REGULATION OF THE RELEASE OF BIOLOGICAL CONTROL AGENTS OF ARTHOPODS IN NEW ZEALAND AND AUSTRALIA

Libby HARRISON[1], Abdul MOEED [1], and Andy SHEPPARD[2]

[1]Environmental Risk Management Authority
P.O. Box 131
Wellington, New Zealand
Libby.Harrison@ermanz.govt.nz

[2] CSIRO European Laboratory
Campus de Baillarguet
34980 Montferrier-sur-Lez, France
Andy.Sheppard@csiro-europe.org

ABSTRACT

Regulation of biological control agents in New Zealand is legislated by the Hazardous Substances and New Organisms (HSNO) Act 1996 and administered by the Environmental Risk Management Authority (ERMA New Zealand). In Australia the Department of the Environment and Heritage and the Agriculture Fisheries and Forestry Australia - Australian Quarantine Inspection Service jointly regulate the import, testing and release of biological control agents under the Quarantine Act 1908, Wildlife Protection (Regulation of Exports and Imports) Act 1982 and Biological Control Act 1984. A comparison of the two regulatory systems highlights the pivotal role of information from the host-specificity testing in the decision making process and the valuable opportunity for researchers to interact with the public.

INTRODUCTION

Historically, releases of exotic biological control agents and associated regulations were within the framework of quarantine and plant protection legislation managed through agricultural authorities. However, an increasing public understanding and concern for the environment towards the end of the 20th century brought environmental issues associated with such releases to the fore along with an increasing involvement of environmental authorities. Parallel to this, environmental legislation being implemented around the world following the Convention on Biological Diversity (CBD) Decision VI/23 in 1992 on "alien species that threaten ecosystems, habitats or species", designed to protect against such invasions, adopts the 'precautionary approach' within it. This has in turn has led to increasingly precautionary attitudes towards classical biological control releases.

The legislative risk assessment process for biological control agents prior to permissions being granted for release has therefore increased in scope and also complexity in most countries as the regulatory responsibilities for releasing exotic organisms now equally concern both agriculture (the traditional arena) and the natural environment. Similarly proposed re-

leases of genetically modified organisms (GMOs) have also instigated general concerns about releasing novel genotypes into the environment along with increased awareness of critical issues in ecological risk analysis of such introductions recognized internationally through the Cartagena Protocol on Biosafety. Finally international plant protection legislation has also adopted policy in relation to biological control releases. The International Plant Protection Convention (IPPC) Code of Conduct for the Import and Release of Exotic Biological Control Agents and its recent updates are an illustration of this. It is within this context that we review the current regulations for biological control agent releases in New Zealand and Australia comparing attitude to risks as well as procedural differences.

REGULATION OF BIOLOGICAL CONTROL AGENTS IN NEW ZEALAND

The introduction of biological control agents (BCA) into New Zealand is regulated under the HSNO Act by ERMA New Zealand. Practitioners of biological control may apply for 'containment approval' to import a BCA for host-specificity testing followed by a 'full release approval' when they wish to release the agent. Applications are assessed in accordance with the purpose of the Act which "is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of …new organisms". This is done by taking into account the following matters identified in the Act:

i. Sustainability of native and valued introduced flora and fauna
ii. The intrinsic value of ecosystems
iii. Public health
iv. The culture and traditions of Mâori (indigenous people)
v. Market economy
vi. International obligations

ERMA New Zealand is an 'autonomous' crown entity, partially funded by government that reports to the Minister for the Environment and is overseen by the Ministry for the Environment. Under the Crown entities legislation, ERMA New Zealand must have regard to government policy when directed by the Minister for the Environment but importantly, statute provides that the Minister may not give a direction that relates to the exercise of its core decision making powers to consider or grant approvals. ERMA New Zealand is composed of three parts; the Agency, the Authority and the Mâori Advisory Committee. The Agency works directly with applicants to facilitate submission of, and process applications but the decision making power resides with the Authority. The Authority is a quasi-judicial body[1] of 6-8 people appointed by the Minister for the Environment who are selected to represent a 'balanced mix of knowledge and experience in matters likely to come before the Authority'[2] so may or may not have a scientific background. In making their decision the Authority undertakes a risk, cost, benefit (RCB) analysis using a consistent methodology prescribed by regulation in 1998[3].

[1] Under the HSNO Act they have the same immunities and privileges of High Court judges when undertaking their core decision making powers and the power to operate under 'court-like' procedure ie to permit cross-examinations or questions of clarification.
[2] Section 16 of the HSNO Act.
[3] The Hazardous Substances and New Organisms (Methodology) Order 1998.

In the case of a full release application this RCB is done on information provided by the applicant, submissions (these may be received from members of the public, government departments, industry and community groups), the Agency and, where relevant, external experts and the Mâori Advisory Committee. Figure 1 summarises the application process for a full release application for which the applicant is charged NZ$30,000. It should be noted that in addition to obtaining an ERMA New Zealand approval applicants must also obtain an Import Permit under the Biosecurity Act 1993 from the Ministry of Agriculture and Forestry (MAF). MAF is responsible for New Zealand's Import Health Standards (IHS) designed to prevent accidental or illegal introductions of viable organisms (in this case associated organisms such as pathogens).

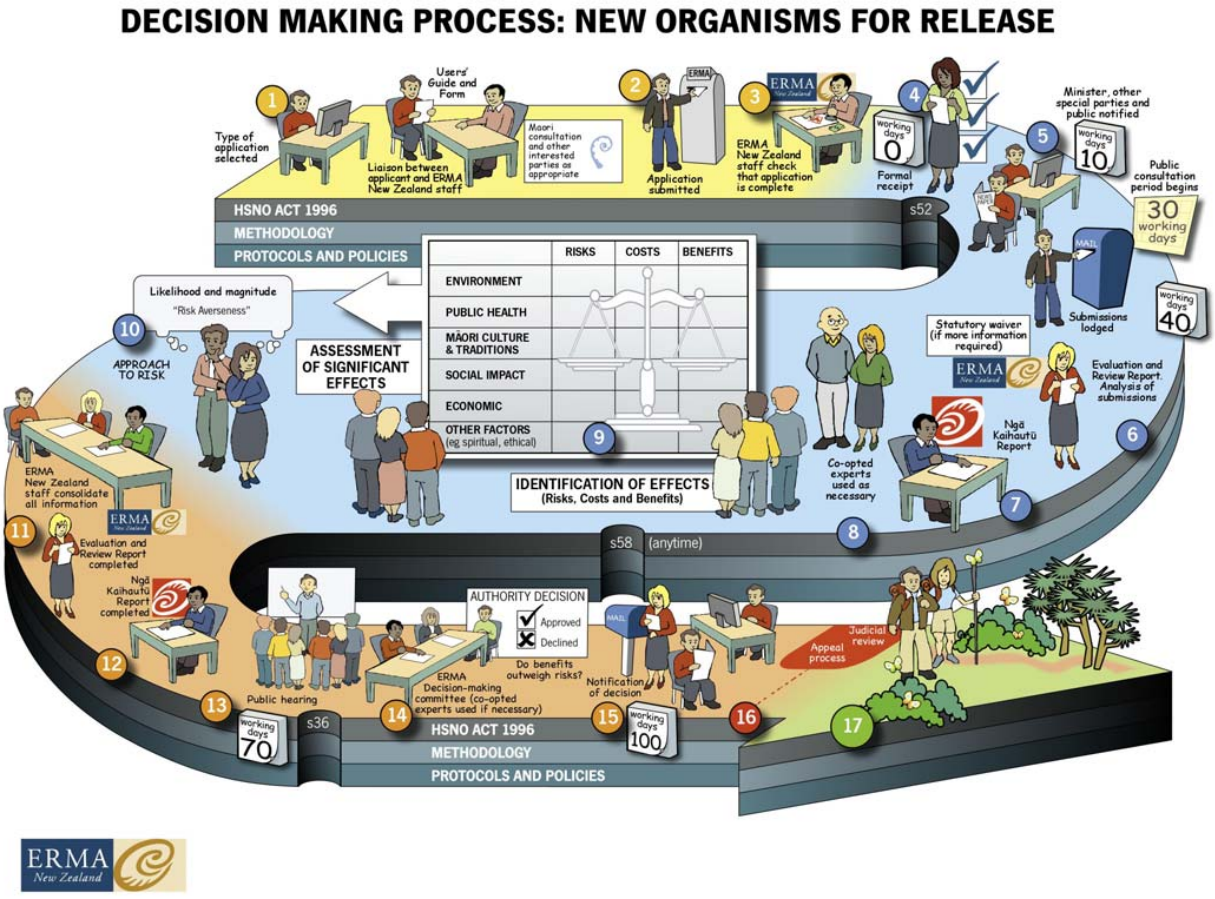


Figure 1. A diagrammatic representation of the application process for the full release of a biological control agent in New Zealand.

REGULATION OF BIOLOGICAL CONTROL AGENTS IN AUSTRALIA

Introduction of BCAs is regulated by two departments the Department of Agriculture, Fisheries and Forestry – Biosecurity Australia (DAFF-BA) and the Department of the Environment and Heritage (DEH) under three pieces of legislation:

i. the Quarantine Act (1908)
ii. Biological Control Act (1984)
iii. Environment Protection and Biodiversity Conservation Act (1992)

DAFF-BA is responsible for managing risks to primary industries and agriculture whilst the DEH is responsible for managing risks to the environment. Approvals are issued and implemented by the Department of Agriculture, Fisheries and Forestry – Australian Quarantine Inspection Service (AQIS).

The Australian process for arthropod targets is similar to that for weed targets and is all encompassing with four major steps to the process as summarised in Figure 2 and listed below:

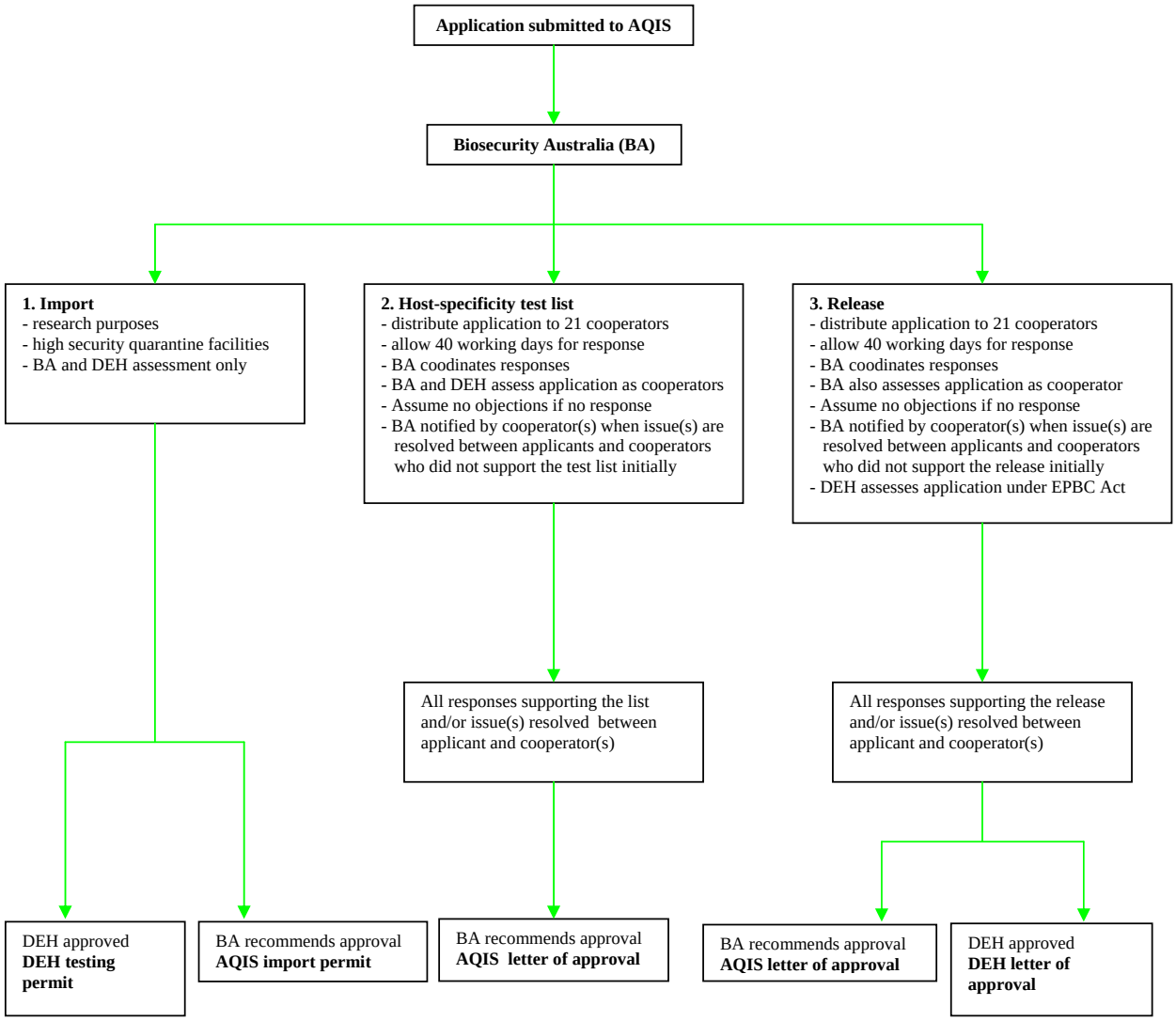
1. A potential BCA is identified and approval is sought to import into containment.
2. Application submitted for acceptance of list of species against which the potential agent will be tested for specificity
3. Application submitted to release biological control agent
4. The applicant reports on BCA establishment, efficacy and any non-target effects.

The Australian process currently allows for two phases of public comment through the DEH; one phase prior to importation when terms of reference for the assessment of likely impacts of the agent on the environment and one phase with respect to the draft release application through the DEH web site (Sheppard *et al*. 2003). Following this the final assessment is tabled in Parliament to allow comment from government departments. The final decision to release is made by the relevant Minister on the advice of the associated department. Approval may be reviewed within 5 years of approval.

Australia operates biological control within a formal legislative acceptance of its benefits under the Biological Control Act (1984) (Cullen and Delfosse 1985). This Act itself was set up to assist in the resolution of conflicts of interest by allowing for public consultations and enquiries, but is rarely used in practice as biological control projects with significant conflicts of interest rarely eventuate (Sheppard *et al*. 2003). No biological control project against an arthropod pest has ever been scrutinized under the Act.

COMPARISON OF THE TWO SYSTEMS

Table 1 summarises some of the key components of the systems. A comparison of the two systems reveal that there are some key differences in the way in which this ‘guidance’ has been implemented (Table 1).



Abbreviations:
AQIS - Australian Quarantine and Inspection Service
BA - Biosecurity Australia
DAFF - Australian Government Department of Agriculture, Fisheries and Forestry
DEH – Australian Government Department of Environment and Heritage

Figure 2. DAFF and DEH protocol for biological control agent applications. Note that application for import and for release will need to be submitted to both AQIS and DEH separately; application for hos specificity test list only needs to be submitted to AQIS. Credit: Australian Government, Department of Agriculture, Fisheries and Forestry, http://www.affa.gove.au; retrieved April 18, 2005.

PROCESS SCOPE

The entire process from importation of potential BCA through to host-specificity testing and eventual release is regulated in Australia. In New Zealand only the import into containment for host-specificity testing and subsequently the release is regulated, with the applicant determining how host-specificity testing is done. While the New Zealand process provides the

Table 1. Comparative analysis of the key components of the New Zealand and Australian regulatory systems.

Component	New Zealand	Australia
Process scope	Regulates import into containment and release but not host-specificity testing.	Regulates import into containment, host-specificity testing and release.
Public participation via a hearing	Occurs if requested (has happened in every case to-date).	Only if the agent is declared under the Biological Control Act (never happened for an agent proposed against an arthropod).
RCB analysis scope	Includes direct and indirect effects.	Limited to direct effects.
Risk averseness	Risk neutral or averse.	Risk neutral or accepting (at present).
Decision-maker	Quasi-judicial body and not necessarily government employees or scientists.	Minister for the Environment and Heritage and the Chief Plant Protection Officer.
Post approval activities	None - organism is no-longer 'new' so is not subject to HSNO regulation.	Post-release monitoring of establishment, efficacy, and non-target effects is required but not enforced.

applicant with more autonomy, the Australian process would seem to avoid the risk errors/ omissions in the host-specificity testing as it is regulated. For example, a decision on a recent application for full release of a weed BCA in New Zealand was delayed over a year as the Authority were concerned that the applicant had failed to include key species in the host-specificity testing. The Agency is attempting to avoid this happening again by making potential applicants more aware of the importance of adequate host-specificity testing. In the past New Zealand applications have relied heavily on host-specificity testing data from overseas and the regulation of host-specificity testing means this would not be an option in the Australian system.

PUBLIC PARTICIPATION

The New Zealand system has a unique feature where any person may make a submission on a publicly notified application[4] and request a public hearing into the application. While hearings may be viewed by the applicant as an obstacle, this is the only opportunity for the applicant to discuss in person their application with the decision-makers. This interaction has in the past provided a valuable forum for clarification of issues that have contributed to positive outcomes for applicants. Submitters also comment favourably on having the opportunity to 'be heard'. In an article discussing regulation of genetically modified organisms in New Zealand, which is also covered under the HSNO Act, Herrera (2005) noted that the public participation "gives New Zealanders more power to participate in the approval process...than any other people in the world." Holding a public hearing remains a practical option in New Zealand due to the comparatively small population and limited geographical area. It is anticipated that

[4] All full release applications must be publicly notified whereas applications to import new organisms into containment are only publicly notified if the Agency considers that there will be significant public interest in the application.

attempting to hold such a hearing in Australia would be a significantly larger and more costly undertaking. However, the Australian public do have an opportunity to comment on applications in a written form.

SCOPE OF EFFECTS CONSIDERED IN THE RCB ANALYSIS

In a review of regulators worldwide Sheppard *et al.* (2003) noted that "currently only the New Zealand approach closely matches a full ecological risk-benefit-cost analysis". This is probably a reflection of the fact that the HSNO Act requires a wider range of effects to be considered beyond the biophysical as demonstrated in the following two case studies. Furthermore, there is also some acceptance of a quantitative approach to risk-benefit analysis conducted by the Authority, for example in economic analyses of potential savings of insecticides.

In Australia the process still reflects a historical bias that biological control releases are largely beneficial, the decision-makers being somewhat risk accepting to risk neutral in attitude. As a result, beyond evaluating the potential risks to non-target species, there is no formal requirement for an extensive evaluation of potential benefits or secondary indirect effects of BCA. That means the Australian system does not follow as clearly a formalised RCB analysis approach as that adopted in New Zealand.

New Zealand Case Study. *Pseudococcus viburni* or obscure mealybug is a pest of pipfruit with its presence resulting in the formation of sooty mould which can result in fruit being unsaleable. In 2000 the release of the parasitoid *Pseudaphycus maculipennis* (Mercet) (Hymenoptera, Encyrtidae) (Fig. 3) was approved as a biological control agent of *Pseudococcus viburni* (Maskell) (Hemiptera, Pseudococcidae).

Figure 3. *Pseudaphycus maculipennis*. Photo: Shaun Forgie, HortResearch. UGA1390027

The Authority considered the most important potential adverse effect associated with approving this application to be parasitism of native mealybugs. This concern was in relation to a particular endemic mealybug but it was also pointed out that because of the incomplete knowledge of the native fauna, there was a potential for effects on as yet undescribed species. If this adverse effect was realised this would have flow-on effects to Mâori culture.

The Authority considered the most significant potential benefit of approving the application to be reducing the application of organophosphates, which would subsequently reduce:

- Insecticide residues in soil
- Impacts on human health through residues on food, spray drift and occupational exposure to insecticides
- A reduction in adverse effects of insecticides to native insects with flow-on cultural benefits to Mâori

- A reduction in adverse effects of insecticides to beneficial insects with flow-on benefits to integrated pest management of apples systems
- A reduction in the development of insecticide resistance.

The Authority also noted the economic gains to the horticultural industry via direct savings in insecticide applications, and improved sustainability.

Australian Case Study. In 2004 the release of *Eretmocerus hayati* (Zolnerowich and Rose) (Hymenoptera, Aphelinidae) (Fig. 4) a parasitoid for the control of *Bemisia tabaci* (silverleaf whitefly) was approved.

Figure 4. *Eretmocerus hayati.* Photo: CSIRO Entomology. UGA1390028

Bemisia tabaci (Gennadius) (Homoptera, Aleyrodidae) is a pest of ornamental nursery crops, vegetables and cotton causing feeding damage and reducing quality through the formation of sooty mould.

A summary of the potential impacts on the Australian environment noted that the results of host-specificity testing "predicts an extremely narrow host range". It also stated that "the risk to non-target whitefly is extremely low", particularly when compared to the risk of the widespread use of pesticides.

The discussion of the benefits in the application was limited to recognising that the amount of insecticide applied against the pest has "reduced the profitability of growers and has threatened the viability of existing low pesticide input management strategies".

RISK AVERSENESS

Inherent in the New Zealand legislation is a need for the decision-maker to consider indirect impacts. Due to the wide scope of the risk assessment (as previously discussed) and because there is no mechanism for compensation to affected parties, the New Zealand decision-makers are likely to be risk averse. In comparison, the Australian system provides for compensation of individuals exposed to adverse effects and so decision-makers are likely to be risk accepting or risk neutral.

DECISION-MAKER

In New Zealand the focus has been to select decision-makers that are experts in a wide range of fields to better represent the opinion of the general New Zealand public:

- Retired Foreign Diplomat
- Professor of Chemistry
- Hazardous Substances Advisor to public sector groups
- Senior Lecturer in Mâori
- Senior Scientist of Insect Ecology
- Associate Professor of Molecular Biology
- Senior Scientist of Molecular Biology
- Partner in a law firm

Advice on scientific, cultural, ethical and economic issues is provided by the Agency or relevant external experts. All documentation has to be produced in a manner that is also accessible to a lay audience. In Australia there is a reliance on scientific experts and staff in the Ministers office to aid the Minister in making a decision. This means that in New Zealand there is a degree of separation from the politics of the day which is in contrast to the Australian system where Ministers may be lobbied by special interest or industry groups. Although the New Zealand Authority is not completely removed from the influence of the political arena as has been previously mentioned, members are appointed by the Minister. It should be noted that in New Zealand there are limited grounds of appeal in relation to the merits of an application, however, given the quasi-judicial nature of the Authority the High court can undertake a judicial review of administrative decision-making. In its decision-making the Authority is required to take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those risks.

In Australia the decision can be challenged through the courts. In such a case, however, the agency that made the releases can apply to have the biocontrol agent declared under the Biological Control Act. To achieve this, a public enquiry is required and the outcome must be a clear demonstration that the benefits of releasing the agent clearly out-weigh the risks. Once the agent is declared under the Act the agency responsible for the release is legally protected from indemnity. Not surprisingly certain agencies have requested the Act be simplified so that all agents can be declared under it prior to release. However, this would require a major revision of the Act and so has not occurred. In practise biological control projects with significant conflicts of interest are no longer undertaken.

POST APPROVAL ACTIVITIES

In a continuation of the more holistic approach of the Australian system, applicants are required to submit a report to AQIS 12 months after release of the BCA regarding establishment, efficacy and any non-target effects. As the full release approvals granted in New Zealand have no associated controls post-release monitoring is not regulated, but is often encouraged. Recent changes to the HSNO Act have introduced a new category of approval, 'conditional release', which differs from full release in that controls can be placed on approvals for the purposes of mitigating risk, including but not limited to the following:

- Controlling the extent and purposes for which organisms could be used
- Requiring any monitoring, auditing, reporting, and record-keeping
- Compliance with relevant codes of practice or standards
- Development of contingency plans to manage potential incidents
- Limiting the dissemination or persistence of the organism or its genetic material in the environment
- Requiring the disposal of any organisms or genetic material
- Limiting the proximity of the organism to other organisms
- Setting requirements for any material derived from the organism

- Imposing obligations on the approval user (e.g., training, number of approval users)
- Specifying the duration of the approval

The requirement for controls that 'mitigate risks' associated with an individual approval presents challenges for decision-makers wanting assurances regarding the outcomes of an approval. Conditional release provides an opportunity for decision-makers to limit importations of BCA to the same geographical location from which individuals for testing were collected, hence mitigating the risk of non-target effects due to 'ecotype' differences. While not applicable to the parasitoid scenario, conditional release could allow for pre-release monitoring of effects using sterilised BCA.

FUTURE CHALLENGES AND OPPORTUNITIES

The challenges that the regulation of BCA present to researchers in the field are immediate and obvious. Concerns about the additional costs and time associated with gaining regulatory approval has resulted in an additional obstacle to the scientific community. However, participation in the regulatory system presents many opportunities for researchers beyond the obvious attainment of approval. Key to both the New Zealand and Australian system of regulating BCA is the results of host-specificity testing. Having to provide assurances to regulators that adverse effects are unlikely to occur has challenged researchers to ensure that testing protocols are robust and sound. This has generated opportunities for investigating the principals and practices of host-specificity testing. In Australia this is part of the regulatory system and ERMA New Zealand is also taking a pro-active role in promoting and supporting research in this area by acting as partner in a recent successful bid by experts for government research funding. The regulatory system provides an opportunity for peer review of host-specificity testing to ensure rigour and accuracy of results, particularly in the Australian system. In New Zealand, this process takes place, but only after the application has been received.

Both the New Zealand and Australian systems provide researchers with an invaluable opportunity to interact with members of the public. Applicants can use the process as an avenue to achieve public education of a science the benefits of which are poorly understood. A recent report released in New Zealand has demonstrated the value of this kind of interaction in enhancing a more positive image in the public perception of science. When discussing the issue of human biotechnology (HBT) researchers found that in discussion groups which did not include scientists, the attitudes of members of the public "towards scientists became more negative and they grow more concerned about HBT. On the other hand, when engaged in dialogue with scientists, their attitudes became more positive towards scientists and HBT, they had more empathy with scientists, and they had less concern about HBT" (Roper *et al.* 2004).

In conclusion, while it would initially appear that the regulation of biological control agents present obstacles to researchers, if applied constructively it may have the potential to provide other benefits beyond ensuring the release of efficacious agents that will cause minimal adverse side effects.

DISCLAIMER

The views presented in this publication are those of the authors and not necessarily their employer.

ACKNOWLEDGEMENTS

The authors would like to thank Dr Sonia Whiteman for helping to prepare the paper.

REFERENCES

Herrera, S. 2005. New Zealand: Green Haven for Biotech? From TechnologyReveiw.com: http://www.technologyreview.com/articles/05/02/issue/brief_newzealand.asp?p=0 (last accessed April 15 2005).

Roper, J. R., Zorn, T., and Weaver, C. K. 2005. Science Dialogues. The Communicative Properties of Science and Technology Dialogue. A project for the Ministry of Research, Science and Technology December 2004. Produced by the Department of Management Communication, University of Waikato.

Sheppard, A. W., Hill, R., DeClerck-Floate, R. A., McClay, A., Olckers, T., Quimby, P. C., and Zimmermann, H. G. 2003. A global review of risk-benefit-cost analysis for the introduction of classical biological control agents against weeds: a crisis in the making? *Biocontrol News and Information* 24, 91N-108N.