Design principles for a better regulatory system for biopesticides
Introduction

UK farmers and growers face the considerable challenge of using more environmentally acceptable methods of crop protection while maintaining food quality, productivity and profitability.

There are additional pressures from retailers who are moving increasingly to wanting fresh produce with zero detectable pesticide residues. There are good opportunities to reduce synthetic chemical pesticide inputs on crops using biologically-based agents as part of Integrated Pest Management (IPM). This paper concerns a wide range of biologically-based crop protection products known collectively as biopesticides. The agents used in these products are based on living organisms or natural substances and they have a range of properties that make them desirable for IPM. We are particularly concerned with biopesticide products that are regulated in the UK by the Pesticides Safety Directorate.

This paper arises from the RELU (Rural Economy and Land Use) project conducted at the University of Warwick on the Role of Regulation in Developing Biological Alternatives to Pesticides. Aimed at practitioner audiences it is intended to set out underlying and operational design principles for a better regulatory system for biopesticides in the UK and, where appropriate, to make practical suggestions for change in the current arrangements. The aim is to have a regulatory system that does not inhibit the commercial development of these products while protecting human and environmental safety, and thus makes best use of biopesticides for sustainable farming and food.

Definition of biopesticides

We define biopesticides as mass produced, biologically based agents used for the control of plant pests. This definition encompasses not only the active ingredient of a biopesticide but also how it is used. The term ‘pest’ includes invertebrates, weeds and microorganisms that are injurious to plants. Biopesticides can be divided into three categories: (1) living organisms (i.e. natural enemies), which include invertebrates (e.g. predatory insects), nematodes and micro-organisms; (2) naturally occurring substances which includes plant extracts and semiochemicals (e.g. insect pheromones); (3) in some countries – but not in the UK - genetically modified plants that express introduced genes that confer protection against pests or diseases (so called plant
Biopesticides cover a wide spectrum of potential products, but for the purpose of PSD and our Biopesticides scheme these are divided into four categories:

- Products based on pheromones and other semiochemicals (for mass trapping or trap cropping)
- Products containing a microorganism (e.g. bacterium, fungus, protozoa, virus, viroid)
- Products based on plant extracts
- Other novel alternative products (considered on a case by case basis)

Biopesticides have a key but specific role to play in crop protection

The management of plant pests relies heavily on synthetic chemical pesticides, which in many respects are a precious resource for crop protection and should be treated as such. However, problems of natural resistance and the withdrawal of some products for either regulatory or commercial reasons mean that fewer chemical pesticides are available on the market. This is especially a problem for the minor crops sector which has suffered from loss of registrations. Alternative crop protection tools are needed for growers; therefore, Biopesticides have an important and increasing role to play in crop protection, although normally in combination with other tools including chemical pesticides as part of Integrated Pest Management (IPM). They are generally less toxic than conventional pesticides, are often very specific, have little or no residue and are inexpensive to develop. Nevertheless, those agents with a narrow spectrum of activity will be niche market products.

Biopesticides should be regulated

A fundamental assumption we make is that biopesticides should continue to fall within the ambit of the regulatory system for pesticides which is rightly one of the most stringent systems of regulation. Just because something is ‘natural’ does not mean that it is safe. However, the regulatory system has tended to follow a chemical pesticide model which is often not relevant in the questions that it poses and does not facilitate the efficient registration of biopesticides.
The regulatory system must support sustainability objectives

The regulatory system must seek to support sustainability objectives. It should be informed by a proper understanding of the precautionary principle and it should avoid imposing costs on future generations. Although environmental sustainability must have a special emphasis in relation to the regulation of pesticides, other aspects of sustainability must be taken into account, including economic sustainability. The regulatory system should enable small and medium-sized firms producing biopesticides to flourish and should equip growers with the plant protection tools they need to control infestations economically and produce products which meet the expectations of consumers.

Pest management should be ecologically based

Pest management should be ecologically based, should make use of natural enemies of pests and should be undertaken within the context of Integrated Crop Management (ICM) and IPM. It is important that biopesticides are seen as linked with wider farming systems such as IPM/ICPM and not just seen as case-by-case replacements for chemical pesticides. In the public debate, methods of production do not have to be conceived in terms of a stark choice between intensive farming and organic farming. Moreover, there needs to be broader recognition of the role of ICM and IPM and of biopesticides in particular. Biopesticides offer benefits to both conventional and organic farming, providing an aspect of unity where there is otherwise division. The regulatory system needs to give greater recognition to public goods in the form of positive externalities. This could be done through an ‘IPM Innovator Awards’ as operated through the California Environmental Protection Agency.

It should be credible with all stakeholder groups including consumers

The regulatory system needs to have the confidence of all relevant stakeholder groups: growers, manufacturers, consultants, scientists, retailers and consumers. It is particularly important that the regulatory system has the confidence of consumers in relation to human health issues. Misperceptions of the regulatory system and a lack of confidence in it may undermine the achievement of health policy objectives such as the consumption of a sufficient quantity of fruit and vegetables.

Operational principles

An improved knowledge base and chain

There still needs to be better understanding of the ecology of microbial control agents, the fate and behaviour of microbial releases, and of the effects of secondary metabolites/toxins produced by micro organisms, a minority of which could have consequences for human health. Data on appropriate external expertise needs to be readily available to the Pesticides Safety Directorate (PSD) and the Advisory Committee on Pesticides (ACP). There needs to be a more effective knowledge chain linking, for example, growers and public sector researchers. Researchers have been the one target audience that PSD have most difficulty in engaging with. The absence of a state extension service in the UK (it still exists in the US) does make the dissemination of objective information to growers more difficult, but it is a constraint one cannot expect to be removed. It should be noted that experience is developing considerably as numerous Biopesticides are considered under the fourth review of Directive 91/414/EEC.
Stakeholders need to be fully involved in the debate on regulation and its implementation and to have effective communication links with each other.

Our research suggests that the biopesticides policy network is relatively weakly developed compared to other networks analysed in the political science literature and sometimes lacks political sophistication. Our own workshops have sometimes facilitated contacts. The REBECA (Regulation of Environmental Biological Control Agents) programme funded by the European Commission has also brought together relevant actors who might not otherwise have had contact, culminating in a successful congress in Brussels in September 2007. One challenge is how these contacts can be maintained, although it has been argued that the annual conference of the International Biocontrol Manufacturers Association (IBMA) in Lucerne is emerging as a ‘one stop shop’ for the policy network. Nevertheless, environmental groups often seem to have been relatively isolated from the debate, while the IBMA, although developing in terms of organisational effectiveness, often lacks sufficient resources to carry out its role. It may be, however, that there are additional activities that they could undertake at relatively little cost, e.g., contacting MEPs in their constituencies.

This is in contrast to the situation in the Netherlands where there appears to be a much more effective relationship between different stakeholders, in part through the medium of the Genoeg project. There are specific features which have made this possible in the Netherlands, but this does not mean that there could not be more effective dialogue in the UK.

However, a key problem is the lack of an influential constituency of support for biopesticides. Interventions by government have been somewhat ad hoc and sporadic and it is questionable whether there is the organisational or policy support that is evident in the Netherlands. There is no clear environmental constituency of support with the debate about a more sustainable agriculture being framed around discourses about organic farming. The IBMA is a relatively low profile organisation. Retailers seem to be relatively isolated from policy discussions, although they are potentially important actors.

A biopesticides ‘champion’ organisation: there needs to be an organisation, preferably quasi-governmental in character, which can act as an advocate for biopesticides.

In the United States this role is to some extent performed by the Biopesticides and Pollution Prevention division of the Environmental Protection Agency (EPA). However, it is able to do so in part because of cultural differences, but more because of the long-standing existence of the IR-4 programme. The US model cannot simply be translated to Britain. The PSD’s principal task is to determine whether biopesticides can be safely marketed and it cannot take on an advocacy role for which it has no authority and is not equipped or suited.

Admittedly, ‘The aim of PSD is to protect the health of human beings, creatures and plants, safeguard the environment and secure safe, efficient and humane methods of pest control, by controlling the sale, supply, storage, advertisement and use of pesticides.’ More specifically, as part of the strategy for sustainable food and farming, it is tasked with reducing negative impacts of pesticides on the environment. One approach to that task could be promoting the wider use of biopesticides. However, the adoption of a proactive role in that area would require ministerial guidance. It may also be questioned whether the approvals side of PSD, which is set up to undertake the task of registration to ensure the safe use of pesticides, is equipped for such a task.
One organisation that could undertake such a role is Natural England. It would certainly be compatible with its broad tasks and objectives. These include a pledge to ‘Develop and promote sustainable solutions to environmental problems at a national, regional and local level and as a result increase the social and economic value provided by the natural environment’ and playing ‘a lead role in helping people to learn more about, and take action for, the natural environment.’ However, Natural England is a new organisation which is still establishing its policies and priorities. The principal predecessor organisation, English Nature, had no tradition of acting as an advocate for biopesticides. It is not reasonable to expect an early commitment from Natural England in this area, if at all.

Nevertheless, without an organisational champion with a clear advocacy role, the case for biopesticides risks being sidelined. All too often the alternative to the extensive use of synthetic pesticides is presented in terms of organics or even genetically modified (GM) crops which remain politically controversial in Northern Europe.

Organisation of PSD
Changes in structure may not be helpful

Following the report of the Royal Commission on Environmental Pollution on bystander exposure, but also strongly influenced by the Hampton Report on better regulation, there has been discussion within government of the future organisational arrangements for pesticide regulation. We would not favour the transfer of PSD’s policy function from the agency to Defra itself as if it became simply a technical regulator, it might be less open to change. It has also been suggested that the technical side of PSD should become part of the Environment Agency (EA). A recent informal consultation exercise by Defra does not favour the status quo but recommends either a merger with Central Science Laboratories (CSL) and two smaller agencies to form a Regulatory Science Agency (RSA), or a merger into the Health and Safety Commission/Executive. (HSE) In our response we have indicated a preference for the status quo, but also a preference for the RSA option as we think that offers a better chance for maintaining the momentum of biopesticides work. The HSE option might be feasible if PSD was not moved to Bootle which would inevitably lead to the loss of experienced staff and disruption to the Biopesticides programme. HSE is already responsible for Biocides. However, it is not easy to see how a HSE division at York would fit easily into the HSE structure.

Further development of a biopesticides team

There is already a Biopesticides Champion within PSD and a small group of people with an interest in, and knowledge of, biopesticides regulation. A challenge for PSD in the past few years has been to improve its understanding of biopesticides and it has responded effectively and with real commitment. At one time we thought that there should be a dedicated division within PSD concerned with biopesticides on the EPA model. We no longer think this is appropriate. The climatic diversity of the US and the size of the domestic market offer more opportunities for biopesticides and a dedicated division would have insufficient work. As it is, trained staff at York would welcome more applications to process. However, we think that the existing arrangement should continue to be supported and developed in terms of enhanced coordination and training, a clear group identity and strong organisational support. This does not mean that work cannot be shared around the approvals group in order to broaden experience of working with biopesticides. Indeed, it would desirable if more individuals within the approvals branch could have experience of biopesticides work. PSD may also wish to develop a directory of external experts on biopesticides.
Advisory Committee on Pesticides (ACP): strengthening its capacity

The role of the Advisory Committee on Pesticides in the regulatory process was the subject of some criticism in the Royal Commission on Environmental Pollution report, e.g., for limiting parameters of debate. It should be noted that in the course of our research we have heard many positive comments about the ACP. Dealing with biopesticides poses particular challenges for ACP, although even within the evaluation process of conventional pesticides difficult questions are often asked and ACP members have recourse to consult outside their own immediate area of knowledge and expertise. The ACP secretariat liaises with the PSD so that they are aware of particular applications likely to require approval over a year or so. If, for example, they were expecting a number of applications concerning microbial control agents based on entomopathogenic fungi, they could take that into account in recruitment for the committee. Given that biopesticides cover a wide diversity of niche market products, a more likely scenario is that the applications received for biopesticides over the course of a year are likely to include small numbers of very different agents. Appointments to the ACP are in any case constrained by the code of the Office of the Commissioner for Public Appointments (OCPA) that seeks to ensure fair and open competition and compliance with the Nolan rules on public appointments and also the absence of a commercial interest in products under consideration.

Nevertheless, our view is that there is a lack of deep knowledge in ACP on biopesticides in general and the biology of microbial control agents in particular. This is understandable given that (a) most of the work of the ACP is concerned with chemical pesticides and (b) biopesticides are a wide array of products and organisms with properties and behaviours that are often very different to those of chemical pesticides. This lack of deep knowledge could disturb the balance between protecting safety without inhibiting commercialisation. As the system of European level regulation develops and the approval of active ingredients is done at EU level, there will need to be changes in the role of ACP and some forethought needs to be given to this. Given that it may not be practical for the ACP to have a new committee member who can function as an impartial expert in biopesticides, the way forward may be to create and utilise a network of experts with appropriate specialisms. This could be achieved by drawing up a list of biopesticide ‘experts’ which the ACP could refer to either in advance of meetings or subsequently to resolve some of the unknowns and to further streamline the authorisation process. This would be more helpful than using an ‘ad hoc’ process to contact biocontrol experts. This could be done with the help of the IBMA, the RELU team and others working in the area, but in order to make the process transparent and widen the net, learned societies such as the Society for Invertebrate Pathology and the British Society for Plant Pathology could be involved.

Efficacy testing: necessary, but the procedures could be adjusted

Efficacy testing is a major issue in relation to biopesticides because according to interview information it can account for as much as 50 per cent of registration costs for biologicals compared with 10 per cent for chemicals. Chemicals can use quite small treatment plots but biologicals need larger plots to get statistical significance because individual replicates are more variable: there is greater complexity and variation because they are living organisms. Efficacy trials don’t always work the first time, e.g., in one set of trials the pest didn’t turn up two times out of three, although this can also be a problem for trials of synthetic pesticides also. Could the market be left to decide whether a particular product works?

In the United States applicants for registration are not required to submit efficacy data, although they must have it available. The US is rather unusual in this respect in terms of national systems of regulation. In any case PSD see themselves as bound by the requirements of the 1985 legislation.
Efficacy testing is in any case needed for marketing purposes otherwise it is difficult to write the label. It is also a means of protecting users from deceptive claims in the form of ‘snake oil’ products. PSD takes a flexible approach to label claims and no preconceived level of effectiveness is required. The Canadian Pest Management Regulatory Agency (PRMA) emphasises the value dimension of efficacy testing.

We are therefore of the view that efficacy testing should continue to form part of the registration process, but with some variations. There may be scope for varying some of the requirements imposed in efficacy testing and hence for reducing the cost. These issues are being considered by the Biopesticides Steering Group at an OECD level. Appropriate consideration should be given to the findings of the EC funded Efficacy Extrapolation Project carried out by PSD. A report was produced which presents proposals for harmonizing efficacy and crop safety extrapolations with the aim of reducing the need for trial data whilst maintaining high standards of performance and selectivity. A key area for review is the number of tests required over what time period. The applicability of Good Agricultural Practices (GAP) standards needs to be considered. There is an issue about whether it is necessary to destroy crops used for trials.

The UK is a relatively expensive place to generate data, but the high quality of work leads to global acceptability. A further category was recently introduced to the UK Official Recognition scheme for ‘Biologicals and Semiochemicals trials/tests.’ This 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.

In particular we endorse proposal 9E made by REBECA which was made in the knowledge that efficacy testing may form part of the EU approvals system after the revision of 91/414 (thus overtaking any arrangements made at member state level). Applicants would be able to choose whether to undergo efficacy testing as part of the registration process or defer it for five years (although it may be that three years would be more appropriate). This would facilitate the registration of a Biological Control Agent against an emerging pest or for minor uses. This would facilitate product development and market entry of SMEs with very limited research funds. The downside risk is that products on the market with low efficacy might compromise the reputation of biopesticides.

Biopesticides Scheme: an important development

We welcome the development of a pilot project into a permanent Biopesticides Scheme. This offers reduced fees for registration and it is noted that these were not increased when PSD announced adjustments to its fee structure from March 2007. It is anticipated that the next fee adjustments may see an even more favourable ratio between the cost of biological and synthetic approvals. In the context of developing European regulation, the PSD is to be applauded for securing ‘first mover’ advantage by leading the field in biopesticides regulation.

There is still an issue of reaching out to companies that may have products they wish to register. To some extent previous experience with the regulatory system has undermined the confidence of product developers. Even when they do make contact, they may be reluctant to provide relevant information, making it difficult for PSD to assist them. It is possible that some products appear in forms that lie outside the scope of the regulations, e.g., as plant strengtheners, leaf enhancers etc.

PSD has developed an effective working relationship with IBMA, but its resources are limited and problems involved in identifying and contacting products remain despite the best efforts of PSD. Given that not all product developers are members of IBMA, there is no easy way of overcoming these problems.

For those firms that do make contact, pre-submission meetings are a vital part of the process and are conducted in a helpful and professional way by PSD. Given that PSD operates on a cost recovery basis for its approval activities, they should help PSD to reduce the cost of handling the
actual application by identifying areas in which additional information is required and how it can be obtained. Companies need to be in contact with PSD at a sufficiently early stage in product development to ensure that the right information for approval is collected or that time is not wasted on collecting data that is not required. In many cases published information can provide the required support for a case.

There may be a case for giving products registered through the Biopesticides Scheme a distinctive approval number. Instead of a MAPP number this could be a Bio number that would flag them up as distinctive. In the past a special A-mark was given to products assessed for efficacy.

The role of retailers: substantial, but posing challenges

Retailers often impose requirements on growers which go beyond the regulatory system in terms of prohibiting products that are permitted or allowing their use only after consultation with the retailer. Retailers see themselves as proxies for consumers and as reflecting consumer concerns about pesticide residues. They are able to exert their substantial influence in the food chain to influence grower decision making in order to protect their brand reputation. It should be noted, however, that there is considerable variation in the practices of retailers, influenced by the resources available to them, their analysis of their market position and their assessment of the social composition of their consumers. Some retailers are more proactive in this area than others.

What in practice amounts to a supplementary approval system contributes to misconceptions over pesticide safety by in effect the retailers running their own approvals system, e.g., not wanting farmers to use OP or carbamate insecticides. This gives the perception that not all approved pesticides are safe. Their standards can be very difficult for growers to meet and can be contradictory. For example, they would encourage the use of natural predators but would reject any pre-packed foods that have insects in them.

This supplementary system of private governance for pesticides does pose some challenges. First, different retailers have different requirements, enhancing the complexity of decision-making for growers and producing in effect what is a non-standardised system of pesticide use. Second, retailers prohibit rather than promoting alternatives including biopesticides. They would reasonably argue that they cannot endorse particular products. Third, retailers lack public accountability and their actions are often driven, quite legitimately, by a desire to gain an edge over their competitors.

The European dimension: growing in importance, but still problematic

A dual approval system is evolving in the EU with the member state approvals process being replaced by an EU based system under which 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 the member state 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 an EU level and work has begun on the review of older pesticides that are already being marketed. It will be some years before this process this complete and until then the UK and EU systems will operate alongside each other.

With the establishment of the European Food Safety Authority (EFSA) risk assessment was separated from risk management. EFSA is responsible for the risk assessment of new active substances (where dossiers were complete after June 2002) and existing active substances. New and existing active substances are first evaluated by a rapporteur state. EFSA will then undertake in cooperation with member states a peer review of the initial assessment. The role of EFSA is still evolving, but concerns have been expressed that their rules may be too inflexible, and more data will be requested for a risk assessment than is absolutely necessary.
It should be noted that informal contacts between the PSD and other EU registration agencies have been very much on the increase and have led to the development of an effective informal network for the exchange of knowledge and information. This is reinforced by contacts within the Biopesticides Steering Group of OECD. However, there are considerable variations in the resources and effectiveness of national agencies within the EU. The general pattern is for those in northern Europe to be perceived as more effective than those in southern Europe or new member states. It also needs to be appreciated that, given resource constraints, there are limits to what PSD can do at EU (or OECD) level.

A key requirement is to ensure that mutual recognition works effectively between member states. This would create a larger market for biopesticides and overcome some of the economies of scale problems.

Directive 91/414 is still under revision at the time of writing. An important element of the proposal is splitting the EU into three regions – northern, central and southern – so that future pesticides authorisations would be given for a specific area rather than a specific country (it has been suggested recently that there should be a fourth zone made up of some East European countries). A member state would therefore not be able to ban an approved substance, although it would be permitted to introduce ‘risk mitigation measures’ such as stipulating the permitted level of use, distance from water courses etc. There are clearly different perspectives in the Commission and member states on how authorisations should be handled.

The eco zones proposal has attracted some criticism. There have been reservations expressed about the fact that all of France is in the one zone although it is geographically diverse. France will always be a source of difficulty because climatically it is split in two between northern (temperate) and southern (Mediterranean) zones and this split is used for residues extrapolations. Concerns have also been expressed about the fact that the proposed central zone is too large and would cover diverse geographical regions from Ireland to Slovenia. There is an alternative map available, the EPPO climate comparability map which uses four zones, but the Commission tends to be uneasy about solutions that cut across country boundaries. It may be that the proposal in its present form is too simplistic, but other than further developing the welcome growth of cooperation between national registration agencies, there is no alternative proposal on the table at the moment.

The Warwick project has participated fully in the work of the EU policy action on the Regulation of Environmental Biocontrol Agents (REBECA) and was represented on its steering group. REBECA has made recommendations of its own with which we are in broad agreement.

www.rebeca-net.de/?p=320

**Assistance with registration costs: a needed intervention?**

Considerable sums of public money have been spent on the development of biocontrol products which have then not been registered or marketed. Private firms have encountered considerable difficulties with the cost of the registration process, not just the registration fee, but the cost of development and testing.

An innovative approach to this question has been adopted in the Netherlands through the Genoeg project (Effective Use of Natural Pesticides) which has operated since 2002, leading to the registration of four new natural products. An expanded second phase is now in operation. Successful applicants receive a grant to cover 50 per cent of the registration costs up to a limit of €100,000 and also receive consultancy assistance, for example with literature search. The overall budgetary cost to date is estimated at 1.5 million.

The project does not overcome all the problems of registration costs. Some potential applicants estimate the total cost of registration at, say, €400,000 and therefore consider that the assistance provided is insufficient. Not all the products have been commercial successes. Nevertheless, it has enabled products to be brought to the market that might otherwise not have been registered.
Similarly in the United States, there has been a biopesticides programme under the IR-4 programme which was started in 1982 and was expanded in 1994. Working closely with EPA, it has funded 43 projects since 1994 at a cost of $2.85m and also gives regulatory advice.

Such assistance might be seen as too ‘near market’ in the UK, notwithstanding that it is provided in another member state and the US. The LINK scheme does not really meet this need. There is a market failure to be addressed in terms of the positive externalities of biopesticides not being realised. Hence, a variant of such a scheme might usefully be adopted in the UK and, alongside the Biopesticides Scheme, could produce significant results at not too great a cost.

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The UK research councils’ Rural Economy and Land Use Programme was launched in 2003 to carry out interdisciplinary research on the multiple challenges facing rural areas.

These include:

- Restoring public trust in food chains
- Tackling animal and plant disease in a socially acceptable manner
- Enabling sustainable farming in a globalised market
- Promoting robust rural economies
- Developing land management techniques to deal with climate change
- Managing land and water use for sustainable water catchments

The programme is an unprecedented collaboration between the Economic and Social Research Council (ESRC), the Biotechnology and Biological Sciences Research Council (BBSRC) and the Natural Environment Research Council (NERC). It has a budget of £24 million, with additional funding provided by the Scottish Government and the Department for Environment, Food and Rural Affairs.