EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Brussels,
SANTE/E4/DD/ai (2022) 2225100

Dear Mr Praaning Prawira Adiningrat,

Subject: Your email of 16 February 2022 concerning questions from the PA International Foundation and the Microbial Plant Protection Products Task Force on regulatory developments with regards to plant protection products

Thank you for your above-mentioned email to Mr [redacted], Member of the Cabinet of Executive Vice-President Timmermans, who asked me to respond on his behalf. With your mail you shared a proposal for a potential Commission Communication related to Recital 17 of Regulation (EC) No 1107/2009 on the placing on the market of plant protection products and you recalled that you had asked a number of questions to DG SANTE.

In the following, please find the responses to your questions.

Question 1, 4, 5, and 6: The Commission agrees with the Task Force that biological tools for plant protection such as micro-organisms have a strong potential to replace chemicals. That is why four Implementing Regulations[1] were prepared by the Commission, setting out new data requirements, approval criteria, and decision-making principles for micro-organisms and plant protection products (PPP) containing them. These draft implementing regulations will contribute to speed-up the access to the market of micro-organisms and PPP containing them, reducing the burden of preparing and evaluating applications by making the assessments more focused (e.g. with a "weight of evidence approach" in human toxicology, rather than requiring animal studies compulsorily). The implementing regulations were endorsed by the Member States in the Standing Committee on Plants, Animals, Food and Feed in February 2022 and will be subjected to scrutiny of the European Parliament and the Council.

We maintain the view that Regulation (EC) No 1107/2009 on the placing on the market of plant protection products already contains provisions that require Member States to evaluate applications for authorisation of plant protection products (PPP) containing micro-organisms

[1] https://ec.europa.eu/food/plants/pesticides/micro-organisms_en

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(and other low-risk active substances) faster than other PPP (120 days compared to one year). Likewise, Member States acting as rapporteurs for the approval of micro-organisms as active substances can give priority to these applications and deliver their assessments faster than for other active substances. The Commission regularly encourages Member States to give priority to the assessment of applications for biological active substances and PPP containing them and has provided specific support to Member States to re-enforce their expertise in this area through a Better Training for Safer Food programme[2]. A Commission Communication as you suggest would essentially only repeat the same messages already given multiple times to the Member States at all levels.

Thank you for informing us of the letter from the Dutch Government dated 25 January 2022 to the Dutch Parliament. In that letter, the Dutch Government mentions that the Commission's proposals represent a clear improvement in technical terms, and that it is expected that these improvements will lead to better dossiers and assessments. In the same letter, the Dutch Government calls for more actions to accelerate access to the market of micro-organisms. Please be informed that the Commission is already working on additional actions, e.g. two new Communications which will complement the new data requirements set out in Part B of Reg. (EU) 283/2013 and Reg. (EU) 284/2013, respectively, defining where relevant the test methods and guidelines needed to fulfil the data requirements.

It is now up to Member States to show the political will to make the necessary resources available and give priority to the processing of applications for micro-organisms and products containing them, and/or reducing application fees for their assessment to encourage this kind of applications. We encourage you and interested companies to approach the responsible Ministers in the Member States directly in this regard.

Question 2. The Commission values open and transparent debate between regulators and stakeholders. Stakeholders have been kept informed during the drafting of the four Implementing Regulations mentioned above through the Advisory Group on the Food Chain and Animal and Plant Health, through presentations at conferences, as well as through several meetings. For instance, an *ad-hoc* Biopesticide Working Group meeting with stakeholders was proactively organised by DG SANTE on 11 November 2021, when the public consultation on the four draft Regulations was still open (i.e. from 26 October 2021 to 23 November 2022). Several relevant suggestions provided by stakeholders were taken over in the texts that are now endorsed by Member States. In addition, on 11 January 2022 DG SANTE organised a meeting with the Microbial Plant Protection Products Task Force to further discuss the comments the Task Force had provided through the public consultation.

Question 3. As mentioned in the response above, the Commission agrees that Member States should give priority to and speed up the evaluation of applications related to micro-organisms. However, a comparison with regulatory frameworks for pesticides of other countries is not useful, as those mentioned by you also authorise chemicals much more quickly, including many chemicals that are banned in the EU because of safety concerns. In addition, the EU is a major contributor to the harmonisation works steered by the OECD at global level regarding biopesticides.

Question 7. We do believe that the new data requirements mentioned above will facilitate access to market of micro-organisms used in PPP. Compared to the Regulations currently in force, the four Implementing Regulations are more fit-for-purpose as they focus on the

[2] https://btsfacademy.eu/training/course/view.php?id=304

specific biological and ecological properties of each microorganisms under assessment, instead of mirroring the chemical assessment as it is done today. During the public consultation, several stakeholders have explicitly appreciated this approach.

The new data requirements will therefore foster the quality of dossiers, accelerate swift assessments, and hence speed-up the access to market of micro-organisms. The burden and costs for applicants and evaluators will be reduced due to the focus on needed-to-know data, while still keeping safety standards high. This reduction of burden can be illustrated by the following (not exhaustive) examples:

i. **Explicit introduction of conditional data requirements**. For instance, the whole Section 6 of the amended Reg. (EU) 283/2013 (i.e. "Residues in or on treated products, food and feed") is triggered only if metabolites with hazard to human health are identified.
ii. **Explicit introduction of the weight of evidence (WoE) approach.** In several sections of the Regulations, less data generation will be needed compared to what is required under the current data requirements. For instance, point 5.2 of the amended Reg. (EU) 283/2013 (i.e. "Assessment on potential infectivity and pathogenicity of the micro-organism to humans") explicitly enables applicants to conclude on absence of infectivity and pathogenicity of micro-organisms to humans by using weight of evidence based e.g. on biological properties of the micro-organism, published peer-review literature, and other reliable sources. Compared to the current framework, this reduces the need of performing animal studies, reduces the burden for dossier preparation (less pathogenicity/infectivity studies, hence less costly application dossiers), embraces a more ethical approach (less tests on vertebrate animals), and provides more scientifically reliable conclusions.
iii. **Removal of several not necessary requirements.** Compared to the framework currently in force, based on scientific evidence the new data requirements have no explicit provisions for tests to be performed on earthworms and non-target soil micro-organisms (respectively points 8.5 and 8.6 of the Reg. (EU) 283/2013 currently into force).
iv. **Metabolites of concern (MoC)**. The new data requirements are more explicit in establishing conditionality, thus no longer requiring a complete data package on MoC by default, and thus reducing the amount of data to be provided (and studies to be performed) if these data are not relevant for the risk assessment. In addition, the new data requirements do not require data on unknown metabolites which are only produced *in-situ* as they are expected to occur at low levels. In addition, for micro-organisms that are ubiquitous, exposure to such metabolites is expected to occur already naturally. These approaches derived from new scientific knowledge lead to risk assessments which are robust while requiring only strictly-necessary data.

In response to your request to establish a specific definition for "low-risk microbial plant protection products", please note that the status of "low-risk" may apply also to chemical active substances, not only to micro-organisms. Regulation (EC) No 1107/2009 already specifies the conditions when an active substance may be considered "low-risk", namely in Article 22, Article 47(1) and point 5 of Annex II.

Question 8. As regards your point on the approval system for micro-organisms used in PPP, please refer to the answer to question 1. In addition, we are not aware of any micro-organism being used in all the product categories listed in your question.

Please be aware that the legal requirements for different product categories are tailored to the respective use patterns of these products, and that the potential exposure of humans and the environment from them. It is therefore not surprising that the requirements are different for different product categories.

Possibilities to achieve coherence of assessments conducted for different uses of chemicals are currently discussed in the context of the chemicals strategy for sustainability under the "one substance one assessment" process.

Question 9. As explained under Recital 11 of the Implementing Regulation amending Annex II to Reg. (EC) No 1107/2009, the low-risk criterion set under point 5.2.1 has not been substantially changed in content, but rather clarified for legal certainty. Point 5.2.1 of the Annex II to Reg. (EC) 1107/2009 currently in force refers to multiple resistance to antimicrobials as a reason for excluding micro-organisms from low-risk status, without clarifying the number of effective treatment options that should be available. The amendment in the relevant draft Implementing Regulation specifies the number of treatment options needed that allow to grant the low-risk status, thus increasing legal certainty for the application of this low-risk criterion.

We do believe that there is no need to provide a definition of "classes" of antimicrobial agents. Definitions of "antimicrobial agents" and many other related terms are provided in the Implementing Regulations on data requirements and uniform principles, and an ad-hoc guidance document (SANTE/2020/12260[3]). In addition, please note that certain terms like "classes" (i.e. when referring to "classes of antimicrobials") do not need definitions in legislation, as they are basic terms commonly used in biology. Indeed, the four Implementing Regulations refer to the lists of antimicrobials used by the World Health Organisation[4], where the term "classes of antimicrobials" is used.

Question 10. Indeed, the four Regulations amend only those parts of the existing Regulations that needed an update to the latest science. Point 3 of the Introduction to Reg. (EU) 284/2013 on Good Laboratory Practice (GLP) (including the derogation for micro-organisms under point 3.4) was not amended. This means that the existing derogation will continue to apply, and that micro-organisms tests and analyses may be conducted by official or officially recognised testing facilities or organisations without the obligation to be compliant with GLP.

Question 11. The Commission proposal for the revision of the Directive on the Sustainable Use of Pesticides is in preparation and specific discussions on the content cannot be pre-emptied. As mentioned in several public events, giving priority to non-chemical methods (as long as they offer adequate plant protection) is one of the principles of Integrated Pest Management (IPM), which is already a cornerstone of the Directive. The use of PPP containing micro-organisms clearly falls into this group of less hazardous practices.

Question 12. Article 51 of Reg. (EC) No. 1107/2009 already establishes specific provisions regarding so-called minor uses, such as the possibility to apply for extensions of approvals from major crops or for mutual recognition of minor uses authorised in other Member States. Moreover, other procedures, such as those provided in Article 40 of Regulation (EC) No.

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[3] https://ec.europa.eu/food/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf

[4] https://apps.who.int/iris/bitstream/handle/10665/312266/9789241515528-eng.pdf?ua=1.

1107/2009, may also facilitate the authorisation of PPP in crops or pests concerning minor uses.

Question 13. The application for approval of the active substance and the authorisation of a PPP must demonstrate compliance with what is required by Reg. (EC) No. 1107/2009. It is responsibility of the applicant to demonstrate whether there is a risk that resistance would occur, and which measures need to be taken to reduce such risk, including appropriate use patterns to be described representative use in accordance with Good Agricultural Practices. An application pattern as described in your question seems possible, and it would need to be described in the application at the moment of the submission of the dossier, in order to be then assessed for the specific case.

Question 14. The draft Implementing Regulation amending Regulation (EU) 283/2013 increases clarity and legal certainty on the possibility of using consortia of micro-organisms. The Introduction to Annex I of the draft Regulation clearly states that:

> "*A dossier shall be submitted in accordance with Part B if the active substance is:*
>
> > *(a) a micro-organism, either as a single strain or* ***as a qualitatively defined combination of strains as they occur naturally or by manufacture****, or*
> >
> > *(b) a micro-organism, either as a single strain or* ***as a qualitatively defined combination of strains as they occur naturally or by manufacture****, and one or more metabolites produced by the micro-organism that are claimed to be part of the plant protection action (i.e. when the application of the metabolite(s) purified from the micro-organism would not cause the claimed plant protection action).*"

To conclude, let me emphasise again that we share the Task Force's ambition for more approved micro-organisms and authorized plant protection product uses containing them, as an alternative to chemical pesticides. We believe that the four draft Regulations that we have proposed are a significant milestone to achieve this. Provided the regulations are adopted after scrutiny of the European Parliament and the Council, it will be up to applicants and Member States to make good use of the new provisions and to implement them. The Commission will continue to remind Member States of their obligations in this regard.

Yours sincerely,