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### IBMA comments on the EU Directive 2005/25

The EU Commission published on April 8<sup>th</sup>, 2005 the new Directive 2005/25 on Uniform Principles for the Evaluation of Plant Protection Products (PPPs) containing micro-organisms

This Directive which has been published without any consultation with the concerned industry, take nevertheless in consideration several remarks made previously by IBMA:

- It is clearly acknowledged that PPPs containing micro-organisms are of different nature than chemical pesticides and need therefore to be handled specifically.
- It is recommended to the national authorities in charge of registration, to come to a decision in a reduced time frame, estimated to twelve months after submission of the technical dossier by the applicant.
- It is recommend during the evaluation time, to maintain a close dialogue, maybe a collaboration, between the applicant and the registration authority
- All worldwide available scientific and technical information must be considered, even not specifically included in the application dossier.

These are very positive points. However the Directive remains quite a critical document:

- The Directive establish a long list, almost not ended, of risks and fears related to the production, the use and the potential negative effects of micro-organisms, without mentioning at any place that they are usually considered as less questionable than chemical pesticides and that very few, if any, may run a real risk. That might have been said in the introduction.
- It is therefore required to the applicant to submit an extended number of studies which are in many cases non available, nor possible at reasonable cost.
- Furthermore is will be requested to provide all these studies in the application dossier. This means that the time required to prepare the registration dossier will be is increased to an unacceptable extend

As a conclusion, IBMA is of the opinion that contrary to the EU policies which intend to promote the introduction and the promotion of alternative and biological plant protection systems, the Directive 2005/25 leads to more time spent and costs than before.

IBMA feels justified to have a Directive where recommendations are made to the registrations authorities in order to assess properly Micro-organism Biocontrol Agents (MBCAs). However such a document has already been published with the participation of IBMA by the OECD.

IBMA feels at the end that the EU Directive 2005/25 may be acceptable to a large extend, unless a clear tiers registration system is accepted and implemented through out the EU.

This will open the opportunity to bring to the market in a reasonable time frame and at reduced costs, MBCAs which are effective, and reputed harmless for the environment and the public health.