CerTrust
dynamism, energetics, excellence

NEWSLETTER

DIFFERENCES IN THE EFFICACY TRIAL IMPLEMENTATION METHODS APPLIED FOR THE AUTHORISATION OF CROP ENHANCERS IN HUNGARY:

TRIAL REQIUREMENTS FOR BIOSTIMULANTS ACCORDING TO REGULATION (EU) 2019/1009 AND PLANT CONDITIONING PRODUCTS ACCORDING TO THE HUNGARIAN NATIONAL LEGISLATION (36/2006 FVM DECREE)

INTRODUCTION

Wrtitten by Gábor Bese
Edited by Ildikó Varga, PhD
CerTrust Ltd NoBo 2806

Currently, two different approaches can be chosen to put crop enhancers with biostimulant effect on the Hungarian market. One of them follows the Regulation (EU) 2019/1009 as a biostimulant product (CE-marked EU fertiliser), while the other follows the national legislation (36/2006 FVM Decree) as plant conditioning product. Although the requirements of these two legal approaches are different, the effectiveness of these crop enhancers has to be verified in both cases with efficacy trials.

Meeting the different requirements of these two regulations can be challenging for manufacturers because of the complexity of the regulations. Thus, our aim is to highlight the major differences between the various standards of trial implementation methods. Furthermore, CerTrust would also like to contribute to easing the decision of economical operators to choose between the harmonised and national path.

DIFFERENCES IN TRIAL IMPLEMENTATION

FPR gives details regarding the potential biostimulant claims, while the EN 17700 : 2024 Standard series provides all the requirements regarding the minimum implementation method to justify the efficacy of an EU fertiliser with biostimulant product function category. In the case of national legalisation, the implementation of the efficacy trials has to be followed by EPPO standards and a Hungarian authority published methodology titled by ‘Official methods for testing plant growth regulators and nutrients’. The national decree requires a GEP (Good Experimental Practice) certificate and external verification in addition to internal verification. Periodic inspections are carried out by the plant and soil protection authority.

One of the main differences can be noted between the quality requirement criteria of the minimum competency justification in trial implementation. According to EN 17700 : 2024 the following partners can be chosen by the economical operator to implement an efficacy trial: national research agencies and extension officers, private research centres, contract Research Organizations (CRO), institutes. The EN17700-1 : 2024 Standard also gives the minimum quality requirement regarding the minimum competency in Chapter 7. Efficacy trials can be conducted not only by CROs having GEP certificate, but also by other partners, e.g. universities and external instate capable to justify that the trial implementation was suitable for the quality criteria of EN 17700-1 : 2024.

OPTIONS TO PUT A BIOSTIMULANT ON THE MARKET IN HUNGARY

CerTrust
dynamism, energetics, excellence

EFFICACY JUSTIFICATION

During trial implementation at least four replicates per treatment has to be applied by EN 17700-1 : 2024, while minimum six replicates are required according to Hungarian national legislation. Concerning the tested dosage, those dosages have to be tested during the efficacy test which will be indicated on the biostimulant label according to the FPR. In contrary, the Hungarian legislation demands to set not only a so-called a minimum effective dosage, which has to be 50% of the lowest dosage given on the label, but also a double dose rate for the phytotoxicity measurement. According to the Biostimulant Harmonized Standard phytotoxicity should be recorded during the trials but it is not linked to the provocative, or the double dose.

Photo by Gábor Bese

CerTrust
dynamism, energetics, excellence

Differences can also be noted in the statistical evaluation and result acceptance as well. The confidence level (CV) for EN 17700 : 2024 is 85% for those trials, where environmental circumstances (e.g. temperature) cannot be modified. However, for trials under controlled conditions (e.g. growth rooms, growth chambers, etc.) only CV= 90% is required and significantly positive effect has to be justified. In contrary, according to national rules, CV is generally 90% and it is not mandatory to justify significantly positive effect. The positive effect without statistical justification can be accepted, when growth can be detected in the average values of total yield.

Those trials, conducted according to the EN 17700 : 2024 Standard series, can be terminated when the targeted claim with targeted application time & number is confirmed (e.g. no harvesting is necessary). While during an EPPO Standard based trials the crop must always be harvested and the trials must not be finished earlier than ripening stage. Furthermore, the possible use of reference products can be chosen freely for EN 17700 : 2024 implemented trial, while according to the Hungarian methodology the usage of a reference product, which is already marketed in national market, is strictly required.

It is also noteworthy, that the EN 17700-1 : 2024 Standard defines two types of accepted trial implementation methods: the small plot trials and trial series method with the so-called strip trials. In contrary, the national legalisation allows the usage of solely small plot trials for authorisation purposes. The required circumstances of a single trials and small plot trials are similar. The trials series is composed of strip trials, while only two treatments next to each other can be implemented in the same field to compare an untreated control with a plant biostimulant treatment without replicates.

HOW TO SET A TRIAL

>>> TRIAL NUMBERS

Despite to these major differences, the minimum trial numbers are also different. According to the Hungarian national legislation, the number trials during the test of a soil conditioning crop enhancer is required to be at least 2-4 open-field or pot trials per soil type. For plant conditioner crop enhancers, 3 to 6 open-field or greenhouse trials per crop group, as defined in specific Hungarian legislation, are necessary. In case of micro-organisms with primary soil-mediated activity (e.g. for PGPR based products) 1 to 2 bioassays in culture pots on 2 different physical soil types and 4 to 8 open field (greenhouse if justified) bio-efficacy tests on different physical soil types are accepted. Naturally not only the seed, but also soil application is possible in the case of PGPR (plant growth promoting rhizobacteria) based products. For micro-organisms affecting plants via leaf application, the number of trials required per crop (or, if technically justified, per group of crops as specified in specific legislation) is 2 to 4 open-field or greenhouse trials.

CerTrust
dynamism, energetics, excellence

EFFICACY JUSTIFICATION

According to EN 17700-1 : 2024 Standard the minimum number of trials has to be carried out with plants based on the claim to be justified. At least 3 trials on the target crop are necessary to justify a claim for a specific crop, while 6 trials with a minimum of 2 different crops are needed for the entire crop group. Furthermore 8 trials in total from 2 different groups (4 trials per group with a minimum of 2 different crops per group) for two entire crop groups are required. The effect claimed is proved without being required to limit it to any specific crop grouping, in 9 trials in total from 3 different groups (3 trials per group with a minimum of 2 different crops per group).

The standard specifies the following for trial series to justify the claim: One trial series on the crop is conducted for a specific crop. In the case of two entire crop group, one trial series per crop with a minimum of 2 different crops per group is accepted, which 4 trials series minimum in total. 6 trials series minimum in total (one trial series per crop with a minimum of 2 different crops per group) is required if all specific crop group is the aim. The minimum number of trials has to be carried out on soils-based product. 2 trials in total from 2 different pH categories in one specific soil type are requested at the effect claimed for one specific soil type and all pH categories. 3 trials in total from 3 different soil types in one specific pH category is necessary to carry out if the effect claimed for one specific pH category and for all soil types and 6 trials in total from 2 different pH categories and 3 different soil types for all soil types and all pH categories.

MINIMUM CROP NUMBER AND TRIAL SET DIFFERENCES

Nevertheless, major differences can be found between the two legal approaches, the aim of both implementation methodologies are similar: to justify the efficacy of these crop enhancers.