EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for 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) …/…

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amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for 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/EEC[1], and in particular Article 78(1), point (b), thereof,

Whereas:

(1) Commission Regulation (EU) No 284/2013[2] lays down the data requirements for plant protection products containing active substances. For plant protection products containing active substances that are chemicals, these are laid down in Part A of the Annex to that Regulation, and for plant protection products containing active substances that are micro-organisms, these are laid down in Part B of that Annex, with common requirements set out in the introductory part of that Annex.

(2) The Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system[3] 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 those objectives, it is necessary to specify the data requirements 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) Currently available scientific knowledge on plant protection products containing micro-organisms, in particular concerning effectiveness, efficacy, relevance of impurities, and toxicity of certain chemical substances which may be present in these plant protection products, triggers the need to better specify certain definitions which

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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 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 Text (OJ L 93, 3.4.2013, p. 85).

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).

apply for Part B of the Annex to Regulation (EU) No 284/2013. Taking into consideration that these definitions apply also to Part A of that Annex, concerning plant protection products containing chemical active substances, it is appropriate to amend the introduction of the Annex to Regulation (EU) No 284/2013.

(4) Since micro-organisms are living organisms, a specific approach is needed compared to chemical substances, in order to also take into account the new scientific knowledge that has emerged on the biology of micro-organisms. That scientific knowledge consists in new 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 which are pathogenic and occurring in European environments, potentially affecting the effectiveness of antimicrobials used in human and veterinary medicine.

(5) The current state of 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 ecological characteristics of the respective species and, where applicable, the respective strains of micro-organisms. As it allows for 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.

(6) In order to better reflect the latest scientific developments and the specific biological properties of plant protection products containing micro-organisms, while maintaining a high level of protection of human and animal health and of the environment, it is therefore necessary to adapt accordingly the existing data requirements.

(7) It is appropriate to amend Part B of the Annex to Regulation (EU) No 284/2013, in order to update the data requirements to the latest scientific developments and adapt them to the specific biological properties of micro-organisms.

(8) The current title of Part B of the Annex to Regulation (EU) No 284/2013 refers to plant protection products containing micro-organisms including viruses. However, Article 3, point (15), of Regulation (EC) No 1107/2009 already defines viruses as belonging to the group of micro-organisms. It is appropriate to be consistent with Article 3, point (15), of that Regulation, and therefore there is no need to refer to viruses separately.

(9) It is appropriate to introduce a definition of 'Microbial Active Substance as Manufactured' ('MASAM') because certain tests are required to be performed using a sample of the MASAM, rather than using the active substance or the other components of the MASAM after purification. It is indeed more appropriate to refer, with a unique term, to the micro-organism as manufactured and to those components included in the manufacturing batch which might be of relevance for the risk assessment, such as relevant contaminating micro-organisms and relevant impurities.

(10) New scientific knowledge has emerged on the capacity of micro-organisms to transfer antimicrobial resistance genes to other micro-organisms which are pathogenic and occurring in European environments, potentially affecting the effectiveness of antimicrobials used in human and veterinary medicine. This new scientific knowledge allows 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 medicine. In addition, the Farm to Fork Strategy has set antimicrobial resistance-

related targets. Therefore, further specification is needed on the data requirements to implement the most up-to-date scientific and technical knowledge on transferability of antimicrobial resistance, and allow 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.

(11) A reasonable period should be allowed to elapse before the amended data requirements become applicable in order to permit applicants to prepare themselves to meet those requirements.

(12) In order to permit Member States and interested parties to prepare themselves to meet the amended requirements, it is appropriate to lay down transitional measures concerning data submitted for applications for authorisation, renewal of authorisation and amendment to the authorisation of plant protection products containing active substances that are micro-organisms, and concerning data submitted on the representative uses of plant protection products submitted in the context of applications for the approval, renewal of approval or amendment to the conditions of approval of active substances that are micro-organisms.

(13) 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

Amendments to Regulation (EU) No 284/2013

The Annex to Regulation (EU) No 284/2013 is amended as follows:

(a) the Introduction is replaced by the text set out in Annex I to this Regulation;

(b) Part B is replaced by the text set out in Annex II to this Regulation.

Article 2

Transitional measures as regards certain procedures concerning plant protection products containing active substances that are micro-organisms

1. Applicants shall submit data, in the context of applications for authorisation of plant protection products within the meaning of Regulation (EC) No 1107/2009 containing one or more active substances that are micro-organisms, in accordance with Part B of the Annex to Regulation (EU) No 284/2013 as it stood before being amended by this Regulation in the following cases:

(a) the application for authorisation is submitted by … [2 years and 6 months after the date of entry into force of this Regulation];

(b) the dossiers for all the active substances contained in the plant protection product concerned have been submitted in accordance with Regulation (EU) No 283/2013 as it stood before being amended by Commission Regulation XXX[4] [PO: please, insert number for Implementing Regulation amending Regulation (EU) No 283/2013 and a footnote with reference].

[4] Commission Regulation …. (OJ L…, p. …).

2. As a derogation from paragraph 1, applicants may choose, from [6 months after the date of entry into force of this Regulation] to submit data in accordance with Part B of the Annex to Regulation (EU) No 284/2013 as amended by this Regulation.

3. Where applicants make the choice provided for in paragraph 2, they shall specify that choice in writing when submitting the application concerned. Such choice shall be irrevocable for the procedure concerned.

Article 3

Transitional measures as regards certain procedures concerning active substances that are micro-organisms and are contained in plant protection products

Regulation (EU) No 284/2013 as it stood before being amended by this Regulation shall continue to apply as regards data required on one or more representative uses of a plant protection product, submitted before … [6 months after the date of entry into force of this Regulation] to fulfil the requirements of one of the following provisions:

(a) Article 8(1), point (a), of Regulation (EC) No 1107/2009;

(b) Article 7(1), point (c), of Commission Implementing Regulation (EU) No 844/2012[5];

(c) Article 6(2), point (c), of Commission Implementing Regulation (EU) 2020/1740[6].

Article 4

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 … [6 months after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in 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 252, 19.9.2012, p. 26).

6 Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).