



International Biocontrol Manufacturers Association

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WHITE PAPER ON THE REGULATION OF BIOLOGICALS

PREAMBLE

Over the last couple of years, the biocontrol industry has faced, and continue to face increases in regulations at both national and European levels. These regulations are often based on those which are used in the regulation of chemical pesticides use and are frequently considered to be disproportionate to the risk posed by the products and an economic barrier to the use of alternative pest and disease control solutions. Whilst it is recognised that all products used to control pest and disease will carry a risk and that protection of the consumer and environment is paramount. The present trend in regulation of the biocontrol industry does not appear to take balanced view of the risk-benefit of biocontrol products.

In 1998, in response to the Enterprise Programme which is designed in order to assist the development of SMEs, IBMA suggested in the project ART (Assistance in Registration Technologies). The aim of the project was to improve registration procedures and base the registration requirements on scientific evidence. Although ART was supported by a consortium of major European research organisations: IOBC, BBA, INRA, IRTA, SERTIA, CABI etc.. it was rejected because the DG Research did not recognise and appreciate the "value of the suggested research".

In our joint lobbying with IOBC, we visited the EU Headquarters in Brussels and discussed our problems with influential senior members of the Commission as well as with Members of the European Parliament.

In spite of this, the "Pesticides" and the "Biocides" Directives regulating the registration of biologicals have become even more stringent.

However end 2004, within the frame the Scientific Support to Policy (SSP) of the Sixth Framework Programme, a call for proposals has been published with 3 objectives:

1. to provide a survey on the world-wide regulation of biologicals , showing the pros and the cons of the different systems currently operating.
2. to suggest regulation regarding the research and the testing of new biologicals
3. to suggest new regulatory frame for the introduction of new biologicals on the market.

Professor Dr Ralf Ehlers (Kiel University, Germany) after consultation with different parties including researchers and IBMA provided the Project REBECA in January 2005 which has been accepted by the Commission. REBECA is expected to start early 2006.

SCOPE of the White Paper on the Regulation of Biologicals, December 2005

Taking in consideration that REBECA will have a very strong impact on the biologicals industry, before the project starts, it is important to submit some basic statements which represent the Industry position regarding the regulation of biologicals.

Under the term of "Biologicals" we understand any products which are developed, manufactured, distributed and used as alternative to conventional chemical pesticides. Classically Biologicals cover 4 classes of products, living or not, which are:

1. invertebrate biocontrol agents (IBCA) such as, but not restricted to beneficial arthropods and entomopathogenic nematodes
2. microbial biocontrol agents (MBCA) such as fungi, bacteria, viruses, biorizes and their active principles
3. semiochemicals such as insect pheromones and other natural attractants and repellents
4. natural products, such as botanicals and their extracts, minerals, bio-active molecules etc.

Biologicals can be used, also within classical biological control programmes, as plant protection agents, and also in the area of animal health and public and domestic hygiene

Basic principles on the Regulation of Biologicals

1. The registration of Biological cannot be extrapolated and considered similar to the regulation of chemical pesticides, since their nature, properties and characteristics, their mode of action, their dose and use differ fundamentally from these products:

- chemical pesticides target eradication of pests, weeds and diseases while biologicals aim at to maintain them below economic and other important thresholds, whilst protecting the environment and biodiversity. In addition, the season-by-season accumulative reduction in pest population levels may not be taken into account by current evaluation procedures
- Living organisms and bioactive molecule behave differently than conventional pesticides. Several types of bio-active molecule such as semiochemicals, competitive micro-organisms, elicitors, biorizes etc..have no lethal effects, not even on targeted pest species nor on other arthropods and these must be treated differently and appropriately
- Their activity is influenced to a great extent by the cropping systems and the ecological factors. Often they are preventive and not curative therefore their use has to be anticipated, not isolated as an active ingredient, but as part of a system where plants, animals and/or human being will be healthier. Thus for example, crops, where the aim would be to produce quality foods without negative effects to the environment and human beings .

2. For almost 10 years, IBMA has tried to modify, improve and make the regulatory arsenal more specific. We have been partially successful, at least in an OECD, but not EU, context, for Micro-organisms and pheromones for example and also with the creation of the OECD Biopesticides Steering Group, but there remains much more work to do.

Based on scientific results, little progress can be made in the future to adapt the present registration system, to make it easier, faster and less expensive. We need different and more specific regulation, plus a genuine and guaranteed commitment to follow agreed standards and procedures.

3. Approval to market biologicals should occur after the comprehensive analysis of elements related to:

- the quality of the discovery : to which extensive research and development has been made to satisfy ethical aspects, and to take in consideration safety and protection of the environment
- the quality of the production: making sure that environment is protected, energies safeguarded, waste minimized and under control, health of the employees protected, quality standards of the products established and controlled etc.
- the quality of the follow up: underlying the instruction for use, the information and the training of the users, the benefits obtained and any problems resulting from the use of the product, ensuring that distributors and users will be in a position to benefit correctly from the products, to know the way in which any problems arising after the products are introduced can be solved, obsolete products are disposed etc.
- IPR and protection of technology

A large number of elements relating to the above mentioned subjects should be voluntary and controlled by the Industry itself. IBMA is setting such systems, promoting internal audits, quality standards leading to certification and labelling, (for example EU Eco-Label). This white Paper refers only to those elements which are under the scrutiny of public affairs administrations.

4. Detailed requirements which allow biologicals to be used safely and provide anticipated benefits for consumers, distributors and the industry can be listed according to the experience obtained and scientific results. This should be the task of recognised experts.

5. However, IBMA would like to suggest the conditions (process) and the principles under which the performances of biologicals must be examined

A- Setting a list of specialists who, in given field of expertise, will constitute an European Panel of Biocontrol Experts with the following tasks:

- 1- to provide expert opinions on defined issues
- 2- to set up "Positive Lists":
 - a) to make for each eco-region, a review of biological crop protection, public and domestic hygiene and animal health systems already successfully introduced
 - b) to create an "Eco-regional Positive List" including systems which are easy to use, achieve the anticipated results, and do not cause any harm to the environment and public health (residue in the crop).
Such products and agents will not require further evaluation and can be sold without specific authorisation
- 3- to solve problems arising within the framework of biologicals evaluations
- 4- to provide solutions in case of conflicts between applicants and evaluating bodies

B- When a company intends to apply for an approval, the Competent Authority nominate a person who will be the link between the company and the Authority with the primary purpose of facilitating the authorisation of the best management product. This person will assist the applicant during the evaluation period, providing information two- ways, ensuring transparency and guiding the applicant at all stages of the evaluation process.

C- Tasks of the Competent Authority

Evaluations and decisions must be taken by biocontrol specialists ensuring the Principles of Good Regulation (transparency, accountability, consistency, proportionality and targeting) .

The competent authority should firstly decide which regulatory path should apply to the considered biological and the name of the authorities in charge.

They must also demonstrate and justify the need for and benefit of any studies and information they require that is over and above that of previously agreed standards and principles.

The evaluation must be undertaken in all EU Member states following similar harmonised principles and charges to be paid by the applicant (Uniform principle)

Special provisions must be made regarding data protection and intellectual property of scientific and technical documents provided by the applicants

1- To start with a detailed examination of the candidate biological, using experience and literature:

a) precise identification of the agent/product, mode of action, references to similar uses or related/similar agents/products

b) the evaluation of new products must be very specific (crop, pests, climatic use conditions, soils, etc.) , and within the framework of the forecasted use (agricultural) system.

c) examination of the performances and risks compared with other alternative solutions

d) if risks and performances are satisfactory, the agent/product will receive a sales permit. However, taking in consideration its applicability, a monitoring system adapted to the risks suggested by the experts will be set up.

2- Examination of a novel agent/product

a) to make a global safety and economical audit in order to identify potential problems and benefits resulting from the introduction of the biological control product on the market

b) This audit will enable to design a “proportional” programme of evaluation, avoiding overly long, technically unjustified and uneconomic supporting documentation.

-this programme is setting clear subjects to be studied as well as a time table setting out the period within which the product should be examined

- this programme should specify 3 or 4 tiers to be implemented when issues are discovered during the evaluation

c) Harmonisation

International organisations such as FAO, WHO, OECD, EPPO, NAPO etc. have the task of harmonising and co-ordinating the flow of information, the evaluation rules and the process of decision. NGOs and the Industry (Crop Life International and IBMA) are involved with these efforts which must concern also biocontrol agents/products in order to avoid discrepancies and delays in their registration.

d) To ensure that the proposed new products/systems provides, at least equivalent, if not superior safety, efficacy and environmental performances compared with conventional crop protection practices

e) efficacy will have to be addressed on a case by case basis and must make allowances of possible lower efficacy by taking into account the resulting environmental benefits

- D- The applicant should address security issues and state what measures are to be taken in case of any accident and a monitoring scheme should be considered in order to check and allow early identification of any issues relative to safety, efficacy, environmental problems, resistance, mutation etc.

If the monitoring system detects an unacceptable level of risks, corrective measures must be initiated while the competent authorities will be alerted and the sales permit will be withdrawn. If necessary, specific research studies can be recommended and undertaken with a view to solving the potential problem.

- E- In all circumstances, in order to consider progress in technologies and eventual arising problems, the sales permit should be revised at regular interval, for example every 10 years. If a product/agent did not lead to any problem its inclusion into the Positive List may be considered.

SUMMARY OF SUGGESTED REGULATION PRINCIPLES

1. Exclude from registration procedures all aspects relative to products standards, environmental and occupational safety in research, manufacturing and distribution which will be covered by industry voluntary schemes (EMAS, EU ECO-Labeling etc..)
2. The list of scientific and technical data required for registration of biologicals is elaborated by experts and especially Biocontrol experts.
3. Set up an European Biocontrol Panel of Experts with 3 major tasks:
 - a) to set up a positive list of agents/products which do not require registration
 - b) to solve problem of technical nature arising in the frame of the evaluation
 - c) to solve conflicts between applicants and the registration authorities
4. To nominate a contact person within the registration authority with the task of advising and assisting the applicant
5. Ensure data protection and intellectual property rights to the applicant
6. Secure Uniform principle and harmonisation of registration fees
7. To ensure accountability and proportionality (relation with economy) of registration fees
8. To provide to the applicant a frame on timing and costs for the registration
9. To design registration data requirements based on the direct risks attached to the agent/product in the field of its intended use
10. To design a tiers approach
11. To adopt a Comparative Safety Assessment (CSA) in order to support the most favourable products
12. To set up a monitoring system for newly introduced agents/products
13. To consider safety and remediation actions
14. To ensure transparency all along the evaluation process
15. harmonisation with other international regulations
16. Where established, OECD requirements and waivers must be accepted and implemented
17. Authorities must provide a detailed explanation and justification why an application has been accepted or rejected (the presumption should be that biologicals are “ innocent until proven guilty”)
18. Registration revision after 10 years and inclusion in the Positive List of “safe” agents/products