

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****(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(5) thereof,

Whereas:

- (1) Article 27(1) of Regulation (EC) No 1107/2009 specifies that a co-formulant is not to be accepted for inclusion in a plant protection product where it has been established that its 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 its 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 an unacceptable effect on plants, plant products or the environment.
- (2) Pursuant to Article 27(2) of Regulation (EC) No 1107/2009, co-formulants which are not accepted for inclusion in plant protection products must be included in Annex III to Regulation (EC) No 1107/2009. A first list of unacceptable co-formulants has been established by Commission Regulation (EU) 2021/383 ⁽²⁾ amending Annex III to Regulation (EC) No 1107/2009 listing co-formulants which are not accepted for inclusion in plant protection products.
- (3) Annex III to Regulation (EC) No 1107/2009 may need to be updated in light of new technical and scientific knowledge. In order to ensure a predictable and uniform implementation of Article 27 of Regulation (EC) No 1107/2009, it is appropriate to set out precise rules for the identification of unacceptable co-formulants in those same products, which may then be listed in an updated version of that Annex III. For such purposes, this Regulation establishes a set of detailed criteria to determine whether a co-formulant might have harmful or unacceptable effects as provided for in Article 27(1) of Regulation (EC) No 1107/2009, which should ensure that co-formulants meet safety standards that are protective for human health and the environment.
- (4) Co-formulants are chemical substances which may be used for different purposes, including in plant protection products. Their manufacturing, placing on the market and uses are regulated under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('REACH') ⁽³⁾. Co-formulants must be registered under that Regulation including when they are intended for use in plant protection products. They can be identified as substances of high concern in accordance with Article 59 of Regulation (EC) No 1907/2006 or be subject to restrictions in accordance with Title VIII of that Regulation.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products (OJ L 74, 4.3.2021, p. 7).

⁽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).

- (5) A co-formulant should not be accepted for inclusion in plant protection products when it is or has to be classified as carcinogenic, mutagenic or toxic to reproduction, Categories 1A or 1B. To establish a harmonised hazard classification of co-formulants, Member States or manufacturers, importers or downstream users may submit proposals for harmonised classification in accordance with Article 37 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁴⁾.
- (6) A co-formulant should also not be accepted for inclusion in plant protection products where it is identified as substance of very high concern in accordance with Regulation (EC) No 1907/2006 for reasons other than its classification as carcinogenic, mutagenic or toxic to reproduction, Categories 1A or 1B.
- (7) Consequently, if the properties of co-formulants used in plant protection products give rise to concern that their use in plant protection products could lead to harmful effects on human or animal health, Member States should first take appropriate actions in accordance with those two Regulations as such hazard properties are also relevant for all other uses of the substances concerned, and thereafter propose the inclusion of the co-formulants into Annex III to Regulation (EC) No 1107/2009.
- (8) In addition, a co-formulant should not be accepted for inclusion in a plant protection product in cases where the co-formulant has been identified as a persistent organic pollutant under Regulation (EU) 2019/1021 of the European Parliament and of the Council ⁽⁵⁾.
- (9) Furthermore, if a co-formulant used in plant protection products has been identified as having endocrine-disrupting properties under Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽⁶⁾, has not been approved as active substance for use as preservative during storage, or any restrictions have been established in accordance with that Regulation which affect uses in plant protection products, its use in them should be considered unacceptable.
- (10) In the interest of efficiency, consistency and predictability, with regard to the specific restrictions as provided for in Annex XVII to Regulation (EC) No 1907/2006, it is appropriate to guarantee that such restrictions should also apply for all those substances susceptible to be used, or which are currently used, as co-formulants in plant protection products.
- (11) Lastly, in order to maintain coherence with the approval criteria for active substances, safeners and synergists, the criteria for the approval of active substances concerning human or animal health and the environment, as provided for in Annex II to Regulation (EC) No 1107/2009, insofar as not already covered by the other criteria for not accepting co-formulants, should also apply to co-formulants.
- (12) It is necessary and appropriate to lay down rules on the procedure to follow for the inclusion of co-formulants in Annex III to Regulation (EC) No 1107/2009. The information to be submitted by the Member States for such purposes should be specified. To ensure consistency in evaluation, a technical assessment should be performed by the European Food Safety Authority ('the Authority'), following a notification from a Member State and the submission of a pertinent report by the latter on the reasons why a co-formulant might meet the criteria as established in this Regulation, in cases where no action under other Union legislation has been initiated or completed by the notifying Member State. It is necessary to clarify that the Authority should be entitled to require relevant information from the other Member States and, where appropriate, from the European Chemicals Agency.

⁽⁴⁾ 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⁾ 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, p. 45).

⁽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, p. 1).

- (13) Pursuant to Article 27(3) of Regulation (EC) No 1107/2009, the Commission may review co-formulants at any time. In doing so, it may also take into account relevant information provided by the Member States. It is therefore deemed necessary to establish a procedure allowing Member States to notify the Commission about co-formulants already listed in Annex III to Regulation (EC) No 1107/2009 which may need to be deleted from that Annex or about any conditions established in that Annex for co-formulants which may need to be amended.
- (14) This Regulation does not affect the possibility for Member States to temporarily prohibit or restrict the application of a co-formulant within its territory on the basis of Article 81(2) of Regulation (EC) No 1107/2009 subject the conditions laid down in that Article.
- (15) 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

Subject matter

This Implementing Regulation lays down detailed rules and criteria for the identification of co-formulants that are not to be accepted for inclusion in plant protection products ('unacceptable co-formulants').

It applies to applications for authorisation of plant protection products, including for their amendment or renewal, submitted on or after 3 April 2023.

Article 2

Criteria for the identification of unacceptable co-formulants

The criteria for the identification of co-formulants which are considered unacceptable for inclusion in a plant protection product are set out in the Annex.

Article 3

Assessment and notification of co-formulants

1. When assessing applications for authorisation of plant protection products, Member States shall verify whether co-formulants contained in plant protection products could be considered an unacceptable co-formulant based on the criteria set out in the Annex.
2. For the purposes of the verification provided for in paragraph 1, Member State shall carry out an independent, objective and transparent assessment, in the light of current scientific and technical knowledge, on the basis of the information submitted in an application dossier for the authorisation of a plant protection product in accordance with Regulation (EC) No 1107/2009 and including, where appropriate, the information submitted in accordance with Title II of Regulation (EC) No 1907/2006.
3. Following the verification provided for in paragraph 1, the Member State shall notify the other Member States, the Commission and the Authority where it considers that:
 - (a) the co-formulant used or meant to be used in a plant protection product could meet one or more of the criteria set out in the Annex to this Regulation and therefore be an unacceptable co-formulant;

- (b) in the light of new scientific and technical knowledge, the entry of a co-formulant in the list of Annex III to Regulation (EC) No 1107/2009 should be amended; or
- (c) in the light of new scientific and technical knowledge, the entry of a co-formulant in the list of Annex III to Regulation (EC) No 1107/2009 should be deleted.

Article 4

Content of the co-formulant report

1. A notification pursuant to Article 3(3) shall be accompanied by a co-formulant report.
2. The co-formulant report shall contain:
 - (a) the chemical identity of the co-formulant:
 - (1) for a substance as specified in Section 2 of Annex VI to Regulation (EC) No 1907/2006;
 - (2) for a preparation as specified for mixtures in Article 18(3) to Regulation (EC) No 1272/2008;
 - (b) the criteria set out in the Annex which the notifying Member State considers to be met;
 - (c) where appropriate, any specific conditions of use to be set for the co-formulant in Annex III to Regulation (EC) No 1107/2009.
3. Where a co-formulant meets one or more of the criteria set out in points 1 to 3 of the Annex to this Regulation, and it is listed in Annex VI to Regulation (EC) No 1272/2008, the co-formulant report shall include a reference to the relevant entry in Annex VI to Regulation (EC) No 1272/2008 (i.e. the index number or CAS number).

Where a co-formulant is not included in the list in Annex VI to Regulation (EC) No 1272/2008, but the notifying Member State considers that it should be classified for the hazard classes referred to in points 1 to 3 of the Annex to this Regulation, the co-formulant report shall include a reference to the proposal for harmonised classification and labelling that the Member State or a manufacturer, importer or downstream user has submitted pursuant to Article 37 of Regulation (EC) No 1272/2008 to the European Chemicals Agency ('ECHA').

4. Where a co-formulant meets the criterion set out in point 4 of the Annex to this Regulation, the co-formulant report shall include a reference to the relevant entry in Annexes I to V to Regulation (EU) 2019/1021.
5. Where a co-formulant meets one or more of the criteria set out in point 5 of the Annex to this Regulation, and it is included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006, the co-formulant report shall include a reference to the relevant entry in that list.

Where a co-formulant is not included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006, but the notifying Member State considers that it should be identified as referred to in point 5 of the Annex to this Regulation, the co-formulant report shall include a reference to the dossier submitted as referred to in Annex XV to Regulation (EC) No 1907/2006.

6. Where a co-formulant meets one or more of the criteria set out in points 6 to 8 of the Annex to this Regulation, the co-formulant report shall include a reference to the opinion adopted in accordance with Article 8(4) of Regulation (EU) No 528/2012.

7. Where a co-formulant is included in Annex XVII to Regulation (EC) No 1907/2006 and the restriction is relevant for the use in plant protection products, the co-formulant report shall include a reference to the relevant entry in Annex XVII to Regulation (EC) No 1907/2006.

Where the use of a co-formulant is not included in Annex XVII to Regulation (EC) No 1907/2006, but the notifying Member State considers that it poses a risk to human health or the environment which is not adequately controlled and which needs to be addressed in accordance with Article 69(1) or (4) of Regulation (EC) No 1907/2006, the co-formulant report shall include a reference to the dossier referred to in Annex XV of Regulation (EC) No 1907/2006 and submitted to ECHA in accordance with Article 69 of Regulation (EC) No 1907/2006.

8. Where the notifying Member State considers that the notified substance meets the criterion set out in point 10 of the Annex, the co-formulant report shall include the conclusions of the assessment carried out pursuant to Article 3(2).

9. In cases where the co-formulant report includes information that is confidential in accordance with Article 63 of Regulation (EC) No 1107/2009 or the relevant provisions on confidentiality of the regulations referred to in paragraphs 2 to 8, the notifying Member States shall submit a confidential and a non-confidential version of the co-formulant report.

Article 5

Publication

The Commission shall, without undue delay, make the co-formulant report available to the public in an electronic format.

Article 6

Call for information

1. Where Article 4(8) applies, the Authority shall request all Member States to report whether they have authorised any plant protection products containing the notified co-formulant.

2. Where Article 4(8) applies, the notifying Member State – supported by the other Member States when necessary – shall require the holders of authorisations of plant protection products containing the notified co-formulant to submit to the Authority all information and studies on the notified co-formulant available to them.

The holders of such authorisations shall submit the information and studies by the end of the period set out in paragraph 4.

Article 63 of Regulation (EC) No 1107/2009 shall apply to the information and studies submitted.

3. Where Article 4(8) applies and where the notified co-formulant is registered in accordance with Title II of Regulation (EC) No 1907/2006, the notifying Member State or ECHA may, where appropriate, request information from the persons referred to in Article 36 of that Regulation.

4. Where Article 4(8) applies, the Authority shall allow for a period of 120 days after publication of the co-formulant report pursuant to Article 5 to submit comments on or data relevant to that report. It shall make the comments or data received publicly available without undue delay. The Authority may request ECHA to contribute to the call for data.

Article 7

Assessment by the Authority

1. Where Article 4(8) applies, the Authority shall, following a notification pursuant to Article 3(3), carry out an assessment in an independent, objective and transparent manner and in the light of current scientific and technical knowledge, to verify whether the co-formulant is to be considered as unacceptable for inclusion in a plant protection product.

2. The Authority shall issue the results of its work on the technical assessment carried out in accordance with paragraph 1 and update the co-formulant report within 12 months from the end of the period referred to in Article 6(4).

Upon request of the Authority, the notifying Member State shall provide scientific assistance in the preparation of the technical assessment and of the updated co-formulant report.

3. The Authority shall, where appropriate, organise a consultation of experts, including experts from the notifying Member State and, where relevant, the other Member States. In that case, the period provided in paragraph 2 shall be extended by 1 month.

4. The Authority shall consult the Member States and the Commission on its draft technical assessment and shall address any comments received prior to its adoption.

5. The Authority shall establish the format of the document reporting the results of its work, which shall include sections concerning the evaluation procedure and the properties of the co-formulant concerned.

6. Where necessary, the Authority's document reporting the results of its work shall specify whether specific conditions of use should be set for the notified co-formulant in Annex III to Regulation (EC) No 1107/2009.

Article 8

Inclusion of the co-formulant in Annex III to Regulation (EC) No 1107/2009

1. When Article 4(3), first subparagraph, Article 4(4), Article 4(5), first subparagraph, Article 4(6) or Article 4(7), first subparagraph, applies, the Commission shall present a draft Regulation to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 within six months from the notification submitted by the Member State, taking into account the co-formulant report.

2. When Article 4(3), second subparagraph, applies, the Commission shall present a draft Regulation to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 within six months from the adoption of the relevant opinion of the Risk Assessment Committee of ECHA.

3. When Article 4(5), second subparagraph, applies, the Commission shall present a draft Regulation to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 within six months after the publication of the updated list including the notified co-formulant in accordance with Article 59(10) of Regulation (EC) No 1907/2006.

4. When Article 4(7), second subparagraph, applies, the Commission shall present a draft Regulation to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 within six months after the amendment of Annex XVII to Regulation (EC) No 1907/2006 has entered into force.

5. When Article 4(8) applies, the Commission shall present a draft Regulation to the Committee referred to in Article 79(1) of Regulation (EC) No 1107/2009 within six months of receiving from the Authority the document reporting the results of its work and the updated co-formulant report.

6. The Commission shall adopt a Regulation on the basis of Article 27(2) and, where required, Article 78(2) of Regulation (EC) No 1107/2009 providing that:

- (a) a co-formulant is listed in Annex III to Regulation (EC) No 1107/2009, subject to conditions and restrictions, where appropriate;
- (b) a co-formulant is not listed in Annex III to Regulation (EC) No 1107/2009; or
- (c) the entry of a co-formulant in the list in Annex III to Regulation (EC) No 1107/2009 is amended; or
- (d) the entry of a co-formulant is deleted from the list in Annex III to Regulation (EC) No 1107/2009.

*Article 9***Amendments of national lists of unacceptable co-formulants**

Without prejudice to Article 81(2), second subparagraph, of Regulation (EC) No 1107/2009, Member States that have adopted through national provisions lists of unacceptable co-formulants in plant protection products, shall amend those lists in accordance with any Regulation adopted under Article 8.

*Article 10***Entry into force**

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, 13 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Criteria for identification of an unacceptable co-formulant

- (1) The co-formulant is classified as mutagen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
 - (2) The co-formulant is classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
 - (3) The co-formulant is classified as toxic for reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
 - (4) The co-formulant is listed in Annexes I to V to Regulation (EU) 2019/1021.
 - (5) The co-formulant is included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006 (candidate list) due to its identification:
 - (a) as persistent, bioaccumulative and toxic in accordance with Article 57, point (d), of that Regulation;
 - (b) as very persistent and very bioaccumulative in accordance with Article 57, point (e), of that Regulation; or
 - (c) as a substance of very high concern in accordance with Article 57, point (f), of that Regulation due to endocrine disrupting properties.
 - (6) The co-formulant is identified as having endocrine-disrupting properties in accordance with Regulation (EU) No 528/2012.
 - (7) A decision has been adopted not to approve the co-formulant as an active substance for product-type 6 under Regulation (EU) No 528/2012.
 - (8) A decision has been adopted to approve the co-formulant as an active substance under Regulation (EU) No 528/2012 with restrictions which are relevant for uses as co-formulant in plant protection products.
 - (9) The use of a substance as a co-formulant in plant protection products is included in Annex XVII to Regulation (EC) No 1907/2006, as restricted for the use in plant protection products.
 - (10) The co-formulant does not fall under any of the points 1 to 9, but, having regard to realistic conditions of use and good plant protection practice, it does not comply with one of the criteria for the approval of active substances as provided for in Annex II to Regulation (EC) No 1107/2009, when used as a co-formulant in a plant protection product.
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