



Brussels, **XXX**
SANTE/10686/2021
[...](2021) **XXX** draft

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

of XXX

amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are 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 Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are 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 22(3) and 78(1)(a) thereof,

Whereas:

- (1) Regulation (EC) No 1107/2009 lays down, among others, rules for the procedure and criteria for the approval of active substances, safeners and synergists.
- (2) The Farm to Fork Strategy for a fair, healthy and environmentally friendly food system of the Commission² aims at reducing dependency on 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 approval criteria related to micro-organisms taking into account the most up-to-date scientific and technical knowledge, which has evolved significantly.
- (3) The existing procedures and criteria for the approval set out in Annex II to Regulation (EC) 1107/2009, which are used to assess whether active substances may have harmful effects on human health, animal health, or unacceptable effects on the environment, are referring to the properties of micro-organisms. Since micro-organisms are living organisms, a specific approach is needed compared to chemical substances, in order to also take into account the currently available scientific knowledge that has been gathered on the biology of micro-organisms, such as on their pathogenicity and infectivity, the possible production of metabolite(s) of concern and the capacity to transfer anti-microbial 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.
- (4) The current state of scientific knowledge on micro-organisms allows for a better and more specific approach for their assessment, which is based on the biological and ecological characteristics of the respective species and, where applicable, 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 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>).

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 and plant protection products containing these substances.

- (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 accordingly the criteria in Annex II to Regulation (EC) No 1107/2009.
- (6) Point 3.1(b) of Annex II to Regulation (EC) No 1107/2009 provides for the information to be submitted by the applicant in the dossier in order to reliably predict residues in food and feed. Based on the available scientific knowledge, it is now known that residues for which an assessment is required in the case of micro-organisms are different than those needed to assess chemical active substances: the presence of micro-organisms that are non-pathogenic to humans and animals onto or into edible parts of treated crops does not constitute *per-se* a hazard and only residues of chemical substances which are relevant for human and animal health may constitute a hazard or risk, i.e. the toxic metabolites possibly produced by the micro-organisms. For the sake of clarity, it is therefore appropriate to provide for this differentiation, so that it is possible to reliably predict relevant residues in relation to micro-organisms.
- (7) Point 3.4 of Annex II to Regulation (EC) No 1107/2009 refers to the composition of active substances, safeners or synergists. However, the current provisions do not apply for micro-organisms due to their different nature compared to chemicals. Indeed, the concepts of isomers and diastereo-isomers mentioned in the current provision are only relevant for chemical substances and not for any living organism, including micro-organisms. Moreover, it is necessary to specify the appropriate information required to define the composition of an active substance that is a micro-organism, such as the taxonomical identification, the deposition of the micro-organism strain at an internationally recognised culture collection including its accession number, and the content of the active substance in units which used in microbiology. It is therefore appropriate to specify this suitable information for micro-organisms.
- (8) Point 3.5 of Annex II to Regulation (EC) No 1107/2009 refers to methods of analysis of active substances and other components occurring in the manufacturing batch. Currently available scientific knowledge includes knowledge regarding the risk assessment of relevant impurities and contaminating micro-organisms occurring during manufacturing of micro-organisms, and on metabolites produced by them. In addition, due to the different nature of active substances which are micro-organisms compared to chemicals, manufacturing batches and processes are different, and a specific approach is needed for micro-organisms compared to chemicals. Taking into consideration this scientific knowledge and these differences between active substances which are micro-organisms and chemicals, it is therefore appropriate to specify methods of analysis used for micro-organisms.
- (9) Point 3.6 of Annex II to Regulation (EC) No 1107/2009 refers to the assessment of the impact of active substances, safeners and synergists on human health. As regards active substances that are micro-organisms, currently available scientific knowledge includes knowledge regarding the assessment of pathogenicity of micro-organisms to humans and infectivity of viruses and the capacity of bacteria to transfer anti-microbial resistance genes to other micro-organisms, potentially affecting the effectiveness of antimicrobials used in human and veterinary medicine has been collected. This

scientific knowledge shows that further specification is needed regarding the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009, implementing the most up-to-date scientific and technical knowledge in the risk assessment of micro-organisms. It is therefore appropriate to specify the approval criteria applying for micro-organisms.

- (10) Specifically on anti-microbial resistance, the current state of scientific knowledge on the capacity of micro-organisms to transfer antimicrobial resistance genes 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 to 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 concerning effects on human and animal health.
- (11) Point 5.2.1 of Annex II to Regulation (EC) No 1107/2009 sets out the criteria for considering active substances that are micro-organisms as low-risk active substances and currently refers to the possible occurrence of multiple resistance to antimicrobials. Without any reference to the possibility of this resistance to be transferred, these criteria refer to the number of treatment options with antimicrobials which are effective against the active substance that is a micro-organism. Indeed, although micro-organisms can only be approved if not pathogenic, not infective under the recommended conditions of use, and not infective to humans under any circumstances if they are viruses, it is necessary to ensure that a certain number of treatment options with effective antimicrobials are available in order to maintain a high level of protection of human health in the unlikely event of an opportunistic infection, especially in vulnerable groups of the population. However, the possible occurrence of multiple resistance to a certain number of antimicrobials as currently outlined in point 5.2.1 does not clarify the number of effective treatment options based on antimicrobials which are available. It is therefore appropriate to specify the low-risk criteria applying for bacteria and fungi. For the sake of clarity and legal certainty, it is therefore appropriate to further specify the criteria to consider an active substance that is a micro-organism as low-risk active substance, by referring to the number of antimicrobial agents against which the micro-organism is demonstrated susceptible. In addition, it is appropriate to specify that such criteria apply only for bacteria and fungi and not for viruses, since viruses are usually provided by a narrow host range, and viruses which are infective to humans would be excluded from approval.
- (12) Point 5.2.2 of Annex II to Regulation (EC) No 1107/2009 sets out the criteria to consider baculoviruses as low-risk active substances. However, new applications for approval concerning viruses belonging to species other than the baculovirus species, and used as active substances in plant protection products have been submitted. It is therefore appropriate to include low-risk criteria which are applicable also to other species of viruses. In addition, the currently available scientific knowledge on viruses used as active substances in plant protection products, in particular for those viruses which are non-virulent variants of plant pathogens makes it possible to identify those active substances which may be approved only where, under the proposed conditions of use, the likelihood of regaining virulence and causing adverse effects in target and

non-target plants through mutation is negligible. In light of this concern, it is appropriate to provide that viruses which are non-virulent variants of plant pathogens are not to be considered as low-risk active substances when the likelihood of regaining virulence and causing adverse effects in target and non-target plants could not be entirely excluded, i.e. through further genomic analysis. It is therefore appropriate to specify the low-risk criteria applying to these viruses other than baculovirus.

- (13) As the amended criteria reflect the current state of scientific and technical knowledge and clarify the existing criteria, the new criteria should apply as soon as possible however in for legal certainty a transitional regime needs to be provided for in this Regulation.
- (14) 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
Amendment to Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended in accordance with the Annex to this Regulation.

Article 2
Transitional measures

Regulation (EC) No 1107/2009 in the version applicable on [date prior to the date of application of this act] shall continue to apply 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 substances for which the dossiers provided for in Article 8(1) and (2) of Regulation (EC) No 1107/2009 were submitted before [the date of application of this act];
- (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 Commission Regulation (EU) 2020/1740 was submitted before [the date of application of this act].

Article 3
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 [Office of publications: please insert 6 months after the entry into force].

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