



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10716/2021
[...](2021) **XXX** draft

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

of **XXX**

**amending Regulation (EU) No 546/2011 as regards specific uniform principles for
evaluation and authorisation of plant protection products containing micro-organisms**

(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 Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms

(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 29(6) and Article 78(1)(c) thereof,

Whereas:

- (1) Commission Regulation (EU) No 546/2011² provides for uniform principles for evaluation and authorisation of plant protection products. Part I and Part II of the Annex to Regulation (EU) No 546/2011 lay down, for plant protection products containing chemical substances and micro-organisms respectively, the existing uniform principles for assessing whether the plant protection products may have harmful effects on human health, animal health or unacceptable effects on the environment in view of their authorisation.
- (2) The Farm to Fork Strategy for a fair, healthy and environmentally friendly food system of the Commission³ aims at reducing dependency on and use of chemical plant protection products, including through facilitating the placing on the market of biological active substances such as micro-organisms. In order to reach these objectives, it is necessary to specify the uniform principles related to plant protection products containing micro-organisms taking into account the most up-to-date scientific and technical knowledge, which has evolved significantly.
- (3) Since micro-organisms are living organisms, a specific approach is needed compared to chemical substances, in order to also take into account the current state of Science regarding the biology of micro-organisms, which are living organisms. That scientific knowledge consists of information on key characteristics of micro-organisms, such as their pathogenicity and infectivity, the possible production of metabolite(s) of concern and the capacity to transfer antimicrobial resistance genes to other micro-organisms

¹ 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 (OJ L 309, 24.11.2009, p. 1).

² 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).

³ 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/?qid=1590404602495&uri=CELEX:52020DC0381>).

which are pathogenic and occurring in European environments, potentially affecting the effectiveness of antimicrobials used in human and veterinary medicine.

- (4) The currently available scientific knowledge on plant protection products containing micro-organisms allows for a better and more specific approach for their assessment, which is based on the mode of action and the ecological characteristics of the respective species and, where applicable, the respective strains of micro-organisms. As it allows a more targeted risk assessment, such scientific knowledge should be taken into account when assessing the risks posed by plant protection products containing micro-organisms.
- (5) In order to better reflect the latest scientific developments and the specificities of micro-organisms, while maintaining a high level of protection of human and animal health and of the environment, it is therefore necessary to adapt the existing uniform principles accordingly.
- (6) Currently available scientific knowledge about the capacity of micro-organisms to transfer antimicrobial resistance genes to other micro-organisms which are pathogenic and occurring in European environments, hence potentially affecting the effectiveness of antimicrobials used in human and veterinary medicine allows for a better and more specific approach for the assessment of which genes encoding for antimicrobial resistance are likely to be transferred to other micro-organisms, and which antimicrobials are those relevant for human and veterinary medicines. In addition, the EU Farm to Fork Strategy has set antimicrobial resistance-related targets. Therefore, further specification is needed on the data requirements to implement the most updated scientific and technical knowledge on transferability of antimicrobial resistance, and ensure for an assessment to be made on whether the active substance may have harmful effects on human or animal health, as indicated in the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009 concerning effects on human and animal health.
- (7) For the sake of clarity of the uniform principles, various points that currently appear in sections A, B and C of both Part I and Part II of the Annex regarding uniform principles should be consolidated in a general introduction.
- (8) The current Annex to Regulation (EU) No 546/2011 contains references to Commission Regulations (EU) No 544/2011⁴ and (EU) No 545/2011⁵, which are no longer in force. It is therefore appropriate to update these references and refer to Commission Regulation (EU) No 283/2013⁶ and Commission Regulation (EU) No 284/2013⁷, respectively, which replaced Regulations (EU) No 544/2011 and (EU) No 545/2011.

⁴ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances (OJ L 155, 11.6.2011, p. 1).

⁵ Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products (OJ L 155, 11.6.2011, p. 67).

⁶ 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).

⁷ Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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. 85).

- (9) The uniform principles for evaluation and authorisation of plant protection products aim to ensure that evaluations and decisions with regard to authorisation of plant protection products by Member States result in a high level of protection of human and animal health and the environment as required by Regulation (EC) No 1107/2009. The uniform principles also give some explanations on how the Member States are to assess data submitted by applicants in accordance with the data requirements as set out in the relevant legislation. Considering that the legislation setting out the data requirements is being amended by **XXX [Office of Publications please insert the reference to the Regulation amending the Regulation 284/2013]** it is necessary to ensure consistency in the application of new rules, so that new applications are submitted according to the amended data requirements.
- (10) Part A of the Annexes to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 sets out the requirements for the data to be assessed in accordance with the uniform principles, and refers to chemical active substances and plant protection products containing them, respectively. For the sake of legal certainty, clarity and consistency with Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, Part I of the Annex to Regulation (EU) No 546/2011 should be renamed as ‘Part A’.
- (11) Part B of the Annexes to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 sets out the requirements for the data to be assessed in accordance with the uniform principles, and refers to active substances that are micro-organisms and plant protection products containing them, respectively. For the sake of legal certainty, clarity and consistency with Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013, Part II of the Annex to Regulation (EU) No 546/2011 should be renamed as ‘Part B’.
- (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

The Annex to Regulation (EU) No 546/2011 is replaced by the text set out in the Annex to this Regulation.

Article 2

Regulation (EU) No 546/2011 as it stood prior to being amended by this Regulation shall continue to apply to applications for authorisation of plant protection products, within the meaning of Regulation (EC) No 1107/2009, for which data is submitted in accordance with Commission Regulation (EU) No 284/2013 in the version applicable before **[Office of Publications: please insert date of application of Regulation (...) amending Regulation (EU) No 284/2013]**.

Article 3

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 (...) **[Office of Publications: please insert the date of application of Regulation (...) amending Regulation (EU) No 284/2013]**

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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