Ref. Ares(2021)6603580 - 26/10/2021

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/12040/2020
[…](2021) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms

(Text with EEA relevance)

DRAFT

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 283/2013 as regards the information to be submitted for active substances and the specific data requirements for 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)(b) thereof,

Whereas:

(1) Commission Regulation (EU) No 283/2013[2] lays down data requirements for active substances. For active substances that are chemicals, these are laid down in Part A of the Annex to that Regulation, and for 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 micro-organisms taking into account the most up-to-date scientific and technical knowledge, which has evolved significantly.

(3) The currently available scientific knowledge concerning metabolites produced by micro-organisms allows for a better understanding of the role those metabolites play in the mode of action of micro-organisms producing them. Taking into consideration that metabolites produced by micro-organisms are chemical substances, their possible contribution to the mode of action may lead to legal uncertainty on whether applications are to comply with the requirements provided for in Part A of that Annex concerning chemical active substances, or in Part B thereof, concerning micro-organisms. It is therefore appropriate to amend the introduction of the Annex to Regulation (EU) No 283/2013, in order to better specify, based on the properties of the

---

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 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).

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).

active substances, and in particular of the metabolites produced by micro-organisms, when applications are to comply with the requirements provided for in Part A of that Annex, or in Part B thereof.

(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 micro-organisms allows for a better and more specific approach for their assessment, which is based on their mode of action and the 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 active substances that are micro-organisms.

(6) In order to better reflect the latest scientific developments and the specific biological properties 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 data requirements accordingly.

(7) In general, micro-organisms used for plant protection are active against a specific group of pests, and their specific modes of action may intrinsically not be of relevance as regards effects on human and animal health. They may well produce metabolites that would require specific exposure and risk assessment. Their host-specificity may well limit the risk of persistent effects on non-target organisms, compared to chemical substances, reducing also the relevance of animal testing to establish their pathogenic profile. All these specific characteristics of micro-organisms are important to differentiate the way to conduct the risk assessment for micro-organisms compared to the way it is being done for chemical substances. It is therefore appropriate to amend Part B of the Annex to Regulation (EU) No 283/2013 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 283/2013 refers to micro-organisms including viruses. However, Article 3, point (15) of Regulation (EC) 1107/2009 already defines viruses as belonging to the group of micro-organisms. It is therefore appropriate to adapt that title to be consistent with Article 3, point (15) of that Regulation.

(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 one 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

DRAFT

occurring in European environments, potentially affecting the effectiveness of antimicrobials used in human and veterinary medicine. This new scientific knowledge 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 up-to-date scientific and technical knowledge on transferability of antimicrobial resistance, and allow 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.

(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 fulfil the new requirements, it is appropriate to lay down transitional measures concerning data submitted for applications for the approval, renewal of approval or amendment to the conditions of approval of active substances that are micro-organisms and 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.

(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 283/2013

The Annex to Regulation (EU) No 283/2013 is amended as follows:

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

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

Article 2

Transitional measures as regards certain procedures concerning active substances that are micro-organisms

1. Applicants may submit data in accordance with Part B of the Annex to Regulation (EU) No 283/2013 as it stood before being amended by this Regulation in the following cases:

   (a) procedures concerning the approval of an active substance that is a micro-organism or an amendment to the approval of such a substance for which the dossiers provided for in Article 8(1) and (2) of Regulation (EC) No 1107/2009 are submitted before … [one year after the day of entry into force of this Regulation];

   (b) procedures concerning the renewal of approval of an active substance that is a micro-organism where the application for renewal referred to in Article 5 of

DRAFT

Commission Implementing Regulation (EU) 2020/1740[4] is submitted before [one year after the date of entry into force of this Regulation].

2. Where applicants choose to apply the option provided for in paragraph 1, 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 plant protection products containing active substances that are micro-organisms

1. 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, where the dossiers have been submitted in accordance with Article 2 of this Regulation or a decision on the renewal of the approval has not been taken in accordance with Article 20 of Regulation (EC) No 1107/2009 on the basis of Part B of the Annex to this Regulation, applicants:

   (a) shall submit data in accordance with Part B of the Annex to Regulation (EU) No 283/2013 as it stood before being amended by this Regulation, unless they act in accordance with point (b) of this paragraph;

   (b) 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 283/2013 as amended by this Regulation.

2. Where applicants choose to apply the option provided for in paragraph 1(b), they shall specify that choice in writing when submitting the application concerned. Such choice shall be irrevocable for the procedure concerned.

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 all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

[4] 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).

DRAFT