

Summary regarding the second Stakeholder Workshop organised by AIT (Austrian Institute of Technology)

>>> N E W S L E T T E R <<<



PROGRESS IN THE INVOLVEMENT OF FURTHER MICROORGANISMS AS CMC7 UNDER THE UMBRELLA OF THE EU (NO) 2019/1009 REGULATION

AIMS OF GOOD Agricultural Practice

INTRODUCTION >>>

One of the main goals of the Fertiliser Product Regulation (EU (No.) 2019/1009) is to support sustainable agriculture in the European Union by applying CE-marked EU fertilisers. Good Agricultural Practice supports high-quality food production, among other things, by balancing soil dynamics. Involving further microorganisms as CMC7 has not only economic benefits but could also positively affect soil management and preservation of soil quality. Thus, the Commission has been working on extending the list of approved microorganisms as CMC7 since FPR was published.

The Austrian Institute of Technology started the study in December 2023 to support the inclusion of new microorganisms under CMC7 of the FPR. The first workshop was held in June 2024 to collect the stakeholders' opinions regarding the AIT's position on the potential methodology of CMC7 risk assessment and agronomical efficiency determination. During the last few months, the AIT elaborated on a study for the CMC7 assessment methodology. This aspiration aims to develop such an assessment that is suitable to estimate not only the agronomical efficiency but also the potential risk for humans and the environment of the CMC7 candidates. According to the current approach of AIT, this methodology has three modules: to analyse the CMC7 market potential, study the risk to environmental and human health, and collect evidence for agronomical efficiency.

MODULES OF ASSESSMENT METHODOLOGY

THE TREE PILLAIRS >>>>

The first Module ('CMC7 Market Potential') will be evaluated using a uniform evaluation form, which is under development. The evaluation questionnaire will focus not only on the current legal status of the microorganism ('Does it have approval as a product in any Member State?) and the marketing situation ('Are relevant products already put on the market in one or more Member States?') but also on production-related questions ('How many manufacturers produce such a biostimulant?') as well as microbiological characteristics ('How wide is the usage of the product?).

The assessment tools of the second Module (Risk Assessment of Human & Environmental) involve data collection to implement decision trees to evaluate the potential risk of the microorganisms. AIT developed separate decision trees for environmental and human risk assessment, for which the data submission will also be uniform for all the stakeholders. Based on the forecasts, the following data could be used: literature evidence, genome sequencing and experimental data. The risk assessment will start in Spring 2025.



TIME FRAME OF THE ASSESSMENT METODHOLOGY

The last Module focuses on 'CMC7 Agronomical Efficiency'. This assessment will collect evidence to justify the potential agronomical efficiency of the chosen microorganisms. After the indication of min. one specific function as an EU fertiliser biostimulant (PFC6) the special functional capabilities of the CMC7 microorganism must be justified with literature data, experimental data or a combination of these. These functional capabilities must contribute to the chosen biostimulant effect, for example, to support plant development, soil microbiome, biodegradation of organic matter etc. It is worth noticing that the efficiency justification of the EU fertiliser (biostimulant) products for the conformity assessment. While the efficiency justification aiming the Assessment methodology of the CMC7 candidates, the efficacy justification is used for the efficacy evaluation of a final EU fertiliser product for CE marking.

FUTURE STEPS >>>>

Right after this three-pillar method is finalised, AIT will apply it to evaluate the CMC7 candidates submitted by stakeholders via the 'EU Survey' website. However, stakeholders have contradictory views, so the assessment evaluation will be implemented with microorganism candidates on the microbial strain level. The proposed date for finalising the Assessment Method is 2025 October. During this time AIT is working on a questionnaire-based survey of market potential, as well as on the data collection methods for the two other Modules.

