REGULATIONS

COMMISSION REGULATION (EU) 2022/1438

of 31 August 2022

amending Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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/EEC ([1]), and in particular Article 22(3) and Article 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 Commission ([2]) 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 that objective, 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) No 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 or 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 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.

([1]) 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).

(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 for which an assessment may be required in the case of chemical active substances: the presence of micro-organisms that are non-pathogenic to humans and animals on or in 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 are 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 of 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 actives 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, 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 or veterinary medicine. 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 or veterinary medicine. 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.

(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 several 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 some 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 micro-organisms other than viruses. 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 micro-organisms other than viruses, since viruses are usually provided with 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 reverting to virulent 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 causing adverse effects in non-target plants could not be entirely excluded. It is therefore appropriate to specify the low-risk criteria applying to viruses which are non-virulent variants of plant pathogens, rather than to baculovirus only.

(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, 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 20 November 2022 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 substance for which the dossiers provided for in Article 8(1) and (2) of Regulation (EC) No 1107/2009 are submitted before 21 November 2022;

(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 Implementing Regulation (EU) 2020/1740 ([3]) is submitted before 21 November 2022.

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 21 November 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 August 2022.

For the Commission
The President
Ursula VON DER LEYEN

([3]) 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).

ANNEX

Annex II to Regulation (EC) No 1107/2009 is amended as follows:

(1) point 3.1(b) is replaced by the following:

'(b) reliably predict the residues in food and feed, including succeeding crops, on the basis of information provided in accordance with the data requirements for active substances;';

(2) point 3.4 is replaced by the following:

'3.4. **Composition of the active substance, safener or synergist**

3.4.1. For chemical active substances, safeners and synergists, the specification shall define the minimum degree of purity, the identity and maximum content of impurities and, where relevant, of isomers/diastereo-isomers and additives, and the content of impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.

3.4.2. For chemical active substances, safeners and synergists, the specification shall be in compliance with the relevant Food and Agriculture Organisation specification as appropriate, where such specification exists. However, where necessary for reasons of protection of human or animal health or the environment, stricter specifications may be adopted.

3.4.3. Active substances that are micro-organisms shall be deposited at an internationally recognised culture collection and shall have an accession number. The species' name of the micro-organisms shall be identified unequivocally, based on the latest scientific information, and the micro-organisms shall be named at the strain level, including any other designation which may be relevant (e.g. isolate level, if relevant for viruses). It shall be indicated whether or not the micro-organisms are wild types, spontaneous or induced mutants, or genetically modified organisms.

3.4.4. For active substances that are micro-organisms, the specification shall define the minimum and maximum content of the micro-organism, the identity and content of relevant contaminating micro-organisms, metabolites of concern and impurities of toxicological, ecotoxicological or environmental concern within acceptable limits.';

(3) point 3.5 is replaced by the following:

'3.5. **Methods of analysis**

3.5.1. The methods of analysis of chemical active substances, safeners or synergists as manufactured and of determination of impurities of toxicological, ecotoxicological or environmental concern or which are present in quantities greater than 1 g/kg in the active substance, safener or synergist as manufactured, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.2. The methods of residue analysis for chemical active substances and relevant metabolites in plant, animal and environmental matrices and drinking water, as appropriate, shall have been validated and shown to be sufficiently sensitive with respect to the levels of concern.

3.5.3. The evaluation shall have been carried out in accordance with the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6).

3.5.4. For active substances that are micro-organisms, the methods of analysis to identify and quantify them, and relevant contaminating micro-organisms, shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.

3.5.5. For active substances that are micro-organisms, the methods of analysis of metabolites of concern and relevant impurities shall have been validated and shown to be sufficiently specific, correctly calibrated, accurate and precise.';

(4) the following point 3.6.6 is added after point 3.6.5:

'3.6.6. Active substances that are micro-organisms shall only be approved if, on the basis of the assessment carried out on the information provided in accordance with the data requirements, it is concluded that the strain of the micro-organism is not pathogenic to humans.

In addition:

(a) viruses shall only be approved if, on the basis of the assessment carried out on the information provided in accordance with the data requirements, it is concluded that the isolate of the virus is not infective to humans;

(b) strains of bacteria shall only be approved if, on the basis of the assessment carried out on the information provided in accordance with the data requirements, it is concluded that they do not have any known, functional and transferable gene coding for resistance to relevant antimicrobial agents as defined in accordance with the data requirements.';

(5) point 5.2 is replaced by the following:

'5.2. Micro-organisms

5.2.1. An active substance that is a micro-organism other than a virus may be considered a low-risk active substance unless its susceptibility to at least two classes of antimicrobial agents has not been demonstrated.

5.2.2. An active substance that is a virus may be considered a low-risk active substance unless it is:

(a) a baculovirus with demonstrated adverse effects on non-target insects; or

(b) a non-virulent variant of a plant pathogen with demonstrated adverse effects on non-target plants.'.