

**IBMA POSITION AND COMMENTS ON DRAFT REGULATION CONCERNING THE REVISION OF DIRECTIVE 91/414/EEC (SANCO/10159/2005 DATED 6<sup>TH</sup> APRIL 2005)**

**( 16 May 2005)**

## **Introduction**

On 18<sup>th</sup> April 2005, Louis SMEETS asked IBMA to take position on the latest draft version of the regulation amending Plant Protection Product (PPP) Directive 91/414/EEC.

We highly appreciate that DG SANCO continues the dialog with our association and that we have been invited to comment on this new draft text.

The new Directive draft presents several improvements which can be considerable progresses compared with the original directive:

- the compulsory mutual recognition of national authorisations between MS within the same designated zone and the proposed time periods for evaluation
- the decision especially for PPP containing low-risk substances
- the introduction of a Comparative Risks Assessment system ( although it is not mention if the CRS will include not registered systems such as beneficial insects or mechanical methods for example)
- recognition of a special procedure for “low risks” products ( although not described)

Unfortunately many general suggestions and specific proposals made by IBMA in the past have been disregarded, especially the need to have a specific directive for biocontrol products which takes into consideration the specificities not only of micro-organisms but also of semiochemicals (which act as behaviour modifiers and not as toxicants) and of natural products (which already exist in nature).

We would like to stress again that biocontrol agents, natural extracts and semiochemicals are not conventional chemicals; they are completely different and require a different approach.

Biocontrol products are frequently highly specific (e.g. semiochemicals and many micro-organisms), and they are used to control just one or a few target species or pathogens in a limited number of crops. Consequently, these products are generally developed for relatively small markets.

At the same time manufacturers of biocontrol products, in the majority small companies with limited resources, are confronted with long lists of data requirements and a complex, time consuming and expensive registration process. Data requirements are the main hurdle for the registration of biocontrol products, and especially requirements for risk assessment are generally inadequate and too strict. The registration process as a whole is considered as “too heavy”.

The effort to develop a new specific directive for biological control products can be justified knowing that these products are major tools suitable not just for organic production systems but also for integrated production. They will have a major role in achieving the objectives of sustainable agriculture.

You will find hereafter a summary of the IBMA requests and comments which have already been forwarded to the DG SANCO in two previous position papers  
 IBMA position concerning revision of directive 91/414/EEC dated 4<sup>th</sup> September 2003 and  
 IBMA recommendation for revision of directive 91/414/EEC dated 16<sup>th</sup> March 2004.

This position paper also contains

General comments on draft regulation and  
 Comments on specific articles

### Comparison of IBMA requests and the draft regulation dated 6<sup>th</sup> April 2005

#### Key issues mentioned in September 2003

IBMA requests	Suggested in the last draft regulation
1- There is a need to revise the current directive 91/414, making a clear difference between chemical pesticides and biocontrol agents, including natural products and semiochemicals. At short term the existing directive should be amended to save time but in the following a new specific Biocontrol Products Directive should be developed	- There is no specific status for biocontrol products. The natural origin of products is mentioned only to define those compounds as “substances”. There is not even a definition for semiochemicals and thus there is a risk for these substances to be treated like conventional chemicals in the registration process in general and in comparative assessment in particular. Natural extracts are also treated as conventional pesticides - Nematodes (EPNs) are newly assimilated to “micro-organisms” though they clearly are “macro-organisms” and as such they would not require registration. The inclusion is a major setback.
2- Data requirements should be specifically adapted for each of the three biocontrol classes: natural products (e.g. plant extracts), semiochemicals and micro-organisms	As above : There is no specific approach for semiochemicals and natural products. Annexes IIB and IIIB are specific for “microbials”
3- A better definition of the agent to be included into annex I is required (strain, purity, characteristics etc.).	Clarification for strains microbials only
4- Reduce the amount of required studies and accept extrapolation from safety studies available for related biological agents or substances. - Reduce and harmonise the registration fees for biocontrol products at E.U. level	No proposal
5- Provide specific and harmonised guidance for the implementation of procedures	Annex VI differentiates microbials only but not semiochemicals and natural products
6- Transparency and stewardship Registration authorities should give advice and support to applicants throughout the registration process and the final decision should be more transparent	Suggested in evaluation
7- To speed up registration time and reduce cost for BCAs work Member States should share expertise and put resources in common	Shorter time <b>suggested only</b> , but no fast tracking or specific procedure for biocontrol products

## Key issues mentioned in March 2004

IBMA requests	Suggested in the last draft regulation
1- The call for a specific regulation for biocontrol products (item 1 in September 2003) was reiterated	As above : No specific status for biocontrol products (except for data requirements for micro-organisms)
2- need for a dialogue	Dialogue with IBMA only partial and on cas by case
3. The principle of proportionality for data requirements to be applied to biocontrol products	Not mentioned
4. Fast track registration systems were recommended for alternative plant protection systems and in particular biological products	Suggested. <b>Not mandatory</b>
5. Zoning <ul style="list-style-type: none"> <li>to establish homogenous eco-regions taking into consideration comparable conditions e.g. ecosystems, altitude</li> </ul>	Zones exclusively based on national frontiers are not relevant enough for biological products. The case of France is unsatisfactory because products authorised MS in North and East are not recognised for use in French neighbour regions with similar conditions. No mention of special eco-systems such as semi arid and irrigated zones, montains etc...
<ul style="list-style-type: none"> <li>Decentralisation and harmonisation of evaluations/ decision/<b>fees</b></li> </ul>	Worksharing is promoted, but harmonisation remains a question
<ul style="list-style-type: none"> <li>Mutual recognition</li> </ul>	The introduction of recommendation for compulsory (?) mutual recognition is positive
<ul style="list-style-type: none"> <li>Low risk assessments</li> </ul>	Has been introduced in proposal
<ul style="list-style-type: none"> <li>Positive listing for BCAs</li> </ul>	Possible in annex IB but procedure and criteria should be more precise for biocontrol products
6. Data protection	Nothing relative to living organisms
7. Avoid drastic restriction of aerial spraying, but reinforced control	No restriction introduced but obligation to inform neighbour potentially exposed to spray drift if use of toxic products (should not be relevant to biocontrol products)
8. Comparative assessment and substitution principle	Introduced in the draft, but need for clarification
9. Collection of in-use data, made by the industry with financial support of the Commission	Data collection by the industry, but no support
10. Training of professionals mandatory and sponsoring of educational schemes	Not mentioned
11. EU incentives for IPM	Nothing apart from comparative assessment
12. Support for alternative programmes	No programme is foreseen as such

## General Comments on the latest draft regulation

1. Regrettably most of the essential IBMA suggestions have been disregarded, especially the need to have a more specific directive and consider semiochemicals and natural products (especially plant extracts) specifically.
2. Unfortunately the need for a fast track for BCAs has not been addressed
3. The necessary studies remain numerous, time consuming and expensive while registration fees are not harmonised and generally too high: the total cost of registration ends up at an unacceptable level
4. In the project a positive list for low-risk substances has been introduced, but the criteria and procedures for inclusion have not been defined for BCAs. IBMA suggests that the regulation clearly defines criteria for the inclusion of active substances into annexe IB and that all actives already considered to be low risk as agreed by OECD (e.g. straight-chained Lepidopteran pheromones) as well as substances used e.g. in or as food or as carriers in pharmaceuticals are automatically included
5. The Commission suggests to bring safeners and synergists in the scope of the Directive: this will make [*ou: risks to make*] the registration process extraordinary complicated, costly and questionable for BCAs. For exemple for obvious reasonsm BCAs may need to be mixed with inert material which have not biological nor toxic effects. IBMA suggests that known low-risk substances used e.g. in or as food (e.g. canola oil) or as carriers in pharmaceuticals are automatically included in the positive list of synergists (or safeners).
6. Nematodes are now considered as micro-organisms: this is contrary to the reality, any logical consideration and in contradiction with all other regulations (see OECD Guidelines e.g. Series on Pesticides n°21 which classify them among IBCAs, ie Invertebrates as Biological Control Agents). In this respect IBMA would like to draw the attention of SANCO and regulatory authorities at the EU level that this intention is a major deviation of the registration concept: instead of registering a product or an agent as such, the Commission intends to register a “mode of action “ or an intermediate in the process of action. The consequences of such a decision are huge.
7. The present project is calling for new regulations adapted to BCAs which may provide answer to most concerns , but the Commission should be aware that excess of regulation may be contra-productive and make it more difficult to promote alternative safer plant protection systems.
8. There is concern that the move towards using the definitions from the Biocides Directive 98/8 will lead to unforeseen situations and that substances currently present in the environment suddenly fall in the scope of the directive (see remark on art 3.11 below)

## Comments on specific articles

Article 1.1 (p 2) and related texts : The article should also mention the existence of the positive list for low-risk active substances and could refer to biocontrol products in particular. Note: criteria for the inclusion of substances are not included in the draft document available.

Article 3.1 (p 4) : The definition of a “plant protection product” also covers active substances that “protect plants [...] against all harmful organisms...” or that “influence life processes of plants (e.g. growth regulators), other than as nutrient” This seems to include biostimulants (e.g. elicitors). Is there no specific approach for substances stimulating the natural defences of plants and having an indirect protective effect?

Article 3.7 : Are feeding stimulants like sugar definitely excluded by this definition for a synergist which says that these “substances can give enhanced activity” to the a. s.?

Article 3.11 : The new definition of “active substances” specifying “by chemical or biological means” may still cause confusion. Example : Are simple gases used in grain protection like N<sub>2</sub> or CO<sub>2</sub> active substances though they naturally occur in high or at least significant concentrations in atmosphere or would they be accepted as simple physical O<sub>2</sub> replacements? On the other hand, is silica gel which acts physically on the cuticle of insects a physical protection means? There is a risk that substances that should never be regulated under the PPP directive will suddenly fall in the scope like in several cases for the BPD 98/8. It is the right approach that the new definition excludes physical means (e.g. traps) but it should be given further thought.

Article 3.24 (p 8): In the new draft the definition of micro-organisms now also includes nematodes used in or for PPP. This does not reflect reality, has no consistent logical basis and is in contradiction with other regulations (e.g. OECD Guidelines), biological classification and the use of these beneficial macro-organisms in the practice.

This assimilation must be seen as abusive in particular since it automatically leads to the obligation to register a group of macro-organisms. **IBMA is strongly opposed to this significant change** and if required can ask members involved in the production and/or commercialisation of nematodes to prepare and submit to DG SANCO a rationale for this specific issue.

Article 3.19 (p 6) : According to the definition given for “animals” most wild animals, in particular bumble bees and beneficials, are not considered to be animals. Is this coherent with the specific status of pollinators and beneficials in plant protection ?

Article 3.23 (p 8) : Is there a definition (or are there examples) for the “biotechnological” measures which are mentioned?

Article 4.4 (p 9): The present text may lead to the conclusion that it is prohibited to produce and transport within the EU a PPP which is not authorised in a MS even if it is destined for export to a country outside of the EU. Thus a product registered in the USA but not authorised in the EU could not be manufactured.

The article should contain a clear statement that it does not apply to manufacturing and transport of PPP intended for use outside of the EU.

Article 6.1 (p11): This article could cause a lot of problems in the future. It is advisable to give a definition of neighbours (e.g. in article 3): is a neighbour somebody who lives or is physically present close to the treated site or is the owner of a field or any other piece of land a neighbour as well? If all owners must be informed how can they be identified if they do not live close to the site?

Article 8.1c (p 12) and article 9 item 1 (p 13): The introduction of comparative assessment (CRA) is a positive innovation because it can be expected to be largely in favour of low impact biocontrol products and consequently this innovation is welcome. Nevertheless it is important that article 9 specifically mentions semiochemicals and natural products as valuable alternatives or non-chemicals while micro-organisms are clearly covered by “non-chemicals control methods”. Furthermore article 8 could mention the biocontrol products in general or the three classes micro-organisms, semiochemicals (behaviour modifiers) and natural products (which have to be defined in article 3) in particular.

Article 4.6 in draft (p 9) and article 8 in current 91/41 (p 30): The new regulation does not provide for provisional authorisations any more. We think that this decision is acceptable only if MS meet their obligation to take a decision about the approval of a PPP within 12 months from the date of application as laid down in article 12.1. Unfortunately it is very common that registration authorities exceed this deadline without any explanation. If authorities cannot evaluate substances within given time intervals the existing derogation system should be maintained.

Article 14.2 (p 17) : The mutual recognition is definitely an improvement over the current directive. The article allows the application for mutual recognition of authorisations not only in MS of a same zone but also for use in glasshouses or post harvest treatments. The word glasshouse is too restrictive because in many cases plants are grown under plastic cover (which may even allow heating). Consequently “glasshouse” should be replaced by “protected cultivation”.

Article 17.1 (p 19) : The article does not explicitly mention that the authorisation holder must notify the competent authority if there is any harmful effect on beneficials or pollinators who do not fall under the definition of “animals” either. It would be adequate to include beneficials (especially for species used for biocontrol measures) and pollinators under item 1. Consistent with article 18, harmful effects of metabolites should also be subject to notification to authorities and could be mentioned here.

Article 47 (p 49)

What does the implementation of regulation (EC) n° 882/2004 on official controls performed to ensure the verification of compliance with feed and food law [...] mean in practice for the manufacturing of low-risk actives e.g. semiochemicals? Small manufacturers rely mainly on ISO 9000 while GLP, GMP or HACCP are not used because they would increase costs substantially. IBMA wishes clarification of this issue prior to publication of the text.

IBMA

Basel , 16 May 2005