



Five case studies on the registration of natural pesticides in the Netherlands



GENOEG

the Netherlands,
Culemborg, March 2006



CLM

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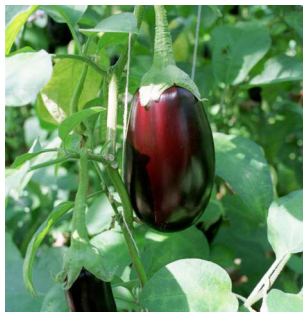
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Introduction

The project GENOEG (GEwasbeschermingsmiddelen van Natuurlijke Oorsprong Effectief Gebruiken) (www.GENOEG.net) supported the registration of five natural pesticides in The Netherlands since 2002. The aim of the project was to get more natural pesticides registered, to learn about the lower risk profiles of these pesticides and to apply this knowledge in statements¹ for registration purposes. The project was funded by the Dutch Ministry of Agriculture, Nature and Food Quality and the Product Board for Horticulture and was done in cooperation with the Board for the Authorisation of Pesticides (CTB), the Plant Protection Service, the Agricultural University, the Dutch Organisation for Agriculture and Horticulture (LTO), the National Institute for Public Health and the Environment (RIVM) and CLM (project coordination).

The registration fees and possible extra studies for the five applications was co-financed to a maximum of € 100,000,=. Besides this subsidy the project provided expertise on specific scientific fields and helped in the process of the application. The applicants were responsible for completing and submitting the actual dossier.

In 2004 this activity was continued and upscaled with ten new products. This continuation is financed by the Dutch Ministry of Agriculture and performed by the Plant Protection Service, Board for the Authorisation of Pesticides and CLM (project coordination).

This brochure covers the experiences with applications for the initial five products.

Cases

The five products were Trianum (*Trichoderma harzianum*), Botanigard (*Beauveria bassiana*), Preferal (*Paecilomyces fumosoroseus*), and a further two products that are still in the application procedure. The first three are notified list 4 substances, while the two other products are considered new substances in Europe.

All applicants involved claim that the applications would have been withdrawn if it wasn't for the support given by the project GENOEG, both in terms of the subsidy and the support in the application process.

Aim and selection

The project aimed to increase understanding on how to use the lower risk profile of a product in answering the dossier requirements, but was not aimed at defining "low risk". The products brought forward by applicants (18 products in total) were therefore screened by experts on expected human and environmental toxicity.

The experts were not given a framework, other than their own experience. Basic risk profile data needed to be submitted by the applicants. Other items that were taken into account were the efficacy, the problem-solving potential of the product in integrated crop protection strategies in the Netherlands and the expected potential of the applicant to complete the needed registration process.

Since the selection criteria were not quantified, the applicants were always invited to comment on the opinions of the experts or engage in dialogue with the experts, before the selection was made final.



Results

Statements based on literature, expert judgement or registrations in other countries, can save performing new, expensive studies. Statements can be based on the profile of the compound, the purity, the efficacy, residues or environmental effects. It is more difficult, and less desired, to use statements when filling in dossier requirements dealing with human toxicology. The envisioned formulation or application needs to be known in order to make statements.

The procedures for application are very complex and hard to communicate, especially for new comers on this market. For new substance in Europe many procedural steps need to be taken compared to the "old" substances. Inexperienced applicants can face strong delay because of (for them) unexpected steps in the procedure. Some examples are: notifying the member states that a dossier is going to be sent to them three months in advance, finding the right addresses to send the dossiers to and translating the dossier or guiding letters in all of the desired languages for the different member states. The procedure is so complex that it seems incomprehensible for laymen. In this project we advised inexperienced applicants to hire a consultant to overcome extra delays, resulting in higher costs for the applicants.

The risks of applying for registration of a pesticide remained high proportionately to the expected market. The main risks of the registration procedure include the high costs for the dossier and the dossier evaluation and the long and unpredictable time frame for registration. The pesticide market on the other hand is still dominated by chemic-synthetic products. Using natural pesticides often require a different strategy for crop protection, similar to the transition to using predator insects for pest control. The market for natural pesticides therefore is a niche market that seems to be growing.



The knowledge about the risk profiles of natural pesticides among evaluation bodies is increasing. Pesticide evaluation has been a chemical-oriented profession for many years. Natural pesticides in general have a different risk profile than chemical pesticides. By looking critically at the risk profiles of these pesticides in relation to the regular dossier requirements, evaluators participating in this project could accept statements as reported earlier and raised questions when appropriate.

A number of member states, with some guidance from the EU, are taking this critical view to make a better fit between the different types of risk profiles of natural pesticides and the regular dossier requirements. This learning process is essential for better evaluation, and seems best pursued in a case-by-case approach.

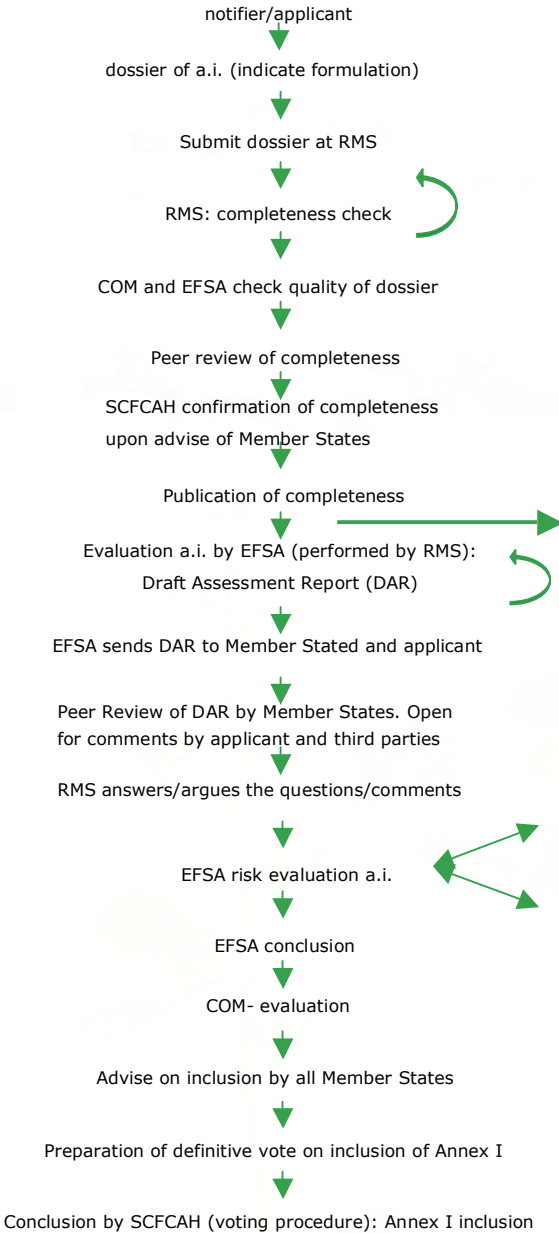
Conclusions

Using statements based on literature, expert judgement or a registration in other (non-EU) countries it is possible to save in costs for a pesticide registration by not having to perform expensive studies.

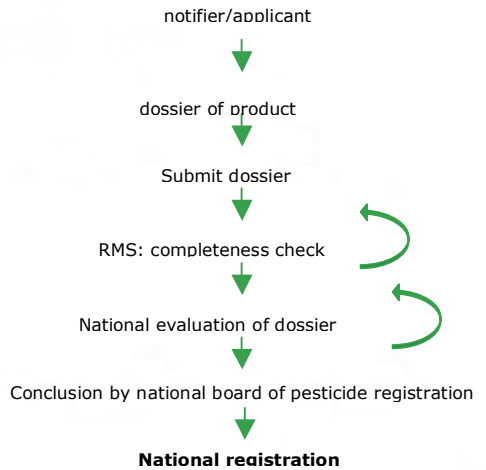
Further reduction of the risks of a registration application seems necessary. Natural pesticides are aimed at an innovative niche market in Integrated Pest Management. In the Netherlands with relatively small pesticide markets, the risks for bringing innovative pesticides that cater for specific problems in integrated pest management are high. To reduce the (added) risk of the registration of these pesticides, the following steps should be taken:

- Further use of statements to satisfy dossier requirements. Both applicants and evaluation bodies need to be aware of this option;
- Reducing the dossier requirements to fit the specific risk profiles of natural pesticides;
- Better prediction of the expected registration costs. Using the experiences of the project and similar initiatives in other European Member States this insight is growing;
- Better communication to potential applicants about the different steps in the application procedures and the time frames involved.

EU-procedures (new substance in EU)



National registration (Annex I-substance)



National registration procedure can start (evaluation of both the a.i. and the product are needed)
(registration valid for max. 3 y)

Expert meetings with Member States on issues: advise to EFSA

Scientific Panel of PPR: advise to EFSA on evaluation and risk assessment

National registration becomes 'permanent'

Registration in other Member States

Mutual recognition

Legenda:

a.i. = active ingredient

↺ = this step is taken again in case of non-compliance.

SCFCAH = Standing Committee on Food Chain and Animal Health (EU)

DAR = Draft Assessment Report

EFSA = European Food Safety Authority

RMS = Reference Member State

PPR = Scientific Panel Plant Protection Products and Residues



Project GENOEG

Clear future for natural pesticides

Aim: pesticides for integrated crop management

obstacles in registration

GENOEG:
process
management
statements
literature &
experts
subsidy



www.GENOEG.net

The following organisations cooperate: CLM, Plant Protection Service (PD), Board for the Authorisation of Pesticides (CTB) and was funded by The Ministry of Agriculture, Nature and Food Quality and the Product Board for Horticulture.

Other partners are: the Ministry of Housing, Spatial Planning and the Environment, Social affairs and employment, Producers' organisations Artemis and Nefyto Dutch Organisation for Agriculture and Horticulture, Platform Biologica (Organic farming) en the Agricultural University.



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