EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Brussels,
SANTE/E4/DD/ai(2022)4967800

Dear Mr Praaning Prawira Adiningrat,

Subject: Your email of 23 May 2022 with questions from the PA International Foundation and the Microbial Plant Protection Products Task Force on microbial plant protection products

Thank you for your above-mentioned email and your suggestions concerning the placing of microbial plant protection products on the market.

With your message, you transmitted a list of comments related to the Commission's proposals for revising the data requirements, approval criteria and assessment principles for active substances that are micro-organisms and products containing them. While some of your remarks are appreciative, most are rather critical, expressing doubts that the new Regulations will not bring significant improvements and repeating your earlier calls for a completely separate legal framework instead.

While I take note of your views, I would like to recall that the newly proposed data requirements, assessment principles and approval criteria have been elaborated in close consultation with experts from the Member States, who ultimately have the main responsibility for conducting evaluations of dossiers for active substances and plant protection products. In the collective view of the Commission and the Member States, they strike the right balance between flexibility and specificity (i.e. to allow data waiving where appropriate to avoid requiring "nice to know" information if not needed). Due to the heterogeneous nature of micro-organisms that are or will be used in plant protection, it was not possible to develop a 'one size fits all' proposal.

I do not agree with your view that the new Regulations will require more data compared to the existing framework - we actually expect the contrary. As regards secondary metabolites, I would like to refer you to an already endorsed guidance[1] that has been developed earlier, precisely again with the objective to avoid unnecessary demands for data. I also note your

[1] Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances in accordance with article 77 of regulation (EC) No 1107/2009 https://ec.europa.eu/food/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf

Mr Rio Praaning Prawira Adiningrat
Secretary General
PA International Foundation
Franklinstraat 106-108 - 1000 Brussels
Email: rdp@pa-international.org

message that "at all cost an outbreak of resistant bacteria (Antimicrobial Resistance - AMR) must be avoided", with which we concur, and which requires to carefully assess the relevant properties of micro-organisms, before they are released into the environment.

I agree with you that applicants, Member States and EFSA need to become familiar and make the best use of the flexibility offered by the new Regulations, and make good use of the pre-submission meetings with rapporteur Member States and EFSA, which are available to applicants when they start preparing their dossiers. We have initiated training activities on risk assessment for micro-organisms under the Better Training for Safer Food initiative to increase the ability and capacity of Member States to process micro-organism dossiers. We also intend to support Member Sates financially via grants for a limited period of time in the coming years, in order to reduce delays and to increase their expertise and capacities for assessing applications for the approval of micro-organisms and for the authorisation or products containing them.

I would like to reiterate that your suggestion for creating a separate regulatory route for approval of micro-organisms would have required much longer than the amendment of the four Regulations, without any guarantee for a substantially different outcome. A separate legal framework does per se also not guarantee a swifter processing of the dossiers by Member States and EFSA. Neither the Member States nor the Commission are prepared to approve micro-organisms or authorise products containing them without having checked their safety for human health and the environment.

The scrutiny procedure for the four Regulations is on-going and the Council has already provided its favourable opinion. If the Parliament does likewise, the Commission can adopt the Regulations in the 4th quarter of this year. At this stage, rather than continuing to criticise what has been delivered, it would now be more productive to identify where priority needs to be given in drafting guidance for a smooth implementation of the new Regulations. Such a prioritisation is already being discussed with EFSA and Member States and your proposals in this regard will be welcome.

I agree with you that harmonisation efforts must be maintained with the different actors involved in the risk assessment of micro-organisms, and, therefore, the Commission will continue organising regular meetings of the Biopesticides Working Group of the Standing Committee on Plants, Animals, Food and Feed and maintaining the Better Training for Safer Food trainings as long as necessary.

To conclude, let me emphasise again that we fully share your interest in bringing faster and more efficiently biological products on the EU-market to provide farmers with adequate tools to replace chemical pesticides.

Yours sincerely,