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Registration of Biological Pesticides in Sweden and the EU

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INTRODUCTION

The fact that a plant protection product has a biological origin does not necessarily mean that it is harmless. This is the main reason why, in Sweden, biological pesticides may be used and offered for sale only if approved by the National Chemicals Inspectorate (KemI). For the purposes of the 1991 Act on preliminary examination of biopesticides, the term "biological pesticide" refers to microorganisms, viruses, nematodes, insects or Arachnida, developed particularly to prevent or counteract sanitary nuisance or damage on property from animals, plants, microorganisms or viruses. Act (1992:605) Here, 'developed' means cultivation of organism, organism reproduction, harvest and concentration, addition of other components, and packaging.

NATIONAL LEGISLATION

The National Chemicals Inspectorate examines applications for approval of biological pesticides. The Chemicals Inspectorates regulations (KIFS 1994:4) on biological pesticides, annexed, contain provisions for the application. According to Section 3, an application for approval of a biological pesticide must contain the information needed for a satisfactory assessment to be made as to whether the preparation is acceptable from the standpoints of human

health and the environment and if it is needed for pest control purposes. Application forms are provided by the Inspectorate, along with a guide in two versions (one for microorganisms including viruses and one for nematodes, insects and Arachnids) to the completion of the form. The applicant himself must decide what information is relevant and submit it. Where there is uncertainty, KemI may request supplementary documentation.

EU-DIRECTIVE(S)

The Council directive on plant protection products (91/414/EEC) is in use in Sweden since 1995, when Sweden became a Member State. The directive includes as active organisms, microorganisms and viruses. So far, draft data requirements for microbials (Annex II and III, working documents 4992/VI/95 - rev 2 and 4993/VI/95 - rev.2) have been established. However, decision making criteria (Uniform Principles) only exist for chemical active substances.

Additional directives which bare impact on the regulation on biological pesticides are the biocide directive 98/8/EC, directives 90/219/EEC and 90/220/EEC, regulating the contained use and deliberate release of genetically modified organisms and directive 90/679/EEC with the aim to protect workers against risks to their health and safety arising from exposure to biological agents at work.

THE EVALUATION PROCEDURE

The evaluation of microorganisms as pesticides is in a developmental phase. We repeatedly need to ask ourselves: are we on the right track or are we just following the deep and familiar tracks already set by experience from dealing with chemicals?

The first step in evaluating would be to identify the organism and already the name will give useful information. Is the organism known to the scientific society or is it "new"?

The second step is to establish the organisms properties, from the literature if available or from tests and studies if appropriate. These include in terms of description; the organisms biology, mode of action, life cycle, host specificity, impact on non-targets, pathogenicity, known opportunism, medical reports, toxin production, efficacy etc. From the properties it is possible to describe what kind of a hazard the organism potentially may possess. Regarding the human health aspects also the lack of information is important. A commonly occurring bacterium or fungus not reported in connection to any disease can probably be regarded as non-pathogenic.

The risk assessment step include factors in connection to the use and who are not directly dependent on the organism in itself. Such factors relate to exposure, natural occurrence, application method, formulation, environmental conditions where the product is to be used, detection methods, residues, background level, post release control, potential resting stages.

When evaluating the risk the exposure situation is important. Even if the organism is naturally and commonly occurring, the exposure, while using it as a pesticide can be expected to be much higher than normally. The method of application as well as the type of formulation can often be of crucial importance and evidently a way to reduce potential risk for workers.

Available identification methods for the purposes of follow up on residues and for post release control are a necessary tool in assessing the risk. It is also important to consider methods for identification of possible resting stages.

ACCEPTANCE CRITERIA

In the absence of specific decision making criteria at Community level, decisions will have to be made on a case by case basis. But some general criteria are in my opinion ready to be drawn up. Biological pesticides that are known to the scientific society, commonly occurring in the area where to be used, of natural origin and repeatedly encountered by humans, not reported to cause human or non-target disease, can be detected for post-release control and for which the mode of action is known could be approved after thorough judgement by experts. A precautionary approach will have to be reflected in the decisions and conditions until more experience is gained in practice in the field and in risk management.

Biological pesticides, through their mode of action, are often very target-specific and should therefore be inherently less hazardous to non-target organisms. This advantageous characteristic also has the negative effect to narrow the market for these products, which in turn puts increasing pressure on regulatory authorities as to not demand extra information not needed for appropriate risk assessment. Biological pesticides are an important alternative to chemicals and may become useful in comparative assessment and the phasing out of problematic chemicals.

CURRENT SITUATION

Since January -95, 45 biological pesticides (products) have been authorized in Sweden with 17 different species, mainly insects and predatory mites, as active organisms. A few applications have been rejected due to technical

reasons (lack of data etc). Restrictions have been made in the use area in some cases and one species (insect) has been denied approval after risk assessment. Based on this experience a document on the risk assessment procedure focusing on the risks connected with the introduction of foreign macroorganisms has been written. Experimental permits have been issued for the development of new products. Aerial application of *Bt* has been approved on two occasions for two severely infested forest areas.

There are presently additional 18 products that are being applied for in Sweden, consisting of 7 different micro-organisms, 4 nematodes and 1 insect species. Many of these products were already in use when the legislation came into force and were therefore granted a temporary exemption from the demand on registration while Keml is handling their application so not to eliminate the market and use.

As Rapporteur Member State Sweden has prepared a monograph on a "EU-new" organism, *Pseudomonas chlororaphis* MA 342, according to the 91/414/EEC. The monograph and proposed decision for inclusion on Annex I have been discussed during summer and will continue to be discussed during autumn of -98 in various expert and regulatory decision meetings at Community level. Two other monographs (prepared by Belgium and France) are also being discussed and these three together are the first microorganisms in plant protection products to be handled and decided upon within the EU-system. Keml has granted the product Cedomon containing *P. chlororaphis* MA 342 a provisional authorization while waiting for acceptance on inclusion in Annex I of directive 91/414/EEC.

The National Chemicals Inspectorate has been contracted by the Commission (DG VI) to organize a workshop on the scientific basis for risk assessment of microbiological plant protection products and to rewrite the available documentation requirements according to the outcome of the workshop. The workshop will be held in Stockholm, Sweden, October 26-28 1998.

EXPERIENCE GAINED

Both authorities and notifiers need a better knowledge about the organisms. A complicating factor is that the data requirements are too influenced by the requirements for chemicals. Many of the tests and studies recommended are measuring only toxicological endpoints and will thus not give overall useful results. Remaining questions can be difficult to answer by a traditional approach of further testing. More basic research in (micro-)biology and ecology is needed to ensure a better understanding of what the potential effects of the large scale release of microbials into the environment could entail.

Information needed for risk assessment is sometimes available but difficult to reach. With the fast development of products out of new research discoveries, conflicts seem to arise between on the one hand scientists wanting to publish their results and on the other hand notifiers wanting to use them for regulatory purposes.

Statistics on sold amounts of pesticides in Sweden is annually being published by Keml. Biological pesticides were for the first time represented in their own category in the account for -97. The interest for these products is large, especially in green house production, and is expected to increase further as more products are becoming available. There is a great potential of "know-how" and interest within the line of growers that must not be forgotten in the search for reliable information.

FUTURE NEEDS

Major resources are being put in to research to find "new" organisms and develop new products. Product development and research are closely linked and focused towards new applications and markets. The risk management enforced by the preapproval system has to meet these new situations on the grounds on scientific documentation provided by the notifier and scientific community. In short; there has to be

more microbiology in the authorisation procedure.

We need to define "critical endpoints" to which the data required aim to correspond. By identifying these endpoints, priorities can be set for the development and establishment of international guidelines and protocols for testing, where needed. They will also be useful in defining mutual acceptance criteria.

I will end as I've been asked by posing a few questions to scientists, regulators and the OECD;

How far in detail is it appropriate to demand information on the identity of an organism? (How well does the species concept apply to different microbials?)

What can be considered naturally occurring; same species but different strains, is that ok?

- I. Ecological effects on a longer time scale - is there a problem?
- II. How can we translate general knowledge/ecology of the organism to "critical endpoints"?
- III. Exposure models applicable for microbials - a way to go?

Species specificity and animal models for infectivity and pathogenicity - how do we interpret the results?

What health problems can be foreseen?

- IV. Secondary metabolites and the need for residue data - a matter of amounts detected?

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