MEMORANDUM ON FASTER MARKET ACCESS FOR BIOCONTROL (INCLUDING MICROBIAL) PLANT PROTECTION PRODUCTS: WHAT CAN AND MUST BE ADDED TODAY
European Parliament High-Level Seminar, 13 October 2022

In 2009 Regulation (EC) 1107/2009 entered into force. It was presented as a legislation facilitating the transition from damaging chemical pesticides to biological/microbial alternatives. In that same year, the Sustainable Use of Pesticides Directive (EC) 2009/128 (SUD) was also published. It stressed that where alternatives are available, authorities and farmers should use these rather than the chemical plant protection products (PPPs). It underlined the general principles of Integrated Pest Management (IPM) and established that sustainable biological non-chemical methods must be prioritised above to chemicals methods. However, these Directive and Regulation texts *did not specify a clear definition of 'biocontrol'*, of '*low risk'* or of *how the biocontrol including microbial alternatives should be authorised.* This omission caused EU and national authorities to use existing *chemical* authorisation procedures *for biologicals.* Relevant authorities were specialised in *chemical evaluation* and *not biological control evaluation*. This caused extreme delays and insufficient numbers of authorised biocontrol products in the EU market.

The European 'Green Deal' and 'Farm to Fork' Strategies y set ambitious environmental and human health goals. Biocontrol is key to achieving these goals and the contradiction between what is needed and the current regulatory environment has finally become apparent to all.

The European Commission's recent Sustainable Use of Plant Protection Products Regulation (SUR) proposal, replacing the SUD, holds the potential to be a major improvement and should now be consolidated in discussions with the EP and the Council. However, while it encourages biocontrol use by farmers it does not address faster market access.

Initial positive steps were taken regarding market access, such as the revised Microbial Data Requirements embedded in implementing regulations and the Better Training for Safer Food initiative. But the continued lack of a specific authorisation procedure for biocontrol including microbials continues to delay market access.

As responsible stakeholders we aim to provide constructive input to EU decisionmakers. In summary we advocate for a fit for purpose robust biological control authorisation process that ensures a fast-track authorisation to realise the agroecological transition in time. Top scientists, lawyers and industry experts provide the detailed list of action items below, which can be implemented without going through a lengthy revision process of Regulation 1107/2009. We strongly advocate that the items be included in European Commission guidelines and measures to apply regulation 1107/2009, the 4 recent implementing regulations on microbial data requirements and accompanying and complementing the future SUR:

A. Prioritise and streamline the evaluation process for biological control
B. Establish definitions of biocontrol (to be dealt with in SUR)

C. Defining *low-risk Microbial Plant Protection Products as substances that are (a) not a human pathogen and (b) do not contribute to anti-microbial resistance.*
D. Include in the SUR a strong definition of IPM clearly prioritising and incentivising the use of biological control solutions and ensuring this at national level through the National Action Plans (to be dealt with in SUR)
E. *Member States should check the low-risk nature of biocontrol active substances including microbial PPPs at the stage of the DAR and encourage the evaluation of biocontrol products at this stage under Article 37(3).*
F. Training of national experts must focus on harmonization of the risk assessments and advocating wider use of the zonal system and mutual recognition, encouraging Member States to trust each other's conclusion and not reopening a dossier for national approvals.
G. Establishment of dedicated teams of biocontrol experts across Member States.
H. Continue to establish more appropriate and flexible data requirements (also for botanicals and semiochemicals) beyond those proposed in the 4 Implementing Regulations and issue additional guidance documents to facilitate the tiered approach to assessment including use of waivers.
I. Enforce timelines established in Reg (EC)1107/2009 for the approval of active substances (cf. Art. 9 – 13; circa 3.5 years); for the authorization for the placing on the market and use of the PPPs (cf. Art. 37; approximately 22 months); for the approval of an application for authorization of biocontrol active substances including low risk MPPPs that do "not contain a substance of concern" and is "sufficiently effective" within the meaning of Art. 47 (1)) (cf. Art. 47 (3); 120 days) and use Member State Competent Authorities that achieve this as "role models" to improve assessment in other MS Competent Authorities.
J. Smart allocation of resources for re-registration for example allowing renewal of biocontrol including microbial PPPs to be extended to 15 years and beyond, so saving competent authority resources while advancing biocontrol.
K. Optimized use of Art. 50 of Regulation 1107/2009 which concerns the "comparative assessment of PPPs containing candidates for substitution" and Art. 53 to establish effective use of temporary emergency authorisations of innovative safe alternatives.
L. Maximise the field of use from proven safety and efficacy for one crop/pest combination, extended to all crops where applicable subject to any mrl restrictions.
M. Acceptance of Non-GLP data as GLP data may only be abundantly available for chemical substances.
N. Encourage the cancellation or reduction of National fees for biocontrol product registrations to facilitate availability of alternatives across Member States.
O. Revive Art. 30 (3) of Regulation (EC)1107/2009.
P. Go for an EU-wide minor use definition/approval for biocontrol products.
Q. Decide on low-risk status for the representative use at the time of Active Ingredient approval and grant immediate registration for this representative use product in all EU Member States.

***