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## IMPROVING THE AVAILABILITY OF BIOPESTICIDES: AN INTERDISCIPLINARY RESEARCH PROJECT

David Chandler\*, Wyn Grant, Justin Greaves, Gillian Prince, Mark Tatchell (University of Warwick) discuss the results of an interdisciplinary research project that looked at regulatory obstacles to the wider use of biopesticides.

**Keywords:** biopesticides; regulation; UK; European Union

### Abstract

There is a need for new, biologically-based crop protection products to serve as alternatives to or to complement synthetic chemical pesticides. An interdisciplinary research team from the natural and social sciences considered whether regulatory barriers were preventing more biopesticides reaching the market. The research coincided with a realisation by policy makers that more needed to be done to facilitate biopesticide registration, exemplified by the UK's Biopesticides Scheme. However, important differences remain between the UK and other countries such as the USA. Changes in regulatory arrangements need careful handling. The scientific work undertaken in the project provided a better understanding of the population biology of microbial control agents. Interdisciplinary work permitted a contribution to the policy debate.

### 1. Introduction

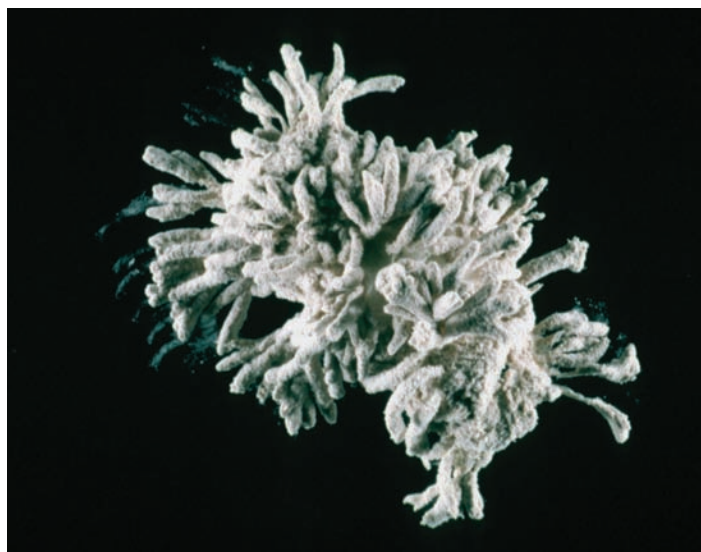
There is a strong requirement for crop protection agents that can be used as alternatives to, or alongside, synthetic chemical pesticides. Chemical pesticides are a precious resource for many farmers and growers, but the availability of pesticide active ingredients is declining as agrochemical companies withdraw products as a result of government reviews. At the same time, growers of fresh produce are now under pressure from retailers to deliver crops with zero detectable pesticide residues, meaning in many cases that non-chemical agents will have to be used during the pre-harvest period when residues would be detectable. There is also the question about how to prevent and manage the development of natural resistance to chemical pesticides in pest populations: alternative pest control agents can have a key role to play here as well. As products are withdrawn from the market, fewer synthetic pesticides are available for plant protection. Biopesticides (mass produced, biologically-based pest control agents) can offer effective pest control with minimal detectable negative impact on the environment.

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The pathogenic fungus *Lecanicillium longisporum* infecting the aphid *Metopolophium dirhodum*; this fungus is used as a commercial biopesticide of aphids

They include living organisms (true predators, parasitoids, pathogens and antagonists) and natural products, such as semiochemicals. They are usually less toxic than conventional pesticides, often very specific, have little or no residue and are inexpensive to develop. Yet despite their potentially valuable role as a component of Integrated Crop



A moth larva infected by the insect pathogenic fungus *Isaria*; strains of this fungus are being used as commercial biopesticides in a number of countries

Management (ICM), relatively few biopesticides (i.e. mass produced biological agents for inundative pest control) are available on the UK market.

## 2. The purpose of the RELU project

In our Rural Economy and Land Use (RELU) programme project on the environmental and regulatory sustainability of biopesticides, we were interested in whether failings in the regulatory process had created a barrier to preventing more products to reach the market. (More information about the project is available at our website:<http://www2.warwick.ac.uk/fac/soc/pais/biopesticides/>). One of the distinctive features of the project was that it involved the cooperation of biologists with substantial experience in the protection of plants against pests with political scientists specialising in the study of regulation. The insights of the two disciplines were brought together in an interdisciplinary approach to the problems being studied. Our focus was on microbial control agents, i.e. microorganisms that function as natural enemies of pests and which can be used for pest management.

In the UK, biopesticides are regulated by the Pesticides Safety Directorate (PSD) using a system that had been developed originally for chemical pesticides (with the exception of 'macro-biological' natural enemies, such as predatory insects and parasitoids; these are regulated by a separate body). A key consideration was whether this system that had been developed to regulate chemical pesticides could work for biologically-based products with their very different characteristics. Another problem was a failure to apply ecological theory to the environmental risk evaluation of microbial products set within an overall regulatory framework that encourages innovation. Just because something is natural does not mean that it is safe. Different species and strains of a microbial species can vary significantly in host range, pathogenicity and other biological characteristics which can potentially affect environmental safety. The assessment of impact on non-target organisms needs to take account of the advance of ecological information and understanding, including insights made in recent years in community ecology and invasion biology.

## 3. Facilitating biopesticide registration

### 3.1 Challenges in the UK

Our project was timely because it took place alongside a growing realisation by policy makers that more needed to be done to facilitate the registration of biopesticides. Responding to initial pressure from the UK Cabinet Office, the PSD set up a pilot project, subsequently converted into a fully fledged Biopesticides Scheme, to help ensure that the registration of more biopesticides was facilitated so that they reached the market. This had a number of elements, but among the key ones were reduced fees for biopesticides, help targeted towards the small and medium-sized companies who generally produce biopesticides through pre-submission meetings and the appointment of a Biopesticides Champion within PSD.

Not as many products have been developed for registration as was hoped. By the end of 2007 five biopesticide products had been guided through the system and approved for use in the UK. Five other products are at various stages of evaluation and a large number of companies are discussing possible applications. There may be a number of reasons for this. Despite considerable efforts by PSD to reach out to manufacturers and developers, there may still be some residual suspicion of the regulator in a fragmented industry. The International Biocontrol Manufacturers' Association (IBMA) has been developing its organisational capacity and engaging in a constructive dialogue with PSD, but not all manufacturers are members. By not making specific claims about control as plant protection products, some products may be marketed outside the registration process by stating that they are 'leaf enhancers' or 'plant strengtheners'.

### 3.2 Greater availability in the USA

Many more biopesticide products are available in the United States (US) than in Europe which constitutes an agricultural market of a similar size. Figures for 2005 indicate that more than 200 products were being sold in the US, compared to only 60 comparable products in the European Union (EU). Products do not have to undergo efficacy testing in the US, but this is probably not a major factor in explaining the difference in availability. Efficacy data still have to be gathered for marketing purposes and manufacturers we have talked to in the US are anxious to 'raise the bar' and prevent the reputation of their products being damaged by 'snake oil' options that cannot be relied upon to do what they say on the label. One of the important functions of efficacy testing in Britain is to help write the label and hence give instructions about most effective use. Products do not have to have one hundred per cent efficacy, the product simply needs to function according to the label claim. Our view is that 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.

A research visit to the Biopesticides and Pollution Prevention Division (BPPD) of the Office of Pesticides Programs of the US Environmental Protection Agency (EPA) suggested that there are substantial differences between the USA and EU in bureaucratic resources, organizational culture, rules, market structure and supporting policy measures which, taken together, help to explain differences in policy outcomes. Apart from the more proactive stance of the BPPD and its sense that it has an administrative mission to secure wider use of biopesticides, there is also more external policy support in the USA in the form of the Interregional Research Project (IR-4) programme.

This programme was started by the Directors of the State Agricultural Experiment Stations (SAES) in 1963 and has been administered since then by USDA. IR-4 works closely with EPA: 'IR-4 is our best mechanism, so helpful,' commented one of our EPA respondents. In 1995, the programme was updated to include a focus on biopesticides and since then \$2.85 million has been provided for biopesticides research. They have an employee whose only

role is to help the registration of biological pesticides. Funding can be provided to help small companies generate the data they need for registration. IR-4 also supported the growth of the industry trade association, the Biopesticide Industry Alliance (BPIA) an entirely US-based organisation. For its part, BPPD has provided \$100,000 for a Biopesticide Demonstration Program to persuade growers of their advantages. The sums involved are not large, but they may be sufficient to ensure that a product is developed, registered and marketed.

Similar effects have been observed with the Genoeg scheme in the Netherlands which is operated by a consultancy company, but with financial support from the Ministry of Agriculture. This scheme has had a limited time frame, but has been renewed, although its future is under discussion. Registration fees were co-financed up to a level of fifty per cent of registration costs provided that the total was not more than €100,000. The UK, in contrast, operates a relatively rigid market failure doctrine on such matters so that those new actives which have been developed with public money often cannot afford to meet product registration costs.

### 3.3 Problems with EU Regulation

The USA offers a substantial internal market for biopesticide products which permits economies of scale. The EU regulatory system is complex and in transition, but in broad terms, the EU approves active ingredients and the member states products. The EU does not have an internal market in biopesticide products because there are twenty-seven national regulatory authorities and mutual recognition generally fails to work. We helped in the exploration of these problems through the European Commission policy action on the Regulation of Biological Environmental Control Agents ('REBECA'). More information on the work of this programme is available at: <http://www.rebeca-net.de/> The EU's pesticides regulations are currently under review, in particular directive EC91/414. An attempt to overcome the mutual recognition problem by dividing Europe into three 'eco zones' where a product registered in one member state would be approved in all the others in the zone ran into resistance from some member states and the European Parliament.

## 4. What we achieved

### 4.1 Working with PSD

We worked closely in our project with PSD, providing training on the underlying biology and ecology of microbials, as well as on the challenges facing scientific regulators. We were also able to observe some of the pre-submission meetings between PSD and potential registrants of products. This led to the development of a document for practitioners based on five underlying principles and containing ten sets of recommendations for further development of the system. A copy of the full document is available on our website and print copies may be obtained from [w.p.grant@warwick.ac.uk](mailto:w.p.grant@warwick.ac.uk) It is hoped that this document will feed into the continuing debate about how more biopesticide products could be made available to growers.

Nevertheless, registration and use of biopesticides are still hindered by their lack of profile relative to other alternatives which reflects the weakness of the supporting policy network. There is a lack of integration in terms of the form, quality and infrequency of interaction. Underlying problems include a policy network still at an early stage of development; limited resources and capabilities; and a lack of trust between some actors. One of the services provided by our project and by REBECA was to run workshops that can bring together growers, manufacturers, regulators, and scientists in a neutral setting that provides opportunities for learning and interaction. Better understanding of the biology and ecology of microbial natural enemies, and of the regulatory issues that arise in their adoption, provided by our project may help to raise their profile among policy-makers and hence enable them to realise their contribution to sustainability.

### 4.2 The future of regulatory bodies

The future of PSD is currently under discussion with the favoured option within government being to merge it into the Health and Safety Executive (HSE), but retaining a distinct identity and location. We have participated in the stakeholder consultation to make known our concerns about this development. In large part, the change seems to be driven by the Hampton Report's preoccupation with the number and size of regulatory bodies and its view that their number should be reduced. This does not give sufficient weight to the fact that smaller regulators can be more flexible and responsive and can develop an organisational culture that favours innovatory responses to new challenges such as biopesticides. In time, a regulatory body which is focused on a particular task and attentive to stakeholders may come to be seen as more appropriate than a larger and possibly more unwieldy body. There is an aspiration that HSE will draw on the consumer and organisational focus of PSD, but will the organisational culture of the smaller organisation be sufficiently strong to influence and change that of the larger one?

In particular, it is important that PSD's pioneering work in the area of Biopesticides is not neglected. This is not mentioned in the proposition for the merger. There is a risk that the greater focus on chemicals strategy within the merged organisation might lead to less attention being paid to the contribution of biological agents to the achievement of sustainability objectives. The features of the Biopesticides Scheme need to be safeguarded, in particular the reduced fee structure for biologicals.

### 4.3 Future scientific work

The scientific work undertaken in our project has provided a better understanding of the population biology of microbial control agents, in particular soil dwelling insect pathogenic fungi which were the focus of attention for the natural science components of the project. These fungi occur naturally in farmed, semi-natural and natural habitats, and selected strains are also developed and used as biopesticides against crop feeding insects. On farmland, natural fungal population levels and the relative abundance of different

intra-specific groups varies between different habitats on the farm, particularly between cropped and non cropped habitats. Establishing a link between fungal biodiversity and habitat type has implications for the selection of the most suitable fungal strains for use as biopesticides, and also for our understanding of how the release of biopesticide strains could affect natural fungal populations. Improved understanding of the ecology of microbial control agents in this way will have a double pay-off of better systems of environmental risk evaluation and more effective and sustainable microbial control.

Areas that require future scientific work include a better understanding of the phylogeny of microbial natural enemies. We also need a better understanding of the biogeography of microbial natural enemies, of the factors that determine distributions of species and strains and influence gene flow. Other areas in which work is required include an improved understanding of the factors determining the persistence and spread of microbial natural enemies.

In our project, the technical expertise of the scientists fed into the recommendations produced by the political scientists for the development of the system of regulation. Practical recommendations based on the underlying science and an understanding of how the regulatory system works in Britain and elsewhere should contribute to the development of the policy debate.

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