

EU Commission/DG SANCO
Attn Mr L. Smeets
Health and Consumer
Protection Directorate
General Directorate D – Food
Safety Unit D.3
Rue Froissart 101 6/72
1049 BRUXELLES
BELGIUM

ref.: wR/HSt/2394

Berkel & Rodenrijs, 18th May 2005

Dear Sir, Madam,

In the draft EU-regulation for Plant Protection Products entomopathogenic nematodes (EPN's) are included in the definition of micro-organisms. This will mean that in future EPN's will have to be approved according to the requirements for micro-organisms (EU 91/414; Annex IIB and IIIB) and will need inclusion on Annex I.

At the moment EPN's are broadly regarded and accepted as macro-organisms and as such also regulated in various countries in the EU and other countries. Also they are classified by the EPPO as macro-organisms in their EPPO Standards for "Safe use of biological products" PM 6/1-2.

EPPO also proposed to include EPN's on the list of Biological Control Agents (BCA's) that have been widely used and are considered to be safe (PM 6/3). The OECD considers EPN's as invertebrate biocontrol agents and not as micro-organisms. In their Guidance Document ENV/JM/MONO (2004 1) requirements are give for invertebrates as BCA's including nematodes.

The FAO also categorizes EPN's in their guidance documents (ISPM 3 and 5) under invertebrate BCA's and not in the definition of a micro-organism (biopesticides). Many countries have adopted these guidelines and EPN's are often regulated according to these guidelines.

The Dutch Ministry of Agriculture considers EPN's as macro-organisms and as such there are regulated under the new Flora and Fauna law. Since they have been used for a long time they are considered safe and thus exempt of this regulation.

From the above it is clear that EPN's are regarded as macro-organisms by many different authorities and that many of these authorities consider EPN's safe as proven by their use over a long period of time and in many countries.

When the EU will now regard EPN's as micro-organisms these BCA's will fall in both categories and will become over-regulated. All these regulations will make it extremely confusing and very difficult to get approval for the use of EPN's.

When EPN's will be regulated through EU 91/414 it will become very difficult to comply with this. The complicated registration procedure to place each nematode species (or even strain) on Annex I is very time consuming and expensive. Beside this each product (formulation) will need to be registered in each member state, again a long and costly procedure. As a consequence of this many products will disappear from the market since they are only used in niche markets. Newly developed nematode products will have no chance at all to come on the market. For biocontrol of pests this will mean the end of a very effective range of products and an increase in the use of pesticides.

Apart from the administrative burden to register these BCA's the question could be asked why they are considered to be micro-organisms and what the risks of using them are. This is probably based on the symbiotic bacteria that the nematodes carry with them and which are essential in their life-cycle and often the cause of death of the target pests. There is, however, no exposure to these bacteria – as in the case of usage of micro-organisms as a true active ingredient - to the applicator, the workers in the crop, the bystanders and the environment and therefore risks are minimal to not existent. Therefore a need to regulate them under 91/414 seems irrelevant.

Many scientific papers have discussed the risks of EPN's and in general the overall conclusion is that they can be used safely and have been used safely already for a long period of time without having led to any environmental or human problems.

As a producer of EPN's for more than fifteen years we would like to formally object to this draft regulation and we would like to ask the EU to leave EPN's out of the Directive and to let them be regulated by the current regulations and guidance documents of EPPO, OECD, FAO and others.

Yours sincerely,

KOPPERT Biological Systems

Drs. W.J. Ravensberg
Manager R & D Microbials
Koppert Biological Systems
Veilingweg 17
P.O. Box 155
2650 AD Berkel en Rodenrijs
The Netherlands