Comments
on the Discussion paper for Stakeholders about the Implementation of EU Regulation 511/2014

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The International Biocontrol Manufacturers Association (IBMA) is the worldwide association of producers of biological control agents. Our industry is entirely based on products with biological origin, which are aimed to control agricultural pests, offering safe and sustainable tools for pest and disease management in IPM programmes on a global basis and thus conserving biodiversity in a direct way.

We herewith give our comments on the discussion paper for Stakeholders which was presented at the Stakeholders meeting on the 9th of December 2014. We would also like to refer to the paper submitted by ECPA as we fully concur with their comments.

Register of Collection (art.5)
The proposed concept of registered collections raises a number of legal issues and poses problems in its practical application:

- The scope of what constitutes a collection is not clearly defined.
- It is not obvious whether the term "collection" refers to virtually any collection of genetic resources or only to those which actually share their inventory with third parties.
- Two obligations impose a heavy administrative burden on a collection and are unworkable in practice, especially for small and medium sized enterprises or start-up companies:
  "…in a situation where only part of a collection is to be included in the register, the description and the distinctive (biological) features of that part will have to be specified…".
  "…notify the competent authority of any changes in the information previously submitted to the competent authority…".
- The list of sources of genetic resources (checkboxes from a) to g)) that is designed to provide information on the type of the collection seems scientifically and taxonomically imprecise. We suggest that the EU Commissions coordinates such a list with biological resource centers, such as the Leipnitz-Institut DSMZ – German Collection of Microorganisms and Cell Culture and other stakeholders in specific business sectors to review the terminology and ensure precise and workable nomenclature.
- Reference is made to codes of conduct, manuals of procedures as indicative documents demonstrating the capacity of a collection to comply with the relevant requirements. These can be confidential business information or trade secrets and should be kept confidential by the Competent Authority or Commission. There is no indication that the provisions regarding collections also ensure business confidentiality.

- With regard to remedial actions, it is necessary to define a reasonable period of time to provide the holder of a collection with the opportunity to remedy deficiencies. The period must take account of the specificities of biological entities stored in a collection.

It is important to make this option applicable to the situation in practice and meaningful for collections and for users. The requirements collections have to meet in order to be eligible as an EU registered collection should not have a deterrent effect or even make it impossible for any collection to be registered.

Registered collections are of little value in the case of invertebrate biocontrol agents. In the first place it applies only to Union genetic resources, while natural enemies of pests in agricultural ecosystems often originate in exotic third countries, as this is commonly the origin of most pests. Secondly it is too difficult, unreliable and costly to maintain invertebrates in culture collections as they can not be kept in an inactive form.

Monitoring User Compliance (Art.7)

There is still a lot of discussion on the scope of the Nagoya Protocol, since definitions of scope and utilisation are still unclear. It is therefore also unclear when we have to fulfill our obligations regarding a Due Diligence Declaration

The current paper describes the obligations for Due Diligence Declarations which will be published in the ABS Clearing House. It is unclear what value, necessity and usefulness are of a Due Diligence Declaration at the moment of Research Funding, moreover we feel that publication of such a declaration with details of the project at that point in time is undesirable since we feel confidentiality is not guaranteed. In many cases also users do not yet have genetic resources in their possession at the moment of application for research funding. Collecting the Genetic Resources is indeed part of the project. In this case nothing else can be declared but having the intention to fulfill the obligations of the source country. We see no added value to publish this in the ABS-Clearing House whilst putting confidentiality into severe risk.

In case Genetic Resources are already obtained the user is asked to provide the ID number of the IRCC. If these certificates will be published as well the risk for confidentiality of research plans is even higher.

Best practices (Art.8)

In earlier communication we have counted on the Commission to help us to develop a recognized Best Practice for the Biocontrol Industry, as being the only way forward to comply with ABS regulations. The current discussion paper however makes clear that recognized Best Practices are not going to provide a realistic solution for the Biocontrol Industry since a high responsibility and unrealistic burden is laid on the shoulder of Associations, which we as a small organization based largely on a limited number of volunteers are unable to bear.

Conclusion

We are open to discuss with the Commission upon more realistic solutions for the industry to deal with their obligations under the Nagoya Protocol. The biocontrol industry is an SME dominated industry and there is an undue burden on enterprises of this type with the implementation of this legislation. Without support of the Commission it is unlikely that any Biocontrol Company can afford to take the risk to spend the required effort and money to get access to genetic resources, thus jeopardizing the future of the Biocontrol Industry and therefore also the future of biological control as a key source of tools to implement sustainable integrated pest management programmes.