



INTERNATIONAL BIOCONTROL
MANUFACTURERS' ASSOCIATION

Basel September 4, 2003

**IBMA POSITION CONCERNING
REVISION OF DIRECTIVE 91/414 CEE**

Introduction

The EU Commission General Directorate SANCO has recently invited IBMA to provide input for revision of Directive 91/414 CEE.

IBMA , the International Biocontrol Manufacturers Association, is the only international organisation representing the biocontrol agent (BCA) industry . Other associations such as ECPA or CEFIC, representing only the agrochemical aspects, cannot speak on our behalf.

IBMA regret that they have only become involved, and merely on an informal level, in the revision process of Directive 91/414 CEE at such a late stage. Until recently, we did not receive any information on SANCO intentions, contrary to ECPA which already on September 17 2002 wrote : “preparatory work for a future revision of the Directive 91/414/EEC is already in hand,”

In order to provide the most complete opinion to Commission, IBMA concerted with research-based representatives of the International Organisation of Biocontrol (IOBC) on September 2nd in Paris, and the conclusions will be presented to the IOBC Council on September 22nd 2003.

Biological control of pests and diseases is a major tool in the development of sustainable agriculture in organic or integrated production systems which favour environmental protection and consumer satisfaction.

Our position will therefore refer principally to biological control : use of semiochemicals, natural products and living organisms (microorganisms).

We appreciate that many aspects need more in depth analysis, therefore our contribution will concentrate on to the most important points.

1. Need for a new Directive for Biocontrol

As stated in the Round Table Discussion on Safety and Regulatory Issues organised by IOBC in Salzau, Germany on May 26, 2003 (see BioControl Journal August 2003, vol 48, issue 4): “The main problem in some of the current and the foreseen regulations is their foundation, which is based on the tradition of regulating chemical pesticides. BCAs are not conventional chemicals, they are completely different and require a different approach”.

We would like to draw SANCO’s attention that EU regulations for BCAs, more stringent and costly than in foreign countries, could create unjustified trade barriers (*cf* WTO principles) and might push producers to allege activities for their biologicals which allow them to escape from the “Pesticides Directive”.

We already expressed our concern to SANCO in September 2002, indicating that IBMA advocates the development of specific regulations (Directives) for biologicals, separate from Directive 91/414/CEE which was originally adopted for chemical pesticides only. IBMA (and IOBC) experts are ready to contribute to the preparation of such Directives.

However IBMA is aware that such a process to adopt a new specific Directive would be long, and would cause unacceptable delay in registration and use of biological control agents.

We therefore consider that an improvement of the existing Directive 91/414/CEE would be preferable, and list hereunder the priorities for this improvement.

2. Most important issues to be considered in the “improved” Pesticides Directive

➤ Specific data requirements for each biological class

The present Directive concerns several classes of biologicals : natural products, semiochemicals and microorganisms. Invertebrates are excluded.

Specific data requirements are mentioned in an Annexe 2 for microorganisms, but not for the other classes of biocontrol agents. It is indicated that “waivers” can be requested.

- Since beneficial invertebrates cannot be classified as “pesticides”, they are not and should not be covered by the Directive 91/414
- The Directive should provide clear and specific data requirements for each of the classes concerned : pheromones, natural products and microorganisms

➤ More specific definition of the BCAs listed in the Annexe 1 (registered products)

It is extremely important to identify clearly the biological agents which are concerned by a registration and listed in Annex 1.

For example : Will the pure or the blended pheromone be registered?
Will the microorganism species or the strain be registered?

This lack of precision is unfavourable to the applicant, induces criticism on the market place and may lead to poor results and environmental problems.

IBMA recommend that the level on which the BCA will be characterised and registered should be clearly defined. Molecular tools can help to solve this problem. For microorganisms, the “strain” only should be registered.

➤ To facilitate the use of BCAs by reducing their development costs

The registration of biologicals remains extremely costly bearing in mind their market potential, principally due to the high cost of fees required by the registration authorities. In addition, fees differ from one country to another, motivating applicants to choose the “cheapest” country to present his dossier.

Numerous safety studies are of generic nature and seem to be unjustified and can be easily extrapolated to other agents.

- It is necessary to reduce and harmonize registration fees at the EU level
- The number of risk assessment studies should be reduced, or undertaken and funded by public institutions, or the Commission itself.

➤ Specific and harmonised functioning principles

Annex VI of Directive 91/414/CEE is dedicated to the functioning procedures. Although this Annex is very detailed, a large number of recommendations remain complicated if not impossible to set up.

The question of the new member states is not considered, leaving the possibility of temporary avoidance of registration requirements.

Furthermore, Annex VI does not consider the specific case of BCAs :

- Clarification is needed, and more important, harmonisation between EU member states.
- Revised Annex VI should cater for each of the different BCA classes.

➤ Transparency and Stewardship

The vast majority of Biocontrol manufacturers are small or very small firms: They cannot employ full time registration specialists. Submission of registration dossiers is therefore a nightmare for them.

Furthermore, in Europe the registration authorities are not in the habit of providing advice maintaining dialogue with applicants. There is no transparency in the final decisions at national level, let alone EU level

We advocate that a system be set up to give advice and support to applicants throughout the registration process, in order to facilitate understanding and acceptance of the final decision..

➤ To speed up and reduce costs of registration

Registration of BCAs requires the expertise of dedicated experts on very specific issues, in particular in the field of biology, ecology, etc...

There are not many such experts in Europe, in some countries they do not exist at all or their working programmes are completely saturated. As a result of this, the procedure dossier assessment is too long. The cost of increasing the number of expert assessors in each country would be prohibitive.

We recommend that a Work Sharing examination system be set up between the different countries. A panel of recognised experts should be set up, with the following additional functions :

- Advice to applicants
- Appeal on controversial decisions.

CONCLUSION

IBMA considers that present European pesticide regulations prevent crop protection products for use in organic and integrated agriculture being brought onto the market.

The revision of Directive 91/414/CEE should be the occasion for introducing :

- Proportionality : Requirements should only be called for when necessary and should be in proportion with the risk involved. Costs should be identified and minimised at all levels
- Accountability : Decisions should be justified and subject to public scrutiny
- Consistency : Rules and standards should be implemented in a fair and uniform way
- Transparency : Regulators should be open and make regulations simple and user-friendly
- Targeting : Regulations should be focused on the problem, and the side effects kept in proportion to the problem

The objective of these IBMA proposals is to achieve these goals, and in our opinion, these suggestions can easily be incorporated into the revised Directive.