with Article 27(1) of Regulation (EC) No 1107/2009, 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, or if their use, consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use, has a harmful effect on human or animal health or has an unacceptable effect on plants, plant products or the environment. Such unacceptable co-formulants are listed in Annex III to Regulation (EC) No 1107/2009.
- (3) In accordance with Article 27(3) of Regulation (EC) No 1107/2009, the Commission may review co-formulants at any time and may take into account relevant information provided by Member States. In particular, it may take into account notifications provided by the Member States in accordance with the rules for the identification of unacceptable co-formulants set out in Commission Implementing Regulation (EU) 2023/574².
- (4) In accordance with Articles 3 and 4 of Implementing Regulation (EU) 2023/574, Member States have identified 12 new substances that are found to be unacceptable for

¹ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

² Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 75, 14.03.2023, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2023/574/oj).

use as co-formulants in plant protection products authorised under Regulation (EC) No 1107/2009, because they fulfil at least one of the criteria set out in the Annex to Implementing Regulation (EU) 2023/574.

- (5) Among those co-formulants, there are substances that have a harmonised classification as carcinogens, category 1A or 1B, as 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 of the European Parliament and of the Council³, substances identified as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), in accordance with Article 57, points (d) and (e), of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁴, substances listed as persistent organic pollutants (POPs) under Regulation (EU) 2019/1021 of the European Parliament and of the Council⁵ and substances not approved for use in biocidal products for product-type 6 (in-can preservatives) under Regulation (EU) No 528/2012 of the European Parliament and of the Council⁶.
- (6) In accordance with Article 5 of Implementing Regulation (EU) 2023/574, the Commission listed those unacceptable co-formulants on its website.
- (7) It is therefore appropriate to amend Annex III to Regulation (EC) No 1107/2009 to include the additional substances that Member States have identified as unacceptable for their use as co-formulants in plant protection products or adjuvants.
- (8) 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 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 that Regulation 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.
- (9) Member States should be provided with time to review the composition of the plant protection products and adjuvants currently authorised in their territory, to assess whether they contain any co-formulants listed in Annex III to Regulation (EC) No 1107/2009 by this Regulation and to withdraw or amend authorisations for plant protection products and adjuvants containing those co-formulants.

³ 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, pp. 1–1355, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

⁴ 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, pp. 1–849, ELI: <http://data.europa.eu/eli/reg/2006/1907/oj>).

⁵ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, pp. 45–77, ELI: <http://data.europa.eu/eli/reg/2019/1021/oj>).

⁶ 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, pp. 1–123, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).

- (10) To allow for the orderly phasing out of products and minimise potential disruption to users and supply chains, in the case of plant protection products or adjuvants containing a co-formulant listed in Annex III to Regulation (EC) No 1107/2009 by this Regulation, Member States may grant a grace period, where appropriate and in accordance with Article 46, first subparagraph, of that Regulation or, where applicable, under national provisions governing the authorisation of adjuvants.
- (11) Co-formulants listed in Annex III to Regulation (EC) No 1107/2009 by this Regulation 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 0,1 % weight by weight (w/w) or less than a specific concentration limit related to CMR properties (carcinogenic, mutagenic and reprotoxic), when established in Annex VI to Regulation (EC) No 1272/2008 for the unacceptable co-formulant at a level lower than 0,1 % 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.
- (12) 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

Member States which have granted authorisations for plant protection products containing co-formulants listed in Annex III to Regulation (EC) No 1107/2009 by this Regulation, shall amend or withdraw those authorisations as soon as possible and, in any case, no later than *[OP please insert the date = 2 years after the entry into force of this Regulation]*.

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 by this Regulation, shall amend or withdraw those authorisations as soon as possible and, in any case, no later than *[OP please insert the date = 2 years after the entry into force of this Regulation]*.

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 the sale and distribution at the latest 3 months after the date of amendment or withdrawal of the authorisations referred to in Article 2 and 3. Any grace period for the disposal, storage and use shall expire at the latest 12 months after the date of amendment or withdrawal of the authorisations referred to in Article 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