MICROBIAL PLANT PROTECTION PRODUCTS TASK FORCE

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[redacted]
DG SANTE, European Commission
By email: [redacted]

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Dear [redacted]

We thank you for your detailed response to the questions we posed to [redacted] of the Cabinet of European Commission Executive Vice-President Frans Timmermans. In particular, we are grateful for your support for our goals – a fast-track and low-cost authorisation for low-risk biological/microbial plant protection products. This response letter intends to help you to put your supportive words into deeds.

This is required in order to achieve the goals and aspirations of the Farm to Fork and European Green Deal strategies. Indeed this requires a significant change in practice by all involved stakeholders and parties. That includes the Parliament, Commission, Council, National Parliaments, EFSA, National Competent Authorities, Farmer Groups, Consumers and Industry. Some of these stakeholders have advanced more than others by changing their objectives, providing more resources to implement the changes and moving at an increased pace. Our appeal to the Commission, and in particular to DG SANTE, has been, and continues to be, to pro-actively facilitate and promote this change in all its facets as this is enabled particularly by art. 77 of Regulation (EC)1107/2009. Our Task Force observes that the European Parliament since February 2017 and through five consecutive Resolutions has called on the Commission to make these changes. This call is shared by several Member States and most notably by Minister of Agriculture of The Netherlands Mr Henk Staghouwer. The fact that on 8 February 2022 [link]/during the 27-28 January 2022 SCoPAFF meeting [link] the Member States agreed with the four proposed Implementing Regulations does not imply that they would not share the views of Minister Staghouwer. But despite this clear voice of those representing the European people, effective procedural improvements by the Commission have been only piecemeal. The changes introduced as regards data requirements may somewhat contribute to a speedier process – but on their own are certainly not going to be the big game changer that brings alternatives to chemical pesticides to the market more quickly. European Commission President Ursula von der Leyen has promised to bring Europe closer to the Europeans. The safety of what Europeans eat may well be a critical element in this. That is why we organised a Euro-wide Press Conference on this subject on 31 March 2022. Political, scientific, health and industrial experts presented their views (attachment 1, media report). We ask your particular attention for the presentation of Dr Jobien Wind (attachment 2), which was replayed globally over 3,000 times; and for the presentation of Ms Diana Lenzi (attachment 3), President of the European Council of Young Farmers who truly need the Commission to enable them to produce sufficient, effective and safe food in the coming decades. The Press Conference was

attended by around 30 senior media representatives. They and others will be kept abreast of further developments including this one.

On that basis, please allow us to now respond to your letter on a point-by-point basis. To ensure that you are enabled to take the required action, each of our comments is followed by a specific and detailed request.

Questions 1, 4, 5 and 6. DG SANTE expresses significantly more confidence in the results of the amendments to the four implementing Regulations, in particular Regulations 283 and 284, than the Task Force. The Task Force has studied the new data requirements for active substances and products based on microorganisms. It has concluded that there are some minor improvements but also that the amount of data requirements has gone up, especially for microbial compounds (metabolites) (see the attached comparison of the old and new data requirements in Reg. 283; attachment 4). Furthermore, some of the reformulated data requirements (such as the use of the concept of "weight of evidence") are multi-interpretable. Given the lack of knowledge and experience in many competent authorities in the Member States we are not convinced that this is a real improvement in terms of better dossiers, better assessments, and last but not least in quicker access of products to the market. The Commission says that the four implementing Regulations will contribute to speeding up market access and reduce the burden of preparing and evaluating the applications. However, the only potential improvement is the lesser weight attributed to the evidence on human toxicology as this may reduce the need for animal studies. All in all, we believe that the burden of the dossiers will rather increase than reduce. At best, we will only know in about 5-8 years whether the new data requirements will lead to faster market access and more alternatives for microorganisms.

Request A. Our Task Force has made a detailed analysis of the new data requirements and in summary concludes that there are some clarifications, some areas where requirements have been moved to other areas for whatever reason, some other areas where a waiver exists but at the discretion of the evaluator (so we need to see this is accepted in practice by all competent authorities) and some new data requirements. These new data requirements place additional cost and time burdens on the applicant. We ask you to follow up on our detailed assessment of the revised data requirements of the two Regulations 283 and 284 as attached (attachment 5), and ask you to provide clarity where needed through explicit guidelines to the Member States and applicants.

More generally, we agree that action by, and changes in the behaviour of, the Member States are of paramount importance in gaining a faster and cheaper route to the market for microbial plant protection products. This is precisely why we urge DG SANTE to significantly step up its efforts to encourage the Member States to accommodate this mutually agreed goal. Our position is supported for instance by the letter of the Dutch Government which, whilst being hopeful that the proposed implementing Regulations will lead to an expected improvement of dossiers and assessments, calls for a specific accelerated authorisation procedure to accelerate market access of microbials. Under the existing procedure, many Member States have a great lack of resources for assessing dossiers of pesticides and insufficient experience with, and

knowledge of, microorganisms. This is explicitly confirmed in a letter to the Task Force by the [redacted] of European Commission Executive Vice-President Mr Frans Timmermans who is responsible for the EU's Farm to Fork and Green Deal strategies. This dramatic gap leads to delays in submitting dossiers because timeslots are only available after 1-3 years on the waiting list. Such delays do not exist in other Commission policy areas such as Information Technology. This leads to delays in the assessments and in the commenting and decision process in the SCoPAFF. Although PPPs with low-risk active substances should be assessed within 120 days, not a single Member State is able to meet that deadline. Although we have been hammering on that nail for more than 10 years, we do not see meaningful progress in the Member States in this regard. The Task Force strongly believes that only a separate route-to-market procedure for biologicals involving separate expert teams will improve the time to market.

Request B. The Commission should advocate this point along the lines of what has been set out in the draft proposed Communication attached to the legal opinion we submitted (attachments 6 and 7). On this basis, we therefore ask you to i) consider introducing concrete steps under the current legislation (and encourage Member States to implement these) in order to accelerate the approval and with that time to market, and simultaneously ii) start the preparations for a proposal for introducing a specific approval procedure for microbial PPPs.

Question 2. The Task Force appreciates the efforts of DG SANTE to accept feedback on the mechanisms and to have set up a meeting with the Task Force. The Task Force believes that DG SANTE does not appreciate that the key need of manufacturers is for an accelerated assessment process at a price commensurate with the available returns for registered substances and products and that DG SANTE needs to facilitate this. This claim is indeed supported by the calls of the Dutch Government.

Request C. The Task Force proposes that the Commission publishes its own understanding of the market dynamics that do or do not promote the use of chemical pesticides versus the use of low-risk biological/microbial PPPs. The raison d'être of Regulation (EC)1107/2009 also worded in Recital 17 is to promote the use of better alternatives for potentially harmful chemical pesticides. The authorising of these alternatives through a procedure developed for chemicals and managed by chemical experts is bound to work against the goals of both the Regulation and indeed the goals of the Farm to Fork and Green Deal both at Member State and EU Brussels level. The Commission is requested to confirm this and to make proposals to both repair such omissions and compensate advanced SMEs that – since the introduction of Reg (EC)1107/2009 – have lost markets and have experienced delays in markets access as a consequence of these omissions.

Question 3. Your answer to question 3 supports our claim that Member States should indeed give priority to and speed up evaluations for new products. We appreciate the intent but want to see measures to deliver this. You may not find the comparison with other countries' regulatory frameworks useful. However, we are convinced that such a comparison will considerably enhance your understanding that safe and effective microbial plant protection tools will not come to Europe as a priority when other markets are significantly more

accessible. In this regard, it makes no sense to compare approving systems for chemicals with those for biologicals. As a matter of fact, the opposite is true: market access in countries with separate teams and procedures for biologicals approvals is much faster than in the EU.

Request D. We call on the Commission to at least use the comparisons on this point in order to promote this concrete idea of establishing separate teams and streams in the Member States. Once again, otherwise, the EU will not have the optimal tools in place to achieve the goals of the Green Deal and the Farm to Fork strategies. We appreciate the work of the Commission in the OECD on the harmonisation of regulating biopesticides, but this has not led to bringing more products on the market and faster market access. We strongly encourage the Commission to accept OECD dossiers and approvals from other regions and in doing so avoid duplication, gaining time and resources.

Question 10. Your response to question 10 is similar in nature to the possibility for data waivers discussed above, as experience has shown that the derogation for non-GLP data to be admissible is not always accepted by competent authorities. EFSA does use non-GLP data but apparently rather to raise concerns than to assist a process forward. This leads to data gaps and sometimes areas of concern, resulting in non-renewals and non-approval proposals – even if a product is explicitly considered both safe and effective. This also leads to contradictory conclusions between the reporting Member State and EFSA which illustrates the different interpretations of the dossiers.

Request E. The Task Force requests the Commission to put forward the appropriate guidelines for a harmonised approach within all competent national authorities and EFSA.

Question 11. We take good note of your response to question 11. It is good to hear that micro-organisms play a key role in reducing reliance on chemical plant protection products and we anticipate that the Commission will move towards increased support for the use of microbial and other biological plant protection products as a first option for crop protection applications under the upcoming revision of the Sustainable Use Directive ("SUD"). The SUD proved to be toothless after national implementations and use of chemical pesticides was not reduced over its period of validity. For example, *Pythium oligandrum* products are widely authorised in the field crops (oil seed rape, cereals) and no authority requested the fulfilment of the mandatory replacement of the chemical treatments based on the Annex III of the SUD. Despite this, the producer has manufactured and sold 81t of *Pythium oligandrum*-based products between the years 2014 and 2020, corresponding to 810,000 treated hectares and replacing 810,000 litres of chemical fungicides. Instead of Commission support for this accomplishment, this micro-organism continues to face a threat of non-renewal.

Request F. The Pythium oligandrum example demonstrates the opposite of what Regulation (EC)1107/2009 seeks to obtain. The revised Directive must reinforce the obligation of a professional user to give priority to non-chemical methods. So far, the industry has experienced the opposite response with a lack of incentives for the user to switch. The Commission is invited to explain why this is so. The Task Force thus calls on the Commission to fully reinforce the use of Article 50 of Regulation (EC)1107/2009 regarding the Comparative Assessment as it was

intended to rid the markets of Candidates for Substitution. As for Pythium oligandrum, it must be stated that the continued non-renewal threat causes harm and revenue losses to the SME producer. A re-approval and low-risk status are imperative.

Question 12. Your answer to question 12 is perplexing to us. The active substance needs to be evaluated and approved. This carries a significant cost and time burden. This may itself be beyond the possible returns from the market let alone the additional cost of registering a product in one or more Member States. The Commission does not seem to appreciate the fact that many microbial PPPs are target-oriented and very selective. That is precisely their value vis-à-vis broad-spectrum 'kill all' chemical pesticides. This is exactly what our society needs to safeguard because it improves biodiversity and the health of both farmers and consumers.

Request G. The Task Force calls on the Commission to draft new guidelines and create new budgets to promote the development, production and marketing of especially those microbial PPPs that facilitate the achievement of the Farm to Fork and biodiversity goals. The Orphan Drugs Regulations may serve as a relevant example. The Task Force also calls upon the Commission to make use of the requirement to provide a representative formulation for the assessment of low-risk status by granting immediate EU-wide market access for this well-described, evaluated and commented formulation at the time of the low-risk active substance approval. The Task Force additionally calls upon the Commission to define Minor Use cropping on an EU-wide basis by planted area and to permit the use of low-risk products in these Minor Use cropping situations.

Question 13. Your answer to question 13 is clear and can be incorporated into applicants' dossiers but it requires guidance to be accepted by evaluators who have sufficient knowledge and correct training to understand the functioning of biologicals and their interaction within the agroecosystem.

Request H. The Task Force calls on the Commission to draft clear guidelines for Member State authorities authorizing microbial PPPs.

The Task Force is pleased that you share our ambitions. After over a decade of delay, this gives us hope that the European Commission recognizes the importance of the relevant European Parliament Resolutions and indeed European citizens' ambitions regarding the promotion of innovation and SME development, particularly in the area of accelerated market access for microbial PPPs as worded in our proposed draft European Commission Communication. We fully appreciate that the Commission may not wish to take on board all elements of this proposed draft, but through your letter and our response the Commission may find itself in support of at least the above requests.

Today, on a daily basis we are reminded of the importance of Europe's democracy, its transparency and its capacity to defend and protect what is vulnerable yet valuable. Your letter indicates your willingness to defend and protect what our Task Force tries to develop and market. Therefore we are at your disposal to work constructively with you to realise the

bold steps identified in both of our letters. We are certain we both view this as essential for sufficient and safe food for future European and indeed global generations.

Yours sincerely,
Also on behalf of the Microbial Plant Protection Products Task Force,

Prof. Mark Eyskens
Chairman
Former Prime Minister of Belgium

Ad Melkert
Vice Chairman
Former UN Under-Secretary-General

Rio Praaning Prawira Adiningrat
Secretary General

David Cary
Board Member
Board Member of PAN Europe

Attachments:

1. 31 March 2022 Press Conference media report
2. 31 March 2022 speech by Jobien Wind, Parkinson Association
3. 31 March 2022 speech by Diana Lenzi, European Council of Young Farmers
4. Comparison of the old and new data requirements in Regulation 283
5. Microbial Plant Protection Products Task Force Critique of the European Commission documents on Regulations 283/2013 and 284, 26 November 2021
6. Draft proposal for a European Commission Communication
7. Legal Opinion by Arnold & Porter