Institution: University of Birmingham

Unit of Assessment: UOA5 – Biological Sciences

Title of case study: Environmental risk assessment of non-native biological control agents

1. Summary of the impact

The research described has contributed to the design and testing of an environmental risk assessment (ERA) methodology as part of the licensing system for the import and release of non-native invertebrate biological control agents (IBCAs) in EU countries. Both the ERA and a wider protocol are now used in a number of EU countries, and have been recently adopted as a 'Standard' viz. 'Import and release of non-indigenous biological control agents' by the European Plant Protection Organisation (EPPO) – Standard PM 6/2(2). This research programme has enabled the ERA information requirements in licence application dossiers for the release of non-native biocontrol agents to be standardised across national regulatory authorities in different European countries, thus reducing costs of commercial production and use.

2. Underpinning research

The environmental risk assessment of non-native invertebrate biological control agents is based around a step-wise testing procedure that evaluates in turn, establishment potential, host range and dispersal ability of candidate species depending on the area of release (e.g. glasshouse or open field), climatic region (e.g. temperate or Mediterranean) and management strategy (e.g. augmentative or classical control). Assessment of establishment potential is a critical first test because it identifies whether (i) low temperatures kill-off escapees from glasshouses in augmentative control, in which case there would be minimal impact on non-target species before winter intervenes, (ii) establishment of escapees is likely, in which case release would not be safe without knowledge of the host range, or (iii) establishment is likely and essential e.g. in classical biocontrol, where establishment is a pre-requisite for success.

Various laboratory measures of cold hardiness (freezing temperature, lethal temperature, lethal times at different low temperatures) have been conducted on 10 non-native candidate agents (insect parasitoids and predatory insects and mites). Field survival in winter was then assessed in each species, with experiments starting in early and mid-winter, to represent different severities of cold exposure. The strongest correlation identified across these species was between laboratory survival at 5°C and maximum period of survival outdoors in winter ($R^2 = 0.929$). Research is currently underway on a further 2 species.

This research has been conducted over 14 years at the University of Birmingham, starting in 1998, supported by 2 research contracts from Defra (which is responsible for the licensing of non-native biocontol agents in the UK based on advice from the 'Advisory Committee on Releases to the Environment- ACRE), an EU grant, funding from industry and 7 PhD studentships, including 4 Research Council CASE awards with market-leading European producers of biocontrol agents. This research has been led by Professor J. Bale (Chair of Environmental Biology) who was the sole University of Birmingham PI on all of the above awards, apart from the most recent PhD studentship (starting in October 2011).

3. References to the research

1. Hatherly, I.S., Hart, A.J., Tullett, A.G.T. and Bale, J.S. (2005) Use of thermal data as a screen for the establishment potential of non-native biocontrol agents in the UK. *BioControl* 50, 687-698. doi: 10.1007/s10526-005-6758-5

2. van Lenteren, J.C., Bale, J.S,. Bigler, F., Hokkanen, H.M.T. and Loomans, A.J.M. (2006) Risks of releasing exotic natural enemies of arthropods: prospective analyses and an environmental

risk assessment methodology. *Annual Review of Entomology* 51, 609-634. doi: 10.1146/annurev.ento.51.110104.151129

3. Bale, J.S., van Lenteren, J.C. and Bigler, F. (2008) Biological Control. In 'Sustainable Agriculture', special issue of *Philosophical Transactions of the Royal Society* 363, 761-776. doi:10.1098/rstb.2007.2182
4. Hatherly, I.S., Pedersen, B.P. and Bale, J.S. (2008) Establishment potential of the predatory mirid *Dicyphus hesperus* in northern Europe. *BioControl* 53, 589-601. doi: 10.1007/s10526-007-9099-8
5. Bale, J.S. (2010). Regulation of invertebrate biological control agents in Europe: recommendations for a harmonized approach. In '*Regulation of biological control agents in Europe',* pp 323-373. Ed. R. Ehlers. Springer. doi: 10.1007/978-90-481-3664-3_16
6. De Clercq, P. and Bale, J.S. (2010). Benefits and risks of biological control – a case study with *Harmonia axyridis*. In '*Regulation of biological control agents in Europe',* pp 243-255. Ed. R. Ehlers. Springer. doi: 10.1007/978-90-481-3664-3_11

4. Details of the impact

This research programme has enabled the ERA information requirements in licence application dossiers for the release of non-native biocontrol agents to be standardised across national regulatory authorities in different European countries, thus reducing costs of commercial production and use.

The main method of biocontrol in the UK and Europe more generally is the augmentative release of non-native predators and parasitoids into glasshouses – such species are not intended to establish outdoors. Currently, around 170 species (mainly insects and mites) are used in augmentative biocontrol with Europe accounting for 75% of the £260m annual world market. The UK regulates the import and release of non-native biocontrol agents under the Wildlife and Countryside Act 1981, but in the late 1990s it was recognised that the information required from companies seeking to release non-native species was not 'fit for purpose'.

For example, the climatic origin of a species was used as a proxy for the direct assessment of cold tolerance and overwintering ability; and there was no required assessment of diapausing ability (diapause being a dormancy mechanism used by many insect species to survive unfavourable environmental conditions such as low temperature). It was an undiscovered diapause trait in the glasshouse predatory mite *Neoseiulus californicus* first released in the UK in 1991 that led to its outdoor establishment by 1998.

In 1998 Defra commissioned a project at Birmingham to assess the cold tolerance and overwintering ability of previously released non-native agents, as a possible means of predicting establishment potential. This study provided a retrospective explanation for the establishment of *N. californicus* (high level of cold tolerance and diapause trait) and the failure of other released species to do likewise. [*s1*] On submission of the final report from this project, Defra modified the information requirements for applications to release non-native invertebrate biocontrol agents in the UK. [*s2, s6*]

Based on the publications arising from the work, Bale then supervised a number of CASE PhD studentships in collaboration with leading European biocontrol companies (Koppert, Biobest) interested in acquiring 'independent data' on the establishment potential of non-native biocontrol agents as part as the information required by national regulatory authorities in applications for release licences e.g. Defra in the UK. **These data have been used to support successful licence applications for a number of species in different EU countries over the period 2008-**

13. As an example, data produced by Bale's laboratory in Birmingham on the predatory mite *Amblyseius swirskii* was the basis for successful release licence applications by Koppert to regulatory authorities in the UK, Netherlands, Norway, Switzerland and Canada. [s7] Koppert have said "*The research performed by Prof. Bale and his team from the University of Birmingham to produce a laboratory method to assess the overwintering potential has offered a major improvement and resulted in an easy, quick and reliable method which replaces the time consuming and doubtful outdoor test*". [s3] Research conducted by Bale in Birmingham thus has world-wide importance and impact.

As more species were added to the database of laboratory measures of cold hardiness and duration of winter survival in the field, a predictive relationship was established and confirmed, in which survival at 5°C in the laboratory was found to be strongly correlated with the maximum period of survival in the field in winter. This relationship is currently based on 10 species, with studies underway on a further 2 species. It was envisaged that with confidence in this relationship companies would be able to carry out their own studies to collect data on overwintering potential, and that it would also be possible to predict likely field survival from laboratory studies alone, providing a rapid, robust and reliable method of risk assessment; both of these objectives have now been achieved. [*s3, s5*]

In 2011, a 'commercial in confidence' dossier was submitted by a biocontrol company to the Netherlands regulatory authority to release a non-native predatory mite for glasshouse biocontrol. **The company cited the 'Bale methodology' to assess overwintering potential, and estimated winter survival from laboratory data alone, based on the published correlative analysis. [*s8*].** The regulatory authority granted a release licence. Such reliable ERA laboratory methods are more cost and time-effective than field studies, an important consideration for biocontrol companies, which are mainly SMEs with limited R&D budgets. [*s3, s*5]

The ability to identify 'safe' biocontrol agents is also relevant to the EU's 'Sustainable Use Directive' (2009/128/EC published in October 2009), which places an emphasis on integrated approaches to pest management and reduction in the usage of pesticides. The EPPO Standard PM 6/3 (Safe use of biological control) contributes to this agenda by an annually updated list (the so-called 'Positive List') of 'biological control agents widely used in the EPPO region' (Europe and North Africa). This list comprises species that have been used in at least 5 EPPO countries for 5 or more years without reported negative effects, and serves as a valuable advisory tool for countries with limited expertise in biocontrol. Bale is a member of the EPPO panel that reviews the list. After its initial release in the UK and the Netherlands, *A. swirskii* was widely adopted across Europe and added to the Positive List in 2011. **Research in Birmingham thus underpinned a series of licence applications for *Amblyseius swirskii* in several EU countries and its rapid addition to the EPPO Positive List. [*s7*]**

The development of biocontrol in Europe has been hindered by, amongst other challenges, the absence of agreed methods by which to acquire ERA data. **The Birmingham methods to assess overwintering and establishment potential have been accepted by a number of regulatory authorities in northern Europe**, as evidenced by the successful applications for release licences that have incorporated data produced by Bale's group. [*s3, s5, s7]* In a wider context, through international collaboration with scientists with similar interests in ERA methodology development and harmonisation of regulatory requirements across Europe (van Lenteren, Bigler, Loomans), a comprehensive approach to ERA was produced and adopted as a 'Standard' in 2010 ('Import and release of non-indigenous biological control agents') by the European Plant Protection Organisation (EPPO) – Standard PM 6/2(2).

5. Sources to corroborate the impact

s1. Reports from two Defra funded projects on biocontrol covering the development of ERA methodologies for establishment and host range testing.

s2. Statement from ACRE secretariat on integration of project outputs into 'information requirements' for the licensed-release of non-native biocontrol agents in the UK, 30th April 2013

s3. Statement from Director of Research at market-leading EU biocontrol company (Koppert B.V. The Netherlands) on contribution of ERA data to licence applications for novel candidate biocontrol species, 8th May 2013

s4. The final report from the REBECA project and related book (copies available from the University) providing an effective summary of work done to produce the 'Standard application form', now an EPPO Standard.

s5. Statement from Senior Entomologist, Ministry of Economic Affairs, Netherlands Food and Consumer Product Safety Authority, 26th June 2013.

s6. Statement from Plant Health Entomologist, Food and Environment Research Agency, York, UK, 9th May 2013

s7. Statement from the President of IOBC-WPRS on role in CHIBCA, EPPO-IOBC Joint Panel on the 'Positive List' and use of ERA in Swiss Regulatory Authority, 7th May 2013

s8. Examples of 'Commercial in confidence' dossiers containing data and/or methods produced by Bale's group in Birmingham.