

Activity of working group 4 (Mycorrhizal Technology) regarding a registration of commercial inocula on an European level

Production and use of mycorrhizal inoculum is a field of technology that is within COST 8.38 covered by WG4. Researchers collaborating in this working group have been involved in discussions on technical aspects of inoculum production for a long time. In the last decades methods have been developed and – besides the *in vitro* production of large amounts – inoculum production of AMP is no longer a problem.

During the last few years an additional aspect of inoculum technology received more and more interest: a possible legal registration on the level of member states or even the EU. The discussion of this registration was accelerated by two facts: inocula of very poor quality were detected on the European market, and the EU started activities to regulate the registration of microbial plant protection products, implicating that AMP might be included due to their beneficial effects on plant health.

Members of WG4 met several times to develop activities of the group towards the potential EU registration of inocula and the possible data requirements. It was agreed that an adequate registration and quality control of mycorrhizal inocula on an EU-level will be the prerequisite for a successful introduction of these fungi into commercial plant production. The key aspect of the registration seems to be the data requirement: A registration with only a few fundamental data required would make not much sense, on the other hand small and medium enterprises will not be able to finance a registration asking for large amounts of data similar to the registrations in plant protection.

It was decided to formulate a position paper which should express the opinion of the European mycorrhizologists regarding the registration of inocula. Drafts of this position paper were developed further in two meetings (Cabrils and Cork) and the position paper was finally accepted by the MC of COST 8.38 during the meeting in Nancy in December 1999.

Henning von Alten

Position paper developed by the management committee of COST- 8.38¹ on: Possible guidelines and data requirements for approval of commercial use of arbuscular mycorrhizal fungi (AMF) in the EU

The use of microbiological plant protection products is regulated by the Directive 91/414/EEC. The data requirements necessary for approval of plant protection products focus on possible unacceptable impacts on plants or the environment, harmful effects on human or animal health and additionally contamination of groundwater.

During the meeting in Stockholm ("Microbial Plant Protection Products – Workshop on the Scientific Basis for Risk Assessment", October 1998) it became clear that there are micro-organisms other than microbial PPPs that need to be appropriately regulated, e.g. Rhizobium and AMF.

AMF do not produce toxins and should be regarded as a natural part of the plant. The guidelines for the approval of microbiological plant protection products should not therefore be directly applicable to AMF.

The COST Action 8.21 followed on by 8.38 (under Biotechnology and Agriculture DG XII) cover all aspects of arbuscular mycorrhiza research and application in Europe. Within COST 8.38 we have initiated discussions on the need for a registration procedure for AMF. This registration procedure should take into account the properties of AMF.

The following document should be regarded as a contribution to establish the requirements necessary for risk assessment of AMF products. The data requirements are based on the already mentioned Directives, but focus on questions that we consider important for approval of commercial AMF products.

***COST Action 8.38
Management Committee***

¹ COST- 8.38 = Managing Arbuscular Mycorrhizal Fungi for Improving Soil Quality and Plant Health in Agriculture

1. Introduction

EC directive

On July 15, 1991 the EC Agricultural Council adopted the Directive concerning the Placing of Plant Protection Products on the Market (Directive 91/414/EEC). This was a community procedure for the approval of plant protection products (PPPs), including microbiological products. Under the directive PPPs can only be authorised if they have no unacceptable impact on plants or the environment and no harmful effects on human, animal health or groundwater. Arbuscular mycorrhiza fungi (AMF) should not be considered as conventional PPPs and should be covered by specific points or conditions beside the above mentioned Directive.

Arbuscular mycorrhiza fungi (AMF)

Arbuscular mycorrhiza fungi are obligate symbiotic fungi associated with the roots of most plants. Under certain circumstances, however, the symbiosis is either sub-optimal or has been eliminated by anthropogenic effects. In such cases it may be desirable to reestablish the symbiosis by inoculation with AMF. The sub-optimal levels of AMF may occur if plants are grown in artificial growth media, or if plants are grown in soils without AMF propagules. A reestablishment of the natural symbiosis may bring back the natural stress tolerance and fitness of the plants and lead to a reduction in the input of agrochemicals .

AMF and microbiological plant protection products

Arbuscular Mycorrhizal fungal inoculum is different from microbiological PPPs. Firstly, the effect of the inoculation is a reestablishment of the symbiosis, and secondly the main beneficial effect of the fungus is via increased and more balanced nutrient uptake by the plants. Improved disease resistance is due to enhanced plant health rather than the result of either toxin production or mycoparasitism.

Risk assessments of AMF products

The application of AMF products can be regarded as microbial inoculation, and should therefore be covered by a EU regulation procedure. The differences, however between AMF products and microbiological PPPs are important and the data requirements for risk identification and assessment will differ at key points. Most of the data requirements for microbiological PPPs relate to information on toxin production or pathogenic abilities of the organisms as effects on non-target organisms. This information is not relevant for AMF as these fungi produce no harmful substances, neither do they attack other organisms. Though these fungi form ecotypes they are routinely found in all ecosystems, from that data on "fate and behaviour in the ecosystem" are not necessary.

2. Definitions

<i>Micro-organism</i>	Any microbial unit, cellular or non-cellular, which is capable of exchanging genetic material or reproducing itself. The definition applies to viruses, viroids, bacteria, fungi, protozoa and mycoplasma, but not nematodes and insects.
<i>Arbuscular mycorrhizal fungi</i>	Micro-organisms belonging to the fungal order Glomales, forming a mutualistic symbiosis with plant roots.
<i>Microbial product</i> ¹	A product containing one or more microbial active substances in the form in which they are delivered to the end-user.
<i>Active substance</i> ²	Living micro-organisms having general or specific action on plants as a result of the action of one or more substances produced by them.
<i>Microbiological fertiliser</i>	A microbial product that promotes plant growth by enhancing plant nutrient uptake. The active substances can be either symbiotic or free-living.
<i>Microbial plant protection product</i>	<p>A microbial product containing one or more microbial active substances in the form in which they are delivered to the user and which is intended for one or more of the following purposes:</p> <ul style="list-style-type: none"> • protection of plants or plant products against all types of harmful organisms or prevention of the action of such harmful organisms • influencing the life processes of plants other than as a nutrient • preserving plant products • destruction of undesirable plants or • destruction of parts of plants or checking or preventing undesired growth of plants

¹ Microbial product should be registered at each individual member state

² to be included into Annex 1 of the Directive

3. Outline of data requirements for the registration of genetically non-modified arbuscular mycorrhizal fungi as active substances.

- 1 Applicant (Name , address etc.)**

- 2. Identity of the active substance**
 - 2.1 Common name or alternative and superseded names. Taxonomic name and strain.
 - 2.2 Collection and culture reference number where the culture is deposited (e.g. BEG¹ or INVAM²)
 - 2.3 Appropriate test procedures and criteria used for identification (morphological, serological or molecular methods).
 - 2.4 Microbial purity

- 3 Biological properties of the active substance**
 - 3.1 History of the organism and its use. Natural occurrence and geographical distribution. Information whether it is an European isolate.
 - 3.2 Biology of the micro-organism, Host specificity, relationship to known plant pathogens.

- 4 Further information on the active substance**
 - 4.1 Function (e.g. nutrient uptake, replanting stress, flowering)
 - 4.2 Field of use envisaged.

¹ BEG = **B**ank of **E**uropean **G**lomales

² INVAM = **I**nternational Culture Collection of **V**esicular **A**rbuscular **M**ycorrhizal Fungi

4. Outline of data requirements for the registration of the final microbial product containing genetically non-modified arbuscular mycorrhizal fungi

1 Applicant

- 1.1 Applicant (name, address etc.)
- 1.2 Manufacturer (name, address incl. location of the factory)

2 Organism to be used

- 2.1 Active substance
- 2.2 Mycorrhiza formation when used according to the proposed method

4 Further information on the organism

- 4.1 Field of use envisaged (e.g. field, glasshouse)
- 4.2 Crop commodity group (e.g. temperate fruit trees)
- 4.3 Method of production with description of the techniques used to ensure an uniform product and of assay methods for its standardisation
- 4.4 Methods to maintain the stock culture

5 Analytical methods

- 5.1 Methods for establishing the identity and purity of the stock culture.
- 5.2 Methods to show microbial purity of the final product showing that contaminants have been controlled to an acceptable level, results obtained.
- 5.3 Methods used to show that there are no plant pathogens in the final product.
- 5.4 Methods used to test the final product regarding possible invertebrates e.g. nematodes, mites, insects.

6 Information relating to the final product

6.1 Carrier material

6.2 Host plant used to produce the active micro-organism

6.3 Description of possible co-inoculants (e.g. fungi or bacteria deliberately added to the product.)

6.4 Description of monitoring allergic human health aspects during the production process

6.5 Declaration of the efficiency of the product