Institution:	**University of Warwick**
Unit of Assessment:	**A6: Agriculture, Veterinary and Food Science**
Title of case study:	**Regulation and Growth of the Biopesticide Industry**

1. Summary of the impact

This research represents an interdisciplinary collaboration between the School of Life Sciences and the Department of Politics and International Studies at the University of Warwick. The research focused on the commercialisation of biological pesticides or "biopesticides" - pest control agents from natural sources that are considered safer for humans and the environment than most conventional chemical pesticides and could potentially substitute for synthetic chemical pesticides. Biopesticide products can only be sold if they have been authorised by government regulators under UK and EU legislation. Prior to this research, only six biopesticide products had been commercialised in the UK. The research identified shortcomings in the UK biopesticide regulatory process and its associated policy network that acted as unnecessary barriers to the authorisation of biopesticides. A set of recommendations for an improved regulatory system was developed. The UK Pesticides Safety Directorate used the research to help implement a new scheme to facilitate the registration of biopesticides in the UK and therefore get more products to the market. The research was also used in 2008 to provide policy advice to the European Parliament on making greater use of biopesticides and other alternatives to synthetic chemical pesticides and improving the way they are regulated. In a 2007 report by the Science Advisory Council of the UK's Department for Environment, Food and Rural Affairs (Defra), the work was highlighted as helping to facilitate the emergence of a new biopesticides sector in the UK. Since the research was started, there has been a 430% increase in the number of biopesticide products approved in the UK.

2. Underpinning research

Crop pests are a major constraint on the production of food crops, reducing potential worldwide crop yields by about 40% per year (e.g. see Oerke & Dehne, Crop Protection, 23, 275 – 286 (2004)). Traditionally, pests have been managed using synthetic chemical pesticides (e.g. organophosphates, carbamates, synthetic pyrethroids). However, excessive pesticide use can damage the environment, for example by harming non-target organisms, and lead to pest control failure through the development of resistance in pests that can be inherited from one generation to the next (e.g. see Pimentel, Environment, Development & Sustainability, 7, 229 – 252 (2005). Concerns have also been expressed about the safety of pesticide residues in food. In response, the European Commission has brought in legislation on pesticide approvals that is reducing the numbers of synthetic chemical pesticides authorized in the EU (Regulation EC 1107/2009).

Promising alternatives to conventional pesticides are "biopesticides". These are pest control agents from natural sources including microorganisms, plant compounds and insect pheromones. They are intended for use in Integrated Pest Management (IPM) programmes, which aim to grow healthy crops with the least possible disruption to ecosystems, and with a reduced reliance on synthetic chemical pesticides. Biopesticides offer several benefits, primarily in terms of being safer for humans and the environment[1]. However, the rate of commercialisation of biopesticides in the UK and mainland Europe has been slow compared to that in other countries, for example, in 2011 there were three times as many biopesticide products authorized for use in the USA compared to the EU[1]. We hypothesised that one reason for this delay was the government approval process required in the UK and Europe before biopesticides can be sold to farmers and growers. The approvals process requires the biopesticide company to submit a dossier on the efficacy and safety of the candidate biopesticide product. At the time the Warwick research began (2004), dossier assessment and product authorisation was handled in the UK by a government regulator (the Pesticides Safety Directorate (PSD)), and an independent body (the Advisory Committee on Pesticides (ACP)). This was done under the auspices of EU regulations (Directive 91/414EEC).

The problem of poor commercialisation of biopesticides was originally discussed at a workshop (2003) organised by Dr. David Chandler (an expert in microbial biopesticides, then working at the Horticultural Research International Institute (HRI) which merged with the University of Warwick in 2005) for UK crop protection companies, growers and crop management consultants (HRI Association meeting "Biopesticides – the future?", Warwick, November 2003). A collaboration was formed in 2004 between crop protection researchers (Dr. Chandler and Prof. Mark Tatchell, an expert in IPM, also at HRI) and Prof. Wyn Grant, a political scientist (Warwick University's Department of Politics and International Studies). This collaboration led to a project (2004–2007) commissioned by the Research Councils UK (RCUK) Rural Economy and Land Use (RELU)

programme to investigate whether the UK regulatory process for biopesticides was acting as a barrier to their commercialisation. The activities in this Warwick RELU project were as follows:

- Interviews were held during the Warwick RELU biopesticides project with crop growers, biopesticide manufacturers, consultants and biopesticide retailers. The team closely observed the workings of the PSD and in 2007 Dr. Chandler became the first "outsider" to observe a meeting of the ACP, which meets in closed session. Biopesticide regulators in the USA, the Netherlands and Denmark were also interviewed to compare the regulatory systems in these countries with the UK.
- The Warwick research analysed the existing biopesticide regulatory system and showed that it was unintentionally impeding the successful registration of biopesticides in the UK or EU. The following shortcomings of the model were identified: The risk assessment dossier required by PSD was originally designed for conventional chemical pesticides, and the information required was often not relevant to biological control agents and was expensive for biopesticide companies (many of which are SMEs) to produce, acting as a major deterrent to commercialisation. In addition, there was a lack of knowledge of the science of biopesticides and biological control within PSD and ACP, including a lack of information on the biology and genetics of microorganisms used in biopesticides, which caused delays in approvals (in contrast the US regulator had a specialist biopesticide division and was providing financial assistance to SME biopesticide companies). There was also a need for a better understanding of the regulatory process by biopesticide companies. These issues were adversely affecting product risk assessment and highlighted the need for better dialogue between PSD and biopesticide companies. The situation was made worse by economic barriers to biopesticide adoption including the costs for crop growers of switching from a single, conventional pesticide to a portfolio of alternatives including biopesticides in an IPM programme[1].
- The Warwick RELU biopesticides research formed the basis of a set of design principles for an improved system that was used to help implement a new UK Biopesticides Regulation Scheme by PSD in 2007[1-3]. The research team brought together biopesticide manufacturers, regulators, growers of horticultural crops and supermarket retailers into a policy network.
- An investigation was undertaken, as part of the Warwick RELU biopesticides project, of the population genetics of fungal species used in microbial biopesticides, information which is important for environmental risk assessments of microbial biopesticides carried out by the government regulators[4,5].
- The Warwick RELU biopesticides team worked as a close unit, with Dr. Chandler providing expertise on biopesticides, Prof. Tatchell on IPM and Prof. Grant on regulatory policy. This gave the group credibility with a wide range of stakeholders.
- Other research projects, led by Dr Chandler and funded by Defra and industry, have explored the use of biopesticides in IPM systems.

Key researchers:

- David Chandler, Senior Research Fellow, School of Life Sciences (appointed 1990). Expert on biology, development and use of biopesticides as crop protection agents.
- Wyn Grant, Professor of Politics (1971 – present), School of Politics and International Studies. Expert on regulation and the agricultural economy.
- Mark Tatchell, Professor of Entomology, (1993-2007). Expert in IPM and farming systems.
- Gill Davidson, Research Fellow (1995-present). Ecology of biocontrol agents.
- Justin Greaves, Research Fellow, School of Politics and International Studies (2004-present), now Director of Student Experience and Progression. Research focussed on regulatory innovation for biopesticides.

3. References to the research

1. D. Chandler *et al*., "The development, regulation and use of biopesticides for Integrated Pest Management", *Philosophical Transactions of the Royal Society B*, 366, 1987 – 1998 (2011). Impact Factor 7.3, citations 12.
2. D. Chandler *et al.,* "Microbial biopesticides for Integrated Crop Management: an assessment of environmental and regulatory sustainability", *Trends in Food Science & Technology*, **19**, 275 283 (2008). Impact factor 5.5, citations 25.
3. A. S. Bailey *et al*., "Biopesticides: pest management and regulation", CABI (H ISBN 9781845935597), Wallingford, UK (2010).

4. F. E. Vega *et al*., "Fungal entomopathogens: new insights on their ecology", *Fungal Ecology*, **2**: 149-159 (2009). Impact factor 2.8, citations 57
5. H. E. Roy *et al*., "Deep space and hidden depths: understanding the evolution and ecology of fungal entomopathogens", *BioControl*, **55**, 1 – 6 (2010). Impact factor 1.5, citations 6.

Grants/Awards

RCUK RELU programme: "Biological alternatives to chemical pesticides in the food chain", 2004–2007; Grant reference RES-224-25-0048; Amount awarded £309,544. Further funding of £44,132 received in 2008. PI: Professor Wyn Grant.

Defra: "New approaches to microbial control of insect pests in protected crops and their interaction with waste-based growing media", 2008 – 2011; Grant reference HL0193; Amount awarded £223,278; PI: Dr. D. Chandler.

European Parliament workshop on pesticides, 2008; Amount awarded £4,000; PI: Dr. D. Chandler.

Defra: "A desk study of current knowledge on the combined use of microbial biopesticides and chemical pesticides in IPM", 2010 – 2011; Grant reference PS2135, Amount awarded £29,990; PI: Dr. D. Chandler

Horticultural Development Company: "Biological control of plant diseases using insect pathogenic fungi", 2011 – 2013; Grant reference PE 005; Amount awarded £112,110; PI: Dr. D. Chandler.

4. Details of the impact

The growth in the use of biopesticides depends crucially on the regulation process underpinning their arrival to market. As such, regulation affects the agricultural and horticultural industries, companies wishing to commercialise biopesticide products and also food retailers that are pressing their suppliers to grow fresh produce free of pesticide residues. The Warwick research has led to improvements in the UK regulatory system for biopesticides which is important for facilitating more product approvals[A]. Since the Warwick research was started and the new UK PSD biopesticides scheme was introduced, there has been a 430% increase in the number of biopesticide products approved in the UK (see below). The Warwick research has had a direct impact on the UK government regulator[B], decision-makers in the European Commission and European Parliament[C], biopesticide manufacturers and crop growers[D-F].

Impacts on the regulation of biopesticides:

- UK regulatory policy: A significant impact has been to help facilitate the implementation of a new regulatory system for biopesticides in the UK. The team provided training to the government regulator on biological control science and regulatory innovation, held workshops with government bodies, the biopesticides industry, growers, retailers and others, and proposed for a set of principles to underpin the new biopesticides regulatory system that came into effect in 2006 (enacted by the PSD, now the CRD). This has been widely recognised by PSD and the biopesticide industry as being of importance to the crop protection industry[A-G]. For example, Richard Davis, the then Director of Approvals at CRD, has stated "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"[B].
- European policy advice: Dr. Chandler was invited by the Agriculture and Rural Development Committee of the European Parliament to advise on the potential of biopesticides and other alternative crop protection agents within the context of new European legislation on chemical pesticide use being developed at that time (Directive 2009/128/EC). Dr. Chandler and Prof. Grant gave a lecture at the Parliament (December 2008) and Dr. Chandler was lead author on a detailed policy guidance document[C]. The report recommended increasing the use of biopesticides and other alternative crop protection products in the EU and gave guidance on innovations for the regulatory system for crop protection agents. New EU crop protection legislation (Directive 2009/128/EC, Sustainable Use of Pesticides) was enacted in 2009 which states that biopesticides and other alternative agents must be used in preference to conventional chemical pesticides where they provide satisfactory levels of control.

Impacts on commerce:

- UK & EU biopesticides industry. The number of biopesticide products registered for use in the UK has increased significantly[A]. Prior to the new UK PSD Biopesticides Regulation Scheme, only six biopesticides were approved. Today, there are 26 registered biopesticides in the UK. In the EU the number of registered biopesticide active substances is also increasing, and has gone from 42 in 2008 to around 100 in 2013[D]. The EU biopesticides market is growing at 16%

p.a. compared to 3% for conventional pesticides[D] and in 2010 was estimated at €40M.

- UK retailers and growers. Presentations on IPM, biopesticides and biopesticide regulation were given to Sainsbury's. Dr. Chandler became an invited lecturer on biopesticides for the Waitrose Responsible Agronomy Course (2008 & 2010) which is mandatory for its suppliers (this includes growers, technical managers, and fresh produce sales and purchasing staff). In his lectures, Dr. Chandler teaches about the use of biopesticides in IPM and options for improving the sustainability of crop protection. Interviews with Marks and Spencer done in the Warwick RELU biopesticides project led to M&S having follow-up meetings with researchers on biological pest controls, helping to inform their pesticide strategy[B].
- Recognition of commercial impact by Defra: The Defra Science Advisory Council recognised the value of the project in a report published in 2007[G]. The report stated that the research "has succeeded in opening up a new dialogue among a range of stakeholders from regulators through manufacturers, consultants and retailers to growers, and is helping to prime the emergence of a new industrial sector around bio-pesticides".
- Helping shape the biopesticides sector: In 2011 Dr. Chandler acted as consultant for a biopesticides industry conference organised in Amsterdam by Informa (a global academic publisher and information business). The meeting was significant in being the first industry conference of its size (100 delegates) to be attended by senior representatives of global agri-businesses (Syngenta, Bayer, BASF and Monsanto) and the biopesticides industry. Dr. Chandler and Professor Grant gave lectures based on the findings of their research on the regulation and use of biopesticides. In addition, Dr. Chandler co-managed a pre-conference workshop on the science behind biopesticides and IPM. The meeting provided an opportunity for agrochemical and biopesticide industries to discuss areas of common interest, particularly with respect to IPM. From 2012 there has been significant new investment in the biopesticide industry with at least 22 corporate deals for biopesticides globally[D].

Recognition by the Research Councils:

- BBSRC impact case study: The research was featured on the BBSRC website (2012 – present) as an example of scientific excellence with impact[H].
- RCUK: An independent report for RCUK in 2012 on the UK societal and economic impact of the RELU programme concluded that RELU research has helped change policies and practices concerning the rural economy, and cites the biopesticides research at Warwick as an example[I].

Sources to corroborate the impact

A. Corroborating letter from: **Technical Director**, Fargro Ltd. UK (Identifier 1).
B. Quotes from Chemical Regulations Directorate (CRD) staff, describing the impact of the research on the work of CRD, and from Marks and Spencer, are available from the RELU project impact statement, at: http://tinyurl.com/q8hua54
C. D. Chandler *et al.*, "The consequences of the "cut off" criteria for pesticides: alternative methods of cultivation." Report for the European Parliament (Agriculture & Rural Development) Note 15.12.2008 (2008). http://tinyurl.com/nnn8s4n
D. Corroborating letter from: **Director**, Rationale Biopesticide Strategists, on the size of the biopesticides industry and the role of this research in underpinning the development of the biopesticides sector (Identifier 2).
E. Corroborating letter from: **Executive Director**, International Biocontrol Manufacturers' Association (Identifier 3).
F. Corroborating letter from: **Head of Development**, Syngenta Bioline (Identifier 4).
G. Defra Science Advisory Council Report SAC(07)33. http://tinyurl.com/oxmde3o
H. BBSRC impact case study: This report summarises the impact of the biopesticides 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. http://tinyurl.com/q369xh7
I. RELU Report on Societal and Economic Impact (June 2012), which discusses the impact of RELU research on policies and practices in the rural economy. http://ht.ly/cBbXk.