

Brussels, 21 January 2026
(OR. en)

5598/26

AGRILEG 11
PESTICIDE 3
DENLEG 4
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COVER NOTE

From: European Commission
date of receipt: 20 January 2026
To: General Secretariat of the Council

No. Cion doc.: D105864/06

Subject: COMMISSION REGULATION (EU) .../... of XXX laying down labelling requirements for plant protection products and repealing Regulation (EU) No 547/2011

Delegations will find attached document D105864/06.

Encl.: D105864/06



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2022/1649 Rev. 1
(POOL/E4/2022/1649/1649R1-EN.docx)
D105864/06
[...] (2025) **XXX** draft

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

of **XXX**

**laying down labelling requirements for plant protection products and repealing
Regulation (EU) No 547/2011**

(Text with EEA relevance)

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

of **XXX**

laying down labelling requirements for plant protection products and repealing Regulation (EU) No 547/2011

(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 65(1) thereof,

Whereas:

- (1) Commission Regulation (EU) No 547/2011² contains requirements for the labelling of plant protection products, including standard phrases for special risks to human or animal health and safety precautions for the protection of human or animal health or of the environment as well as the attribution criteria for those standard phrases and safety precautions.
- (2) The labelling requirements for substances and mixtures set out in Regulation (EC) No 1272/2008³ of the European Parliament and of the Council have been amended by Commission Delegated Regulation (EU) 2023/707⁴ and Regulation (EU) 2024/2865⁵. In order to facilitate the implementation and enforcement of Regulation (EC) 1107/2009 and Regulation (EU) 2017/625 of the European Parliament and of the Council⁶, certain elements of the labelling requirements for plant protection products

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

² Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (OJ L 155, 11.06.2011, p. 176, ELI: <http://data.europa.eu/eli/reg/2011/547/oj>).

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, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1272/oj>).

⁴ Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7, ELI: http://data.europa.eu/eli/reg_del/2023/707/oj).

⁵ Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L, 2024/2865, 20.11.2024, ELI: <http://data.europa.eu/eli/reg/2024/2865/oj>).

⁶ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC,

should be aligned to the new labelling requirements applicable under Regulation (EC) No 1272/2008.

- (3) Pursuant to Article 65(3) of Regulation (EC) No 1107/2009, Member States must notify to the other Member States and the Commission the additional national labelling phrases necessary to protect human or animal health or the environment in their territories. The Member States have notified additional phrases requiring personal protective equipment and specific technical equipment for specific tasks. In addition, the Member States have notified phrases that contain risk mitigation measures to address their specific environmental or agricultural circumstances pursuant to Article 36(3) of Regulation (EC) No 1107/2009. The Commission has compiled the additional phrases as notified by the Member States and considered them for inclusion in this Regulation.
- (4) The attribution criteria of some of the standard phrases of Regulation (EC) No 547/2011 were not linked to the outcome of the risk assessment. In order to facilitate the work of the risk managers in the Member States, standard phrases should be assigned to the label of plant protection products for which the risk assessment shows that restrictions of use or specific risk mitigation measures should be applied to protect human health (operators, workers, bystanders and residents) or the environment. Additionally, other phrases that aim to communicate specific good agricultural practices when using fumigants, rodenticides or products for seed treatment are also categorised. At the same time, the Member States should provide supplementary precisions related to the risk mitigation measures identified by the risk managers when authorising a plant protection product pursuant to Article 36(3) of Regulation (EC) No 1107/2009, in spaces or placeholders placed in those standard phrases for that purpose.
- (5) For certain categories of plant protection products, specific precautionary phrases and good agricultural practices should be systematically attributed, independently of the outcome of the risk assessment.
- (6) Digital labels could improve the communication of the potential risks of plant protection products and could offer users advantages like larger fonts, auto-search, voice assistance or translation into other languages. Moreover, digital labels on plant protection products could enhance the transition to digital agriculture and the uptake of precision application techniques, enabling the transfer of the authorised conditions of use to the application machinery, local maps, or weather stations, as well as simplifying the reporting in line with Commission Implementing Regulation (EU) 2023/564⁷. Therefore, it is appropriate to require a digital label for plant protection products, in addition to the physical label, and to lay down requirements concerning the digital labels.
- (7) The physical and digital label of a plant protection product should as a rule contain the same elements, reflecting the content of the authorisation granted, with some limited

2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), (OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>).

⁷ Commission Implementing Regulation (EU) 2023/564 of 10 March 2023 as regards the content and format of the records of plant protection products kept by professional users pursuant to Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ L 74, 13.3.2023, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2023/564/oj).

flexibility during grace periods pursuant to Article 46 of Regulation (EC) No 1107/2009.

- (8) It is appropriate to allow the use of fold-out labels for plant protection products, as well as, for small packages, the possibility to provide the label in a leaflet format accompanying the package. For fold-out labels, the rules applicable to the presentation of fold-out labels under Regulation (EC) No 1272/2008 should apply.
- (9) Following the entry into force of Commission Regulation (EU) 2024/1487⁸ safeners and synergists on the market will become subject to approval at Union level under Regulation (EC) No 1107/2009. It is therefore appropriate that the name of the safener(s) and synergist(s) approved under that Regulation contained in a plant protection product as well as their respective concentration is indicated in the label.
- (10) Pursuant to Article 55 of Regulation (EC) No 1107/2009, proper use of a plant protection product must include the application of the principles of integrated pest management. Therefore, to remind users about the obligation to apply the principles of integrated pest management, a specific standard phrase should be included on the label of plant protection products authorised for professional users.
- (11) The label of the product should inform professional users about the conditions of use of the authorised plant protection product, including the possibility of using precision application techniques. These techniques allow users to apply the authorised plant protection products in a more precise and accurate manner compared to conventional application equipment. They allow a reduction of the plant protection product applied per hectare while maintaining the authorised application rate on the target surfaces. Precision application techniques may contribute to an overall reduction of the environmental exposure to plant protection products and may encourage a more efficient, targeted, and sustainable use.
- (12) To prevent waste from the disposal of the plant protection products' packaging, and not only from the disposal of the plant protection products themselves, standard phrases for their safe disposal should be established.
- (13) To improve the communication to the user about plant protection products potentially hazardous to bees, a specific phrase and pictogram should be established.
- (14) In compliance with Commission Regulation (EU) No 283/2013⁹ and the uniform principles set out in Commission Regulation (EU) No 546/2011¹⁰, all micro-organisms are to be regarded as potential sensitisers until validated tests for assessing their sensitisation are available. Therefore, a specific precautionary sentence to warn about the potential of micro-organisms to cause sensitising reactions should be established.

⁸ Commission Regulation (EU) 2024/1487 of 29 May 2024 defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market (OJ L, 2024/1487, 30.5.2024, ELI: <http://data.europa.eu/eli/reg/2024/1487/oj>).

⁹ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/283/oj>).

¹⁰ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.6.2011, p. 127, ELI: <http://data.europa.eu/eli/reg/2011/546/oj>).

- (15) End users of treated seeds must be informed about the potential risks that may come from the sowing of treated seeds, caused by the plant protection product(s) which have been used to treat the seeds. As the end user of treated seeds does not always have access to the label of the plant protection product(s) with which the seeds are treated, certain standard phrases to communicate risk mitigation measures when handling or sowing the treated seeds should be included both on the label of the plant protection product(s) and on the label and documents accompanying the treated seeds in accordance with Article 49(4) of Regulation (EC) No 1107/2009.
- (16) To provide Member States adequate tools to combat the trade of illegal plant protection products, it is appropriate to establish a specific labelling requirement for plant protection products subject to a parallel trade permit granted under Article 52 of Regulation (EC) No 1107/2009. In line with the judgment of the European Court of Justice in Case C-830/21, Syngenta Agro¹¹, it should be clarified that the batch number of the formulation concerned allocated by the initial manufacturer, the permit number and the name and address of the permit holder should be included on the label of a parallel traded product.
- (17) Pursuant to Article 54 of Regulation (EC) No 1107/2009, plant protection products can be used for research or development purposes. Considering that these products do not require an authorisation and to provide researchers with safety instructions, certain requirements concerning the labelling of plant protection products which are to be used for such purposes should be maintained.
- (18) To ensure that competent authorities, authorisation holders, suppliers and professional or non-professional users have enough time to adapt to the new requirements set out in this Regulation, its date of application should be deferred.
- (19) In addition, a transitional measure should be introduced to ensure a gradual implementation of the new requirements set out in this Regulation on the occasion of new authorisations and renewals of authorisations of plant protection products. Since a draft label must be submitted in applications for such authorisations or renewals, this transitional measure should apply where the respective application was submitted before the date of application of this Regulation. However, where the label of such plant protection products must be amended or is updated, some of the new requirements set out in this Regulation should apply to the amended label without waiting for the next renewal of the authorisation.
- (20) Due to the high number of amendments and in the interest of clarity, it is appropriate to repeal Regulation (EU) No 547/2011 and replace it by a new Regulation.
- (21) 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
General rules

1. The label elements referred to in Articles 3, 4, 5, 6, 7 and 10 of this Regulation shall be provided on a label in a physical form (“physical label”) and in a digital form (“digital label”).

¹¹ Judgment of the Court of Justice of 7 December 2023, *Syngenta Agro*, C-830/21, ECLI:EU:C:2023:959.

2. The authorisation holder or the permit holder of a plant protection product shall ensure that the physical and digital label of the plant protection product contain the same elements. Those elements shall reflect the content of the respective authorisation granted in accordance with Regulation (EC) No 1107/2009.
3. By way of derogation from paragraph 2, where the authorisation of a plant protection product is amended and a grace period is granted under Article 46 of Regulation (EC) No 1107/2009, its digital label may be updated in accordance with the amended authorisation before the end of that grace period.
4. The physical label may be presented in the form of a fold-out label. In that case, section 1.2.1.6 of Annex I to Regulation (EC) No 1272/2008 shall apply *mutatis mutandis*.
5. In the case of small packages, the information required by point (j) to (s) of Annex I may be indicated on a separate leaflet accompanying the package. Such a leaflet shall be regarded as part of the physical label.
6. The authorisation holder or the permit holder of a plant protection product may include additional information on the physical and the digital label, provided it is in accordance with the content of the respective authorisation granted in accordance with Regulation (EC) No 1107/2009.

Article 2 **Digital label**

1. A data carrier as defined in Article 2, point (39), of Regulation (EC) No 1272/2008 linking to the digital label shall be printed on the physical label.
2. The digital label shall be accessible without a need for an account and shall be free of charge.
3. Upon the withdrawal of a plant protection product from the market or, where applicable, upon the end of the grace period referred to in Article 46 of Regulation (EC) No 1107/2009, its digital label shall be deactivated, or a clear statement indicating that the product is no longer authorised in the Member State concerned shall be visible to the user.

Article 3 **Information on the plant protection product identification and its conditions of use**

The label of a plant protection product shall contain information on the plant protection product's identification and its conditions of use as set out in Annex I.

Article 4 **Standard phrases for safe disposal**

The label of a plant protection product shall contain standard phrases for safe disposal of the container of the plant protection product as set out in Annex II, where this is required according to the attribution criteria set out in that Annex.

Article 5

Standard phrases and pictogram for hazard communication

1. The label of a plant protection product shall contain standard phrases for hazard communication as set out in Annex III, where this is required according to the attribution criteria set out in that Annex.
2. The label of a plant protection product shall contain a standard phrase and a pictogram to communicate the potential hazard of the product to bees as set out in Annex III, where this is required according to the attribution criteria set out in that Annex.
3. The label of a plant protection product containing micro-organisms as active substance shall contain a standard phrase to communicate the potential to cause sensitising reactions as set out in Annex IV.

Article 6

Standard phrases for risk mitigation measures

1. The label of a plant protection product shall contain standard phrases for risk mitigation measures as set out in Annex V, where this is required according to the attribution criteria set out in that Annex.
2. The competent authorities shall, if necessary, require supplementary precisions in the standard phrases set out in Annex V where the placeholders or spaces indicate the option of doing so.

Article 7

Standard phrases related to the sowing of treated seeds

1. Standard phrases related to the sowing of treated seeds included in section 7.2 of Annex V shall be placed, where this is required according to the attribution criteria set out in that Annex, both on the label of the plant protection product authorised for seed treatment uses and on the label and the documents accompanying the treated seeds.
2. Where relevant, additional phrases from the label of the plant protection product linked to risk mitigation measures shall be included also on the label and documents accompanying the treated seeds.
3. The competent authorities shall, if necessary, require supplementary precisions in the standard phrases set out in Annex V where the placeholders or spaces indicate the option of doing so.

Article 8

Misleading information on the label

The label of a plant protection product shall not display misleading statements, in particular suggesting that the plant protection product is non-hazardous or statements that are inconsistent with the classification of the plant protection product pursuant to Regulation (EC) No 1272/2008 or inconsistent with the content of the authorisation granted under Regulation (EC) No 1107/2009.

Article 9
Language

The label shall be written in the official language or languages of the Member State where the plant protection product is placed on the market unless the Member State concerned provides otherwise.

Article 10
Parallel traded products

1. The label of a plant protection product for which a parallel trade permit has been granted in one Member State (Member State of introduction) under Article 52 of Regulation (EC) 1107/2009 shall include the following additional elements:
 - (a) permit number;
 - (b) name, address and telephone number of the permit holder. This may replace the name, address and telephone number of the authorisation holder in the Member State of origin.
2. The batch number of the plant protection product shall be the one allocated by the manufacturer of the plant protection product authorised in the Member State of origin.

Article 11
Plant protection products to be used for research and development

1. By way of derogation from Articles 1 to 7 of this Regulation, the label of a plant protection product to be used for experiments or tests for research or development purposes, as provided for in Article 54 of Regulation (EC) No 1107/2009, shall comply, where relevant, only with points (c), (d), (e) and (k) of Annex I.
2. The label shall include information on the specific conditions imposed on the basis of Article 54(1) of Regulation (EC) No 1107/2009 and the words ‘product intended for experimental use, not fully characterised, handle with extreme care’.

Article 12
Transitional measures

1. Regulation (EU) No 547/2011 shall continue to apply to the label of plant protection products for which the authorisation or the latest renewal of the authorisation under Regulation (EC) 1107/2009 has been granted on the basis of an application submitted before 1 January 2028.
2. By way of derogation from paragraph 1, in case the label of a plant protection product concerned has to be amended after 1 January 2028, the amended label of that plant protection product shall contain a digital label as referred to in Article 2.
3. By way of derogation from paragraph 1, the label of plant protection products may already comply with some or all of the requirements of this Regulation. In that case the updated label shall contain at least a digital label as referred to in Article 2.
4. By way of derogation from paragraph 1, by 1 January 2030 at the latest, all labels of plant protection products shall contain a digital label as referred to in Article 2.

Article 13

Repeal

Regulation (EU) 547/2011 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 14

Entry into force and application

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

It shall apply from 1 January 2028.

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