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Guidance Notes for completion of ATMPCA-IE form

Please complete this application form as fully as possible. Omissions or queries will generate additional correspondence, which will delay evaluation timelines. Currently it is taking approximately 12 months to process an ATMPCA-IE application.

Section 1
Please fill in Applicant and Supplier details (if relevant).

Section 2

- This Section must be completed in full and accurately reflect all available knowledge on the MPCA under consideration.
- All answers in this Section must either Yes, No or N/A – do not leave blank.
- Where documentation is required, indicate clearly the section/question to which they relate. Electronic copies of the relevant documentation are acceptable, e.g. PDF, word format etc., but electronic links will not be accepted.

iii. 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.

- Other than a virus, an active substance that is a micro-organism may be considered a low-risk active substance if it has been shown to be susceptibility to <u>at least two</u> different classes of antimicrobial agents.

Section 3
Please include technical details of the MPCA in this section.

Section 4
vi. Persistence is determined by the competitiveness of the MPCA to remain in the environment in an active (or dormant form) under the prevailing environmental conditions. It is influenced by the method of application, formulation and agricultural practices. To assess MPCA persistence, the applicant should provide information to

address the *competitiveness* of the MPCA relative to other micro-organisms in the environment to which it may be exposed – directly or indirectly. Consider also the viability and multiplication ability of the MPCA in the environment under anticipated use conditions. Additionally, state the range of relevant environmental parameters within which growth occurs, highlighting any sensitivities of the microorganism to select environmental conditions (UV light, temperature, pH, humidity, nutrition requirements etc.)? The relevance of the environmental data to Irish agricultural conditions and the EU should be discussed.

A time course study on the population density of the MPCA from pre-application under relevant environmental conditions is useful and considered particularly important for non-indigenous micro-organisms. The duration of the time course study should be such as to allow assessment of the potential population density decline upon application. The relevance of the experimental conditions for Irish agriculture and the intended trials should be justified. Information on relevant environmental parameters should be provided (e.g. humidity, pH, temperature, salinity etc.,) as these parameters may have a large effect on the population dynamics of the micro-organism.

If the MPCA produces resting stages/spores, please discuss the survivability of the spores and any associated hazards. The resistance of spores against environmental conditions (e.g. UV light, heat or possible chemicals present in the environment), survival time of the spores and conditions for germination of spores needs to be provided. In general, the information presented under this point can be based on publicly available scientific information.

Information on persistence or background levels should be provided at the most relevant phylogenetic level (ideally strain level). However, an assessment that considers relevant taxonomic levels can also be accepted if the similarity to the strain under assessment, in terms of biology and MoA, is sufficiently justified and underpinned with relevant data (e.g. phylogenetic relationship, virulence etc.).

A copy of any data relied upon should be submitted to the regulatory authority.

vii. Discuss the potential for the MPCA to disperse (e.g. via air, aerosols, dust particles, host vectors/insects, leaching, spore, rain-splash etc.) from the treated area and to establish in a non-treated area. Consider:

- Conditions (including extremes) affecting the MPCAs establishment in its current distribution
- Indicate any evidence of establishment resulting from previous releases or accidental introductions
- Hosts and habitat availability
- Climatic suitability
- Survival data and spread potential when establishment is likely
- Competition
- The ability of the MO to colonise adjacent habitats is of particular interest.

xi. The Qualified Presumption of Safety (QPS) list is an EFSA safety assessment, initiated in 2007, that identifies microorganisms (bacteria, fungi, viruses) used in

food/feed production that are considered safe based on scientific consensus. It reduces the assessment burden for agents with a history of safe use, requiring only taxonomic, knowledge, and safety evaluations.

Section 5

i) Detail the area (GPS coordinates), distance from water body, soil type for field uses etc. If used in protected structures, specify the nature of the structure e.g. permanent glasshouse, walk-in tunnel etc.

viii) Experimental protocol along with short justification for the trial should be attached to ATMPCA-IE

Please note the following Trial Restrictions

- A 20 m buffer zone must be left between treated areas and water courses (including ditches)
- Trials cannot be performed on soils vulnerable to leaching (e.g. high sand content, karst areas) or above groundwater reserves
- DAFM pesticide safeguards zone for groundwater must be respected
- Any effluent or contaminated water (e.g. washings from equipment, water associated with soilless cultivation in glasshouses) or soil/compost (from glasshouses) arising from the site must be contained and appropriately disposed off
- Treated crops must not enter the food chain for human and/or animal consumption, and must be destroyed and consigned for hazardous waste destruction
- Trials should not be laid down in areas designated Special Areas of Conservation (SAC)
- In the case of non-indigenous MPCA the trial facilitator may be asked to factor in a requirement for post-release monitoring to assess potential spread/impact of the MPCA (currently no guidance is available, and until such times as guidance becomes available, methods will be evaluated on a case-by-case basis).

ix) Identify the time frame for completion of the trial. NB: a licence will only be issued for a maximum of 1 year at a time. A fresh application needs to accompany each proposed trial.

Section 6

Please supply requested information.

Section 7

Please sign and date the declaration.

Efficacy Unit
March 2026