

The Role of Regulation in Developing Biological Alternatives to Pesticides

A Rural Economy and Land Use Programme research project designed to set out principles for a better regulatory system for biopesticides and to make practical suggestions for change



Picture: Abiopesticide nematode on an insect host

Policy and Practice Notes

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The Rural Economy and Land Use Programme is a UK-wide research programme carrying out interdisciplinary research on the multiple challenges facing rural areas. It is funded by the Economic and Social Research Council, the Biotechnology and Biological Sciences Research Council and the Natural Environment Research Council, with additional funding from the Scottish Government and the Department for Environment, Food and Rural Affairs.

Fewer chemical pesticides are available for crop protection because of problems with natural resistance and withdrawal of some products for regulatory or commercial reasons. Biopesticides (mass produced, biologically based agents used for the control of plant pests) have an important and increasing role to play, often in combination with chemical pesticides and other tools. They are less toxic than conventional pesticides, often very specific, have little or no residue and are inexpensive to develop. It is generally agreed that regulation is necessary – just because something is ‘natural’ does not mean it is safe – but the present system is geared to chemical pesticides.

A better system of regulation for biopesticides could be achieved by creating an improved knowledge base, involving stakeholders fully in the debate on regulation and its implementation and ensuring they have effective communication links with each other. There is also a need for a biopesticides ‘champion’, a quasi governmental organisation which can act as an advocate for biopesticides.

What organisational structure is needed?

Two bodies play a central role in the regulation of the pesticides sector in the UK. The Pesticides Safety Directorate (PSD) is an Executive Agency of the Department for Environment, Food and Rural Affairs, and is responsible for controls on pesticides and for ensuring they are used safely. The Advisory Committee on Pesticides (ACP) is a statutory body which advises on all matters relating to the control of pesticides.

— The Structure of Pesticides Safety Directorate should remain unchanged with further development of its biopesticides team

A recent informal consultation exercise by Defra recommends either a merger with Central Science Laboratories and two smaller agencies to form a Regulatory Science Agency, or a merger into the Health and Safety Commission/ Executive. The researchers consider the status quo preferable, but of the above options the RSA would offer a better chance for maintaining the momentum of the biopesticides sector. There is already a Biopesticides Champion within PSD and a small group of people with an interest in, and knowledge of, biopesticides regulation. In the past few years PSD has been working to improve its understanding of biopesticides. Existing arrangements should continue to be supported and developed by enhanced co-ordination and training, a clear group identity and strong organisational support.

— The capacity of the Advisory Committee on Pesticides should be strengthened

As the system of European level regulation develops, there will need to be developments in the ACP. In the course of the research many positive comments about the ACP were noted, but the level of knowledge of biopesticides within ACP was not high. The ACP should have a new committee member, or an informal network of experts with appropriate specialisms, to provide impartial advice on biopesticides. A breadth of expertise is required as ‘biopesticides’ cover such a wide range of entities with varying properties and behaviours.

Is efficacy testing necessary?

Efficacy testing is required by regulations and fulfils several requirements. It determines the effectiveness and safety of products. Testing is also needed for marketing purposes to provide the information for labelling the product, and giving instructions for most effective use. It also helps to protect users from deceptive claims about products.

— Efficacy testing should continue to form part of the registration process but there is scope for varying some of the requirements and hence reducing the cost

- Testing can account for as much as 50% of registration costs for biologicals compared with 10% for chemicals. This is because only small treatment plots are required for chemicals but biologicals need larger plots to get statistical significance and efficacy trials don't always work the first time. The high quality of work in the UK leads to global acceptability but it is a relatively expensive place to generate efficacy data.
- A further category was recently introduced to the UK Official Recognition scheme for 'Biologicals and Semiochemicals trials/tests' which will allow organisations conducting work on micro-organisms or semiochemicals to apply for Official Recognition in a more limited and specialist category of work than was previously possible.

How is the development of the Biopesticides Scheme helping and what more needs to be done?

The researchers see the recent introduction of a permanent Biopesticides Scheme, offering reduced fees for registration, as a positive step. The project provided training for PSD on the scientific and regulatory challenges posed by the scheme. In the context of developing European regulation, the PSD has also secured 'first mover' advantage by leading the field in biopesticides regulation.

— The PSD needs to reach companies that have products they wish to register

Previous experience with the regulatory system has undermined the confidence of some product developers. Even when they do make contact, they may be reluctant to provide relevant information, making it difficult for PSD to assist them. Some products may appear in forms that lie outside the scope of the regulations, eg as plant strengtheners, leaf enhancers etc.

— Companies need to be in contact with PSD at an early stage

This ensures that the right information for approval is collected and that time is not wasted on collecting data that are not required. Published information can often provide the required support for a case.

— There may be a case for giving products registered a distinctive approval number

Instead of a MAPP (Ministerially Approved Pesticide Product) number this could be a Bio number that would flag them up as distinctive.

Is the European dimension important?

A dual approval system is evolving in the EU. A committee of member states assesses the active ingredient (AI) of a pesticide. Once an AI has been approved products that contain it are assessed by individual member states for specified uses. In assessing an application member states are expected to draw on the scientific assessment agreed at the EU level. New AIs are increasingly being approved at this EU level and work has begun on the review of older pesticides that are already being marketed but it will be some years before this process is complete and until then the UK and EU systems will operate alongside each other.

Informal contacts between the PSD and other EU registration agencies are increasing. This has led to the development of an effective informal network for the exchange of knowledge and information. Experience is developing considerably as more biopesticides are being considered. However, there are considerable variations in the resources and effectiveness of national agencies within the EU, and national agencies in northern Europe are generally perceived as more effective in their regulation than those in southern Europe or new member states.

— A key requirement is to ensure that mutual recognition of each other's regulatory systems works effectively between member states

This would create a larger market for biopesticides and overcome some of the economies of scale problems.

Is there a need for assistance with registration costs?

Considerable sums of public money have been spent on the development of biocontrol products which have then not been registered or marketed, and private firms have encountered considerable difficulties with the cost of the registration process, as well as the costs of development and testing.

— Schemes in the Netherlands and the United States help to fund registration and a similar approach might be considered in the UK

What is the role of food retailers?

The role played by food retailers is substantial but poses challenges. They often impose requirements on growers that go beyond those of the regulatory system:

- Different retailers have different requirements, enhancing the complexity of decision-making for growers and producing, in effect, a non-standardised system of pesticide use
- Their supplementary system of approvals may give the impression that not all approved pesticides are safe
- Additional standards may be very difficult for growers to meet and are sometimes contradictory
- Retailers may simply not make products available
- Retailers' actions are often driven, quite legitimately, by a desire to gain an edge over their competitors, rather than a desire to promote alternative products.

— There needs to be a more structured dialogue between retailers and the PSD

— Retailers could consider through the Retail Consortium whether they could harmonise the requirements they impose on growers

Further information

The research has been carried out at the University of Warwick

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Useful resources:

JK Waage, 'Biopesticides at the Crossroads: IPM Products or Chemical Clones?', 1997 BCPC Symposium Proceedings No 69: Microbial Insecticides: Novelty or Necessity?

Project website:

www2.warwick.ac.uk/fac/soc/pais/biopesticides/

RELU project on related topic:

www3.imperial.ac.uk/rebug

PSD website: www.pesticides.gov.uk/

ACP website: www.pesticides.gov.uk/acp_home.asp

