

<b>Institution:</b> University of Warwick
<b>Unit of Assessment:</b> Politics and International Studies
<b>Title of case study:</b> Designing and Implementing a New Regulatory Framework for Biopesticides in the UK and EU
<p><b>1. Summary of the impact</b></p> <p>Biopesticides can help protect crops and offer a more sustainable means of pest protection to offset the withdrawal of synthetic products, as well as offering the potential of a new hi-tech industry. Before Professor Grant's research there were insufficient regulatory mechanisms to authorise biopesticide products. He worked closely with government bodies such as the UK Pesticides Safety Directorate (PSD), industry, growers and retailers to identify and address this problem. The main impact of Grant's research was the design and implementation of principles for a new regulatory system for biopesticides in the UK and EU. A Biopesticides Scheme was introduced in 2006 that increased the registration rate of biological products and retailer awareness. Grant also contributed to the REBECA (Regulation of Biological Control Agents) policy action, which informed and shaped EU debate and legislation that was revised in 2009.</p>
<p><b>2. Underpinning research</b></p> <p>Plant diseases pose a serious threat to food security, biodiversity and the rural environment. UK farmers and growers face the challenge of using environmentally acceptable methods of crop protection while maintaining food quality, productivity and profitability. One solution is to reduce chemical inputs using Integrated Pest Management (IPM) based on biological control agents such as naturally occurring fungi, bacteria, viruses or nematodes. Historically, however, there has been a poor uptake of microbial pesticides in the UK. Relatively few products have been registered successfully and made commercially available.</p> <p>The aim of Grant's research was to identify and overcome barriers to the successful registration of biopesticides in the UK. He was Principal Investigator of the project 'Biological Alternatives to Chemical Pesticides in the Food Chain'. This was part of the BBSRC's £26.5M research programme 'Rural Economy and Land Use' (RELU) between 2004 and 2013, designed to change policies and practices concerning rural economy and land use. Grant worked with Dr David Chandler and Dr Mark Tatchell from Warwick Horticulture Research International (HRI). Also integral to the project was Dr Justin Greaves from Politics and International Studies who worked closely alongside Grant as a Postdoctoral Research Fellow.</p> <p>The underpinning research carried out by Grant investigated the political and intellectual limits of existing policy and regulatory frameworks in the field of biopesticides. It identified and traced the evolution of a model that did not allow for the successful registration of biopesticides in the UK and EU contexts. A total of 49 interviews were conducted with regulators, growers, consultants, manufacturers and retailers in order to identify the obstacles to getting more products available on the market more quickly. In addition, the team observed pre-registration meetings held at the Pesticides Safety Directorate between potential registrants and regulators so that they could identify the issues that concerned both sides of the regulatory process.</p> <p>The findings of the research highlighted shortcomings in the existing regulatory system. Many of the difficulties that had arisen in registering biopesticides arose from the design of the regulatory process to deal with chemical pesticides. The project identified gaps in the incomplete and under developed biopesticide policy network in terms of stakeholder interaction and a need for a more structured dialogue between retailers and the PSD – later known as the Chemicals Regulation Directorate (CRD). The research showed that questions asked about chemical products were not necessarily relevant to biological products and therefore the system had an incomplete and inadequate regulatory design. The results of the research provided the basis for a set of design principles that led to a better regulatory system for biopesticides.</p>

**3. References to the research**

1. W. Grant with D. Chandler, A.S. Bailey, G.M. Tatchell, G. Davidson, and J. Greaves (2011) 'The Development, Regulation, and Use of Biopesticides for Integrated Pest Management', *Philosophical Transactions of the Royal Society B*, 366(1573), pp. 1987-1998. [2012 impact factor 6.230]. Peer-reviewed journal article.
2. W. Grant with J. Greaves (2010) 'Crossing the Interdisciplinary Divide: Political Science and Biological Science', *Political Studies*, 58(2), pp. 320-339. [2012 impact factor 0.917]. Peer-reviewed journal article.
3. W. Grant with J. Greaves (2010) 'Underperforming Policy Networks: The Biopesticides Policy Network in the United Kingdom', *British Politics* 5(1), pp. 14-40. [2012 impact factor 0.689]. Peer-reviewed journal article.
4. W. Grant with A. Bailey, D. Chandler, J. Greaves, G. Prince and M. Tatchell (2010) *Biopesticides: Pest Management and Regulation* (Wallingford: CABI). Peer-reviewed research monograph.
5. W. Grant with D. Chandler, G. Davidson, J. Greaves, and G. M. Tatchell (2008), 'Microbial Biopesticides for Integrated Crop Management: An Assessment of Environmental and Regulatory Sustainability', *Trends in Food Science and Technology*, 19, pp. 275-283. [2012 impact factor 4.135]. Peer-reviewed journal article.
6. W. Grant with Chandler, D., Bending, G., Clarkson, J., Davidson, G., Hall, S., Mills, P., Pink, D., Skirvin, D., Neve, P., Kennedy, R., Greaves, J.M., and Collier, R.H. (2008), 'The Consequences of the 'Cut Off' Criteria for Pesticides: Alternative Methods of Cultivation, a Briefing Note for the Committee on Agriculture and Rural Development of the European Parliament' (Brussels: European Parliament). Peer-reviewed policy paper.

**Associated grants:**

1. BBSRC RELU Programme Research Grant (total award £353,676 from 1 November 2004 to 31 October 2007, with practitioner engagement until 2011), 'Biological Alternatives to Chemical Pesticides in the Food Chain'. PI: Professor Wyn Grant.

**4. Details of the impact**

Grant's research team worked closely with government bodies, the biopesticides industry, growers and retailers and made recommendations for new regulatory systems. The primary impact has been the facilitation and implementation of a new regulatory framework for biopesticides in the UK and Europe. The research has been widely recognised as being of practical importance to the agricultural economy and the crop protection industry (see especially sources 1, 2, 3 and 8). This is demonstrated by the wide range of audiences to which the team was asked to present its findings, including: the European Parliament Agriculture and Rural Development Committee; and companies such as Syngenta PLC and Sainsbury's.

**Beneficiaries and training**

In 2003 the UK Pesticides Safety Directorate (PSD) introduced a Pilot Project to facilitate the registration of biopesticides. This was converted to a Biopesticides Scheme in 2006 offering pre-submission meetings, reduced registration fees and a 'Biopesticides Champion' within PSD. Grant's research studied this process of regulatory innovation and worked closely with PSD to i) provide training to key members of PSD staff to facilitate the achievement of their objectives and ii) enable the development of a model that specified the conditions under which regulatory innovation was likely to occur.

The project was characterised by effective engagement with a range of key stakeholders. There were three principal beneficiaries of the research:

1. Regulators working in the PSD/CRD (sources 5 and 7);
2. Decision-makers in the European Commission and the European Parliament concerned with a revision of the relevant regulatory framework (source 6);
3. Manufacturers of biopesticides organised in the International Biocontrol Manufacturers

**Impact case study (REF3b)**

Association (IBMA) (source 8).

Grant and the team engaged in a continuous dialogue to co-produce knowledge with the PSD regulators between 2004 and 2007, and organised three training events at Warwick HRI and the PSD Head Quarters in York. These knowledge transfer events used the results of the research to improve the regulators' understanding of the underlying science and principles of regulation (sources 5 and 7). Staff who attended these events have confirmed the on-going impact of Grant's research since 2008 and in her testimony a source from the CRD writes: "The series of training events have had a long term impact in assisting technical evaluations by better understanding the underlying science and biology related to some of the potential biopesticide products" (source 7). The events also facilitated the development and subsequent implementation of a new regulatory system more apposite to biopesticide usage (source 4).

**Designing and implementing a regulatory system for biopesticide usage in the UK/EU**

Regulation occurs at both a UK and EU level and the two systems are intertwined. The regulators took up the findings and recommendations of Grant's research and a new regulatory framework at the UK and EU level, which took account of his work, ultimately came into force (sources 4, 5, 6 and 7). Grant was subsequently coopted as an Independent Advisor to the Availability Action Plan Implementation Group of the National Pesticides Strategy, which met until 2012 when it was dissolved and replaced by a group with a narrower membership (source 4). As a direct result of his research, the number of products registered for use in the UK has increased, with 10 new biopesticide active substances registered since the scheme started in 2007 (source 4 and 8). This compares with a low rate of registration before then, for example 3 between 1985 and 1997. In turn, this has broadened the range of options for farmers and heightened environmental sustainability (source 4).

The research has had impact beyond the UK regulatory policy context and has facilitated change at the EU level (sources 5 and 6). In 2008 Grant was invited by the European Parliament Committee on Agriculture and Rural Affairs to advise them on the future of crop protection policy in Europe. His team also published a report, entitled 'The Consequences of 'Cut-Off' Criteria for Biopesticides', for a committee of the European Parliament and addressed questions by committee members in Brussels. Through representation on the Steering Group of the European Commission policy action REBECA, the project informed and influenced policy discussion and decision-making across the EU (source 6). In 2009 the EU passed a new and more effective package of legislation, which involved the substantial revision of the existing directive and two new directives. The legislation made specific provision for enhancing the use of biocontrol agents. This led to a new zonal system of registration across member states, which had been consistently advocated in Grant's research presentations to policy-makers.

**Mechanisms for achieving impact**

A range of impact activities also engaged manufacturers of biopesticides and brought them in closer conversation with the UK PSD and EU regulatory bodies: two well-attended one-day conferences attracting 100 participants from regulation and industry (sources 5 and 7); a series of workshops organised across the EU as part of the REBECA project (source 6); and presentations at the Annual Conference in 2009 and workshops of the IBMA, for example at Grantham in 2010 (source 9). The IBMA had formerly been afflicted by a lack of knowledge and understanding of the regulatory context. Through these activities Grant provided necessary training. Based on the findings of his research he was able to suggest new strategies and tactics that could be used by the IBMA in making its case for greater regulation to the EU and governments of Member States. This work significantly enhanced the quality and effectiveness of the IBMA as a key stakeholder (source 8).

**5. Sources to corroborate the impact****Evidence of impact on UK and EU regulatory frameworks:**

1. **BBSRC Impact Case Study.** Grant's research impact has been showcased by the BBSRC as an example of best practice. This report summarises the impact of Grant's research and includes quotations from staff at Marks and Spencer, the Chemicals Regulation Directorate and Department for Environment Food and Rural Affairs about the value of the project. Available on request and online: <http://bit.ly/19OVXYA>
2. **RELU Report on Societal and Economic Impact**, 20 June, 2012. This Final Report concludes that RELU research, including Grant's (as detailed in Figure 2a, p.19), has helped to change policies and practices concerning rural economy and land use. Available on request and online: <http://bit.ly/H7oWQk>
3. **Environment, Food and Rural Affairs Committee.** Minutes of evidence for session held on 4 February 2009 entitled 'Securing food supplies up to 2050: the challenges faced by the UK'. Cites Grant as co-author of Memorandum submitted by Warwick HRI. Available on request and online: <http://bit.ly/17vVcn6>
4. **Rationale Biopesticide Strategies.** The source advises growers on the use of biocontrol products and companies on the registration process. She can provide a testimonial to corroborate claims about the relevance and value of Grant's work to the developers of biocontrol products and his contributions to the Availability Action Plan Implementation Group and its impact.
5. **Director of Approvals, PSD, later CRD.** The source writes in his testimonial (available on request): "Biopesticides have presented a fantastic challenge to both regulators and those developing alternative control measures, working with the RELU team has helped people over that hurdle [...] Our Biopesticides scheme is now a pathfinder in Europe – no other member state has a scheme like this. The work shadowing and visiting fellowships were of great benefit to the CRD. They provided us with an opportunity to expand people's skills at reasonable cost and also helped in developing the regulatory policy side of our work. Bouncing ideas off [...] Professor Grant is refreshing and helped staff to think about issues in a different way".
6. **Head of EU REBECA Programme and Managing Director, e-Nema.** On request the source can corroborate claims that Grant's research made a key contribution to the EU REBECA programme, particularly in terms of advising on the political feasibility of recommendations in the context of EU decision-making structures and policies.

**Evidence of impact on training and capacity building with key stakeholders:**

7. **Biopesticides Champion, Approvals Secretariat Branch, CRD.** Evidence in the form of an emailed testimonial confirms that Grant's training events have had on-going impact since 2008 (available on request): "The series of training events have had a long term impact in assisting technical evaluations by better understanding the underlying science and biology related to some of the potential biopesticide products".
8. **Executive Director, International Biocontrol Manufacturer's Association.** On request, the source can testify to the way in which Grant's research enhanced the quality and effectiveness of the IBMA as a key stakeholder in the reform of UK and EU biopesticide regulatory frameworks.