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

of XXX

repealing 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

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**

repealing 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

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) and (3) and Article 78(1)(m) thereof,

Whereas:

- (1) Commission Regulation (EU) No 547/2011² has been applicable since 14 June 2011. That Regulation 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 and its attribution criteria.
- (2) Pursuant to Article 65(3) of Regulation (EC) No 1107/2009, Member States shall 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. Since 2011, Member States have notified to the Commission additional phrases that they considered necessary to protect human or animal health or the environment in their territories and as well as their justification.
- (3) Without prejudice to the hazard statements applicable according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council³, Member States have applied additional phrases to require personal protective equipment and specific technical equipment for specific tasks (in order to ensure the protection of the operators and workers).
- (4) In addition, 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.

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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>).

- (5) Since 2011, the European Commission has been compiling the additional phrases as notified by the Member States. These phrases have been considered for their inclusion in the Commission Regulation (EU) No 547/2011.
- (6) These phrases should be categorised following the risk assessment of plant protection products that assess potential risks for human health (operators, workers, bystanders and residents) and the environment. Additionally, other phrases that aim to communicate specific good agricultural practices when using fumigants, rodenticides or products for seeds treatment should also be categorised.
- (7) To ensure as much as possible a uniform communication to the user of plant protection products around the European Union, the format of the additional phrases notified by Member States have been harmonised in order to be included in this Regulation. At the same time, flexibility needs to be provided so that the phrases again could be adapted 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. Therefore, Annex V prescribed the format of such phrases while the specific content may be adapted.
- (8) The attribution criteria of some of the phrases of the Regulation 547/2011 were not always linked with the outcome of the risk assessment. This could challenge the harmonised way to attribute the relevant phrases to the label of plant protection products by risk managers in Member States. It is essential to have clear, transparent and harmonised attribution criteria for each of the phrases in order to facilitate the work of the risk managers in the Member States. Therefore, Standard phrases should be assigned to the label to plant protection products for which the risk assessment according to the uniform principles show that restrictions of use or specific risk mitigation measures should be applied to protect human health and/or the environment. In addition, for certain groups of plant protection products such as fumigants, rodenticides or products for seeds treatment specific precautionary phrases and good practices recommendations should be systematically attributed, independently of the outcome of the risk assessment.
- (9) Without prejudice to the standard phrases applicable according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, to prevent packaging waste coming from the disposal of the plant protection products containers, phrases for their safe disposal should be included in this Regulation.
- (10) To improve the communication towards the user about products that might be potentially hazardous to bees, a specific phrase and pictogram should be established in this Regulation.
- (11) In compliance with Commission Regulation (EU) No 283/2013⁴ and the uniform principles set out in Commission Regulation (EU) No 546/2011⁵, all micro-organisms are to be regarded as potential sensitisers until validated tests for assessing their sensitisation are available. Without prejudice to the standard phrases applicable

⁴ 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>).

⁵ 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>).

according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, a specific precautionary sentence to warn against the potential sensitisation effects of micro-organisms should be included in this Regulation.

- (12) The users of treated seeds have to be informed about the risk arising out of their sowing and linked to the plant protection product with which they are coated. As the end user of the treated seeds does not always have access to the label of the plant protection product with which they are treated, it is important to include, the relevant phrases related to the risk mitigation measures to be applied when using or sowing the treated seeds both on the label of the plant protection product and on the label and documents accompanying the treated seeds in accordance with Article 49(4) of Regulation (EC) No 1107/2009.
- (13) Pursuant to Article 55 of Regulation (EC) No 1107/2009, proper use of a plant protection product shall include the application of the principles of integrated pest management. To remind the professional user about the obligation to apply the principles of integrated pest management, a specific standard phrase should be systematically included on the label of plant protection products authorised for professional users.
- (14) Precision application techniques allow users to apply the authorised plant protection product in a more targeted manner wherever and whenever necessary. These techniques allow a reduction of the volume of the product applied per treatment, or per ground or canopy area treated while maintaining the authorised dose rate. Precision application techniques may contribute to a reduction of the environmental exposure to plant protection products and encourage a more efficient and sustainable use. It is therefore necessary to inform professional users via the label of the product about the possibility to reduce the volume of applied product when using precision application techniques.
- (15) The Farm to Fork Strategy⁶ adopted by the Commission in 2020, aims to reduce dependency on the use of chemical plant protection products, particularly those containing more hazardous active substances, as well as the risks associated with their use. To contribute to the Farm to Fork Strategy and facilitate the identification by the users of low-risk plant protection products under Article 47 of Regulation (EC) 1007/2009 as well as of plant protection products that contain a candidate for substitution under Article 24 of Regulation (EC) 1107/2009 or a low-risk active substance under Article 22 of Regulation (EC) 1007/2009, a coloured scheme should be included on the label of plant protection products.
- (16) In order to provide Member States adequate tools to fight against 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, established under Article 52 of Regulation (EC) No 1107/2009. In order to implement the judgment of the European Court of justice in case C-830/21, Syngenta Agro, the batch number of the formulation concerned allocated by the initial manufacturer as well as its date of manufacture, the permit number and the name and address of the permit holder should be included on the label and/or packaging of a parallel trade product.

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⁶ Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system (COM/2020/381 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0381>).

- (17) Pursuant to Article 54 of Regulation (EC) No 1107/2009, plant protection products can be used for research or development purposes. In order to provide researchers with safety instructions, provisions concerning the labelling of plant protection products which are to be used for such purposes should be maintained in this Regulation.
- (18) Regulation (EC) No 547/2011 needs to be adapted to technological and societal changes in the field of digitalisation. 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 another 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, labels for plant protection products should be also provided in a digital format which is machine readable.
- (19) Due to the high number of amendments, it's appropriate to replace completely Commission Regulation (EU) No 547/2011 by a new Regulation.
- (20) Plant protection products already on the market at the date of application of this Regulation should continue to comply with the requirements of Regulation (EU) 547/2011.
- (21) To provide flexibility and avoid additional burden on the competent authorities and authorisation holders as well as to ensure that manufacturers, importers, authorisation holders and professional or non-professional users have enough time to adapt to the new the requirements set out in this Regulation, transitional measures should be introduced.
- (22) 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

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

1. The label of a plant protection product shall contain information on the plant protection product identification and its conditions of use as set out in Annex I.
2. The information required by points (k) to (p) of Annex I may be indicated on a separate leaflet accompanying the package if there is not enough space available on the package.

Article 2

Plant protection products to be used for research and development

1. Labelling of plant protection products 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 only with points (c), (d), (e), (g), (i) of Annex I.

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).

2. The label shall include information required by the permit for experimental purposes, provided for in 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 3

Standard phrases for safe disposal

1. The label of a plant protection product shall contain, where relevant, standard phrases for safe disposal of the plant protection product and its packaging as set out in Annex II.
2. The standard phrases referred to in paragraph 1 shall be assigned following the attribution criteria set out in that Annex.

Article 4

Standard phrases and pictogram for hazard communication

1. Without prejudice to Regulation (EC) No 1272/2008, the label of a plant protection product shall contain, where relevant, standard phrases for hazard communication as set out in Annex III.
The label of a plant protection product containing micro-organisms as active substance shall include a standard phrase for hazard communication as set out in Annex IV.
2. The standard phrases referred to in paragraph 1 and 2 shall be assigned following the attribution criteria set out in the respective Annex.
3. The label of a plant protection product shall contain, where relevant a pictogram to communicate the potential hazard of the product to the bees as set out in Annex III.

Article 5

Standard phrases for risk mitigation measures

1. Without prejudice to Regulation (EC) No 1272/2008, the label of a plant protection product shall contain where relevant, standard phrases for risk mitigation measures as set out in Annex V. Each of such phrases shall be assigned following the attribution criteria set out in that Annex.
2. The standard phrases shall be in the format set in Annex V.
3. The competent authorities may adapt if necessary the content of the standard phrases under Annex V.

Article 6

Standard phrases related to the use or sowing of treated seeds

1. Standard phrases related to the use or sowing of treated seeds included in section 7.2 of Annex V shall be placed, where relevant, both on the label of the plant protection product authorised or parallel trade permits for seed treatment uses and on the label or the documents accompanying the treated seeds.
2. Where relevant, additional phrases that aim to communicate the protection of human health or the environment included in other sections of this Regulation shall be included on the label and documents accompanying the treated seeds.

3. The standard phrases shall be in the format set in Annex V.
4. The competent authorities may adapt if necessary, the content of the standard phrases under Annex V.

Article 7
Labelling requirements - coloured scheme

The label of a plant protection product shall contain a coloured scheme that is directly visible to the user, as set out in Annex VI.

Article 8
Formats of label

The label shall be in the following formats:

1. a physical label securely affixed to the packaging of the plant protection product.
 - (a) The physical label may be presented in the form of a fold-out label.
 - (b) If there is not enough space available on the physical label affixed to the packaging, the physical label can be accompanied by a leaflet. Such a leaflet shall be considered as a part of the physical label and shall mention on the front part: 'Read accompanying instructions before use'.
2. and a digital label.

Article 9
General content on the label

1. The physical and digital label shall contain the same information reflecting the content of the plant protection product authorisation or the parallel trade permit granted in accordance with Regulation (EC) No 1107/2009.
2. The digital label may not be an exact copy of every character written on the physical label, but it shall reflect the content of the plant protection product authorisation or the parallel trade permit granted in accordance with Regulation (EC) No 1107/2009.
3. Additional information may be included in any format if it has been approved by the competent authority.

Article 10
Requirements for the digital label

1. The digital label shall be accessible:
 - (a) via a link to a website or any other machine-readable format.
 - (b) without a need of an account
2. The access to the digital label should be free of charge.
3. The link to website or any other machine-readable format to access the digital label shall be printed or placed visibly and legibly on the physical label. The packaging may also contain the link to a website or any other machine-readable format giving access to the digital label.
4. Upon the withdrawal of the plant protection product from the market, its digital label shall be removed by the authorisation holder under the supervision of the competent authority.

Article 11
Misleading information on the label

The label of a plant protection product shall not display statements suggesting that the plant protection product is non-hazardous or statements that are inconsistent with the classification of the plant protection product pursuant Regulation (EC) No 1272/2008 on classification, labelling, and packaging of chemical substances and mixtures.

Article 12
Language

The label shall be written in the official language(s) of the Member State(s) where the plant protection products are placed on the market unless the Member State(s) concerned provide(s) otherwise.

Article 13
Repeal

Commission Regulation (EU) 547/2011 shall be repealed.

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

Article 14
Transitional measures

1. Plant protection products authorised or for which a parallel trade permit has been granted at the date of application of this Regulation shall comply only with the requirements of Regulation (EU) 547/2011.
2. In case of applications for authorisation, as referred to in Article 28 of Regulation (EC) 1107/2009 submitted before the date of application of this Regulation, applicants may choose whether to apply the labelling requirements as set out in this Regulation or in Regulation (EU) 547/2011.

Article 15
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 2026.

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