

SESSION 14 INTRODUCTION: LEGISLATION AND BIOLOGICAL CONTROL OF ARTHROPODS: CHALLENGES AND OPPORTUNITIES

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SESSION 14 INTRODUCTION

Regulation of biological control agent introduction in most countries is achieved by legislation. Provisions within such legislation vary considerably between countries. Recent global concerns about globalization, and adverse environmental and economic impacts from biosecurity incursions, has in some cases, resulted in reviews of existing, or the enactment of new legislation. In this session we will see how some countries, particularly those who are key users of biological control technology, have developed regulatory frameworks for biological control. These include Europe, the United States (including details of the regulatory process in Hawaii), Mexico, Australia and New Zealand.

We are fortunate to have David Nowell to introduce the recent review of the International Standard for Phytosanitary Measures No. 3 (ISPM No. 3) which provides guidelines for risk management relating to biological control agents. This review of the 1996 'Code of Conduct for the Import and Release of Biological control Agents' has only recently been completed in April this year, and David Nowell as a member of the IPPC Secretariat was directly involved with the review. He will explain the background and process of the review, and outline the aspects of the standard which have received most emphasis during the review. This standard will almost certainly continue to provide guidance for countries who are developing their own legislative systems for biological control regulation, and as pointed out by Franz Bigler and co-authors in this session, the Code may be seen as a first attempt to harmonize regulation of biological control agents globally.

Harmonization of biological control regulation in Europe is the topic of the contribution from Bigler and co-authors. The revised Code is perhaps now the opportunity for Europe at least to harmonize its regulation of biological control, given their shared borders, the biological control requirements that they have in common, and the similar biological control safety concerns of many European countries. So while achievement of harmonization is certainly a political challenge, it is also an opportunity for some countries to review their, in

some cases, inappropriate legislation of biological control. The OECD initiative to harmonize and simplify regulation of commercially produced biological control agents has been a very timely first step in this process. The OECD guidance document is intended to reduce the need for each country to repeat biosafety testing procedures that have already been completed in other countries. Furthermore, it will open up opportunities for commercial producers to expand the use of their products more easily, and facilitate opportunities for use of biological control options.

Continuing with the theme of harmonization across shared borders, Peter Mason from Canada and his co-authors from the U.S.A. and Mexico address the question of whether legislation can facilitate biological control opportunities in North America. To some extent there has been some harmonization in data requirement for entomophagous biological control agent proposals in that the three countries have agreed to conform to NAPPO guidelines. As in Europe, this would achieve gains for biological control by more readily allowing information sharing. Furthermore the authors point out that a scientific approach to the approval process is likely to ensure that only safe and effective biological control agents are introduced. However, currently the regulatory system with the U.S.A. is cumbersome with a mixture of Federal and inconsistent State jurisdiction. Russel Messing provides an overview of the system for biological control regulation in Hawaii, the State where the most rigorous review procedure has been adopted. While the system appears to be exhaustive in ensuring environmental safety of biological control, and allows for a degree of public consultation, it is steeped in bureaucracy that results in frustration and lengthy delays for biological control practitioners. The case is made for the best of the Hawaiian system to be adopted generally in the U.S.A., but improvements made in efficiency and transparency.

Like Hawaii, two island nations where shared borders are not an issue, and complete control over imported biological control agents can be achieved are Australia and New Zealand. Harrison and co-authors describe and compare the regulatory legislation in these countries. The HSNO Act in New Zealand has attracted considerable attention internationally as very environmentally focussed legislation, and the implementation of it by ERMA NZ has been observed with interest. In Australia, biological control agents are regulated by two agencies under three separate Acts, and has been similarly heralded as a thorough and biosafety-conscious approach. The authors provide a useful analysis of the two systems illustrating very clearly some key differences in approach, and the implications of these, particularly in the areas of scope of the regulatory process, opportunity for public participation, and degree of risk-aversion of the regulatory agencies.

In this session we asked the authors to address challenges and opportunities presented by biological control legislation, and several themes have emerged from both perspectives. We take the approach that each challenge in turn presents an opportunity. One of the major challenges for regulators that most authors have acknowledged is the need to manage the uncertainty inherent in risk assessment for biological control agents, specifically host-specificity determination and prediction of post-release impacts based on quarantine laboratory testing. The opportunity here is for researchers to continue to address this issue and to extract maximum value from post-release validation studies. In Europe and North America, the political and/or bureaucratic challenges are to develop regulatory frameworks that recognise

shared borders and the advantages of a coordinated, harmonized approach across sovereign or regional state boundaries. The respective authors have emphasised the opportunities that can be realised from harmonization, and the benefits for biological control that can potentially accrue from such an approach. The authors commenting on the U.S.A. regulatory system have highlighted the bureaucratic complexity and the challenge to legislators to improved efficiency, consistency and public participation in biological control regulation. The opportunity will then be there for biological control practitioners to work within a time-bound and simplified process where they can interact with the public. Finally in Australia and New Zealand, one of the challenges identified (which almost certainly applies generally) is to convince biological control practitioners that the regulatory process should be seen not as an obstacle, but an opportunity for constructive peer review, improvement of the public profile of science as well as the opportunity to conduct high quality research for good of people, the economy and the environment.

We hope that in bringing together this mix of authors from regulatory and science perspectives, we can benefit from the exchange of ideas and an improved understanding of how a range of regulatory systems operate. The biggest challenge and opportunity of all is to capitalise on the best aspects of each and the collective wisdom that has been presented, so that globally we can maximise the opportunity for safe, cost-effective biological control.

HAWAII AS A ROLE MODEL FOR COMPREHENSIVE U.S. BIOCONTROL LEGISLATION: THE BEST AND THE WORST OF IT

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ABSTRACT

The United States currently has no comprehensive, integrated legislative or regulatory framework to manage the permitting of imported biological control agents. There are unresolved questions of whether the USDA - Animal and Plant Health Inspection Service (APHIS) has jurisdiction over parasitoids that are not plant pests; there are differences in protocol between weed and arthropod biocontrol agents; there are unresolved issues of State vs. Federal authority; and there are overlapping and ever-changing requirements from a wide assortment of Federal and State agencies and a diverse array of laws that were designed for other purposes. In contrast, the State of Hawaii has specific, detailed, and exhaustive rules for obtaining import and release permits for natural enemies. In some respects the Hawaii system could serve as a useful model for national protocols - with coordinated scientific evaluation at several levels of specialization, and input from a wide range of concerned parties. However, some aspects of this system lead to bureaucratic entanglements and unconscionable delays that hinder the practice of biological control in the islands. If we could capture the best parts of the Hawaii system and mitigate the legalistic and bureaucratic redundancy, then a thorough, streamlined, efficient, transparent, accountable, and enabling regulatory framework could be put in place that would safeguard non-target species while facilitating biological control and environmentally sound pest management at the national level.

INTRODUCTION

Classical biological control is a powerful tool for pest management that has been used successfully for over a hundred years in the United States to combat invasive arthropod and weed species. For the greater part of the past century, regulations governing the importation of exotic beneficial species were either non-existent or were cobbled together from a diverse array of tangential legislation that was designed for other purposes, often only marginally related to the most important issues of biocontrol. Within the past decade, however, a consensus has emerged, both among conservation biologists and applied (primarily agricultural) entomologists, that some form of regulation specific to the importation of biological control agents should be established. However, the devil is in the details, and the few attempts that the United States Department of Agriculture, Animal and Plant Health Inspection Service

(USDA-APHIS) has made to establish regulations have been (and continue to be) chaotic, poorly understood, and difficult to implement. The increased scrutiny of both hand-carried and shipped packages following the terrorist attacks in the U.S. in 2001, and the bureaucratic re-organization of APHIS (with segregation of a separate Department of Homeland Security) has further complicated and confused efforts to put a manageable regulatory framework in place.

This short paper will first give an overview of the regulatory process in Hawaii, the most stringent system for oversight of biological control in the United States. I'll then briefly compare the State system to the existing U.S. Federal system, and point out the strengths and the weaknesses in Hawaii's rules that can provide valuable guideposts to those charged with establishing a much-needed national policy.

THE REGULATORY PROCESS IN HAWAII

At its core, the system in Hawaii for regulating newly imported biological control agents is a logical and thorough process with some admirable features that were no doubt designed with the best intentions in mind. The applicant is required to file a dossier with the State Dept. of Agriculture Plant Quarantine Branch (PQ) containing information about the taxonomy, bionomics, ecology, and host range of the proposed species introduction, as well as a justification for its importation, person responsible for the insects, description of safeguard facilities, method of disposal, and relevant supporting literature.

PQ then submits the application to two different committees for review. The first advisory committee is composed of disciplinary specialists (for example, a proposed arthropod introduction would be reviewed by the Entomology Committee). This committee is comprised of individuals representing a wide spectrum of opinion and expertise within the state, from agricultural pest management to insect conservation, from University professors to State agricultural entomologists to Museum specialists.

The Entomology Committee's comments are then forwarded for secondary review to another advisory committee with a broader range of expertise. For example, a botanist, a fish and wildlife specialist, a zookeeper, and a public health specialist sit on this Plants and Animals Advisory Committee. This second level of review considers the comments of the entomological experts, as well as the broader ecological and economic context of all new species introductions. Their decision, which is non-binding but highly influential, is passed on to the State Board of Agriculture, which reaches a final decision, that still must, however, be signed by the Governor. In addition, a concurrent Federal permit must be in place before any organism may be removed from quarantine.

The State process has two distinct components: the first requires placing a proposed species introduction on a specific list; the second requires establishing all of the conditions under which an organism on that list can actually be imported and released. As part of the listing process, public hearings are held throughout the state, during which concerned citizens can provide their input regarding the proposed introduction. These public comments are part of the final dossier used by the Board of Agriculture to make its decision.

In theory, the overall system provides for a fair and thorough review with input from all concerned parties, but in practice its implementation becomes bogged down in a bureaucracy that even the administrators of the process have difficulty in understanding and controlling (for details, see Messing and Purcell 2001). The listing process is subject to repeated and long-delayed reviews by the state Attorney General's office to ensure compliance with legal technicalities. The fact that two different steps are required (first the listing, and then the establishment of conditions for release) means that the same dossier is sent to the various committees and attorneys and Board twice (in succession), rather than considering both steps simultaneously. There is no established time schedule for any of the steps, and no accountability for any person or committee that fails to complete a step in a reasonable time frame. Committees and the Board sometimes do not meet for lack of a quorum. Because of the cost of holding public hearings on different islands, applications are held until a sufficient batch accumulates to justify the expense of organizing and holding the meetings. If there is a problem with a single application in a batch, the entire listing process is delayed – including those applications that are problem-free. There is a lack of communication between State and Federal offices, each of which requires the consent of the other. There is no process for online tracking, nor of reporting the status of a submission to the applicant. It is not unusual for an application to take *years*, rather than months, to make it through the listing process, even in cases where no additional biological data are requested. The process has become so onerous that it is significantly hindering the practice of biological control in the state (Messing 2000).

THE UNITED STATES FEDERAL (APHIS) REGULATORY PROCESS

The United States Department of Agriculture Animal and Plant Health Inspection Service has the statutory authority to regulate plant pests entering the U.S. While the agency traditionally has also issued permits for the introduction of entomophagous biological control agents, there are legal questions of whether, for example, a host-specific insect parasitoid can be considered a plant pest. Despite the fact that the Plant Protection Act of 2000 [PUBLIC LAW 106–224; section 412.a] specifies biological control organisms as subject to regulation, APHIS has been reluctant to take on this responsibility overtly, yet at the same time unwilling to relinquish all control given the lack of any other regulatory authority.

Some applicants for biocontrol permits are obliged to write and submit an Environmental Assessment (EA), a legal document that describes the expected impact of a non-indigenous organism on the environment. This document addresses both positive and negative environmental impacts; those deemed to have a higher risk are then required to prepare a more detailed environmental impact statement (EIS); those of lower risk are issued a finding of no significant impact (FONSI). The EA is a requirement of the National Environmental Policy Act (NEPA), but it is *only* required for employees of Federal agencies (or for projects conducted with Federal funds), not for State projects. NEPA also requires consultation with the U.S. Fish and Wildlife Service and other Federal agencies, but again, only for those projects with Federal backing.

APHIS has a fairly well established system for regulating the introduction of weed biocontrol agents (overseen by a Technical Advisory Group, TAG) – since herbivorous

arthropods obviously have the potential to become plant pests. Imported plant pathogens, on the other hand, are considered similar to pesticides and are regulated by the U.S. Environmental Protection Agency (EPA). For entomophagous arthropods, however, the situation becomes murky: APHIS requires a permit to import species into U.S. quarantine facilities, but then generally leaves it to State Departments of agriculture to make final determinations on field release of organisms from quarantine. For several years the agency has issued “letters of no-jurisdiction” for release – in essence turning responsibility over to the states.

In practice, however, and particularly recently, APHIS has instituted new rules, without significant public comment, regulating both the importation of organisms into quarantine and their removal from quarantine. For example, no hand-carrying of biological control agents by foreign explorers is allowed, only licensed, bonded carriers are to carry packages across national borders; shipments are to be routed through APHIS facilities in Beltsville, Maryland prior to their final destination in State quarantine facilities. Removal from quarantine requires consultation and thorough review of dossiers by Canada and Mexico under the auspices of NAPPO, the North American Plant Protection Organization. NAPPO has its own template of data requirements, including detailed plans for post-release monitoring and evaluation.

GUIDELINES FOR A NEW SYSTEM

It is admittedly difficult (though no less necessary) to institute a comprehensive Federal system for regulating imported biological control agents. Efforts are complicated by legitimate concerns for agro-terrorism; by the complex, diverse, and idiosyncratic nature of arthropod biologies; by geographic anomalies inherent in having some states contiguous with international borders while other states are geographically isolated. Furthermore, inter-agency bureaucratic squabbling, inadequate funding, and the short-sighted dissolution by APHIS of the National Biological Control Institute, leave federal, state, private, and university biocontrol practitioners with no adequate channel for communicating needs and concerns to the agency.

Other countries, particularly Australia (McFayden 1997) and New Zealand (Fowler *et al.* 2000), have overcome these obstacles and established effective regulatory policies for biological control. Hawaii, as we have seen, has regulations that are effective in safeguarding the environment (Funasaki *et al.*, 1988, Henneman and Memmot 2001), though not, to understate the case, particularly efficient. Rather than re-inventing the wheel, APHIS should incorporate the best of Hawaii’s system while avoiding its bureaucratic pitfalls.

The strengths of the Hawaii system are that there are several layers of review with different perspectives (narrow disciplinary specialists and broader ecological and economic perspectives); that within each committee there is a deliberate choice of individuals with a wide range of opinion and expertise; and that there is a formal public notification and input process, whereby the concerns of all interested citizens are taken into account.

The fact that Departments of Agriculture oversee the biocontrol permitting process (both in Hawaii and at the Federal level) is an historical accident; targets for biological control and environmental impacts of greatest concern have traditionally been in agricultural settings. It may be argued, however, that this a case of the fox guarding the henhouse, since the Depart-

ments' mandate is by nature agro-centric. Now that biological control is becoming more commonly accepted as a tool for pest management in non-agricultural settings (Hoddle 2004), and as environmental impacts are increasingly viewed in non-economic terms, it is more logical to have an independent environmental agency supervise the process, as is done in Australia and New Zealand.

The weaknesses in Hawaii's permitting system, alluded to earlier, are partially the result of specific state laws specifying the need for continuous revising and updating of complete lists of imported non-indigenous species. The listing process is fraught with legal technicalities that necessitate repeated review by attorneys who have little knowledge of biology; with no equivalent Federal listing requirement, much of this bureaucracy could be reduced. The use of strictly formatted templates for data entry and evaluation could also help eliminate recurring legal reviews.

APHIS' own TAG system, with a Technical Advisory Group evaluating proposed weed biocontrol agents, could be readily adopted for arthropod biocontrol agents, and made even stronger by adopting Hawaii's system of a two-tiered review process (i.e., specialists and "generalists"). To the extent that NAPPO consultation requires additional review by neighbor countries, the key to a fair and timely response to the applicant is to have as many of these reviews as possible conducted simultaneously.

Online forms and electronic input of all dossier information, comments, and concerns can make the entire system more efficient, responsive, and transparent. APHIS has recently started to gather input on the best way to take this step, but at present the only information available on their web site is a downloadable form (PPQ 526), a list of NAPPO dossier guidelines, and some answers to Frequently Asked Questions (see figure showing home page below).

690

The screenshot shows a Netscape browser window displaying the APHIS website. The page title is "Predators and Parasitoids - Netscape" and the URL is "http://www.aphis.usda.gov/ppq/permits/biological/predators.html". The website header includes "aphis.usda.gov" and "APHIS Services". A navigation menu contains "About APHIS", "Programs", "News", "Hot Issues", "FOIA", and "Jobs". The main content area is titled "AGRICULTURAL PERMITS" and features a sidebar with a "Permits Home" link. The main heading is "Predators and Parasitoids of Arthropods". Below this, there is an "Introduction" section, a "How to Apply" section with two numbered steps, and contact information for USDA, APHIS, PPQ. A small image of a brown insect is visible at the bottom of the page.

APHIS Services

AGRICULTURAL PERMITS Overview of Permit Processing
Permitting FAQ's
Check Status of an Application

Predators and Parasitoids of Arthropods

Introduction:
Predators and parasitoids of arthropods include beneficial or biological control organisms used to control insect and mite pests. Examples of such organisms would include predatory mites, lady beetles, parasitic wasps, Chinese or European mantids, or predatory thrips.

How to Apply:

1. Fill out Section "A" of PPQ Form 526.
2. Fax the permit application and any additional information to (301) 734-8700, or mail it to the following address:

USDA, APHIS, PPQ
4700 River Road, Unit 133
Riverdale, MD 20737

For commercial importations of laboratory reared organisms:

- You must submit a separate permit application for every state that you plan to release the organism.
- If the organism is non-indigenous and has not been released previously in the U.S., click here for additional information that must be submitted with your application.

Timeliness is of utmost concern when biocontrol practitioners are rearing living colonies of arthropod predators or parasitoids at great expense and possible irreplaceable loss of genetic diversity. Timelines in the permit process should be strictly specified and firmly adhered to, so that a lack of response during a specified comment period does not stall an application, but rather is interpreted as “no objection”. Input from the general public can be obtained by electronic notification of a broad suite of interested parties, and by appropriate public advertising and a transparent web site.

Chemical pesticides continue to become less available to land managers due to insect development of genetic resistance and loss of product registration due to public health concerns. However, invasive species continue to plague our farms, cities, and natural ecosystems at an increasing rate; thus biological control is becoming more important than ever as a valuable tool for safe and cost effective pest management. For the benefit of the nation’s agriculture as well as its natural environments, APHIS (or another Federal agency) should adopt regulations that are thorough, streamlined, efficient, transparent, accountable, and that facilitate rather than hinder the practice of biological pest control.

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HARMONIZATION OF THE REGULATION OF INVERTEBRATE BIOLOGICAL CONTROL AGENTS IN EUROPE

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ABSTRACT

The regulation of import and release of invertebrate biological control agents is not harmonized yet in Europe. Each country has its own regulatory system in place that is legally based on either the nature protection and/or the Plant Protection Act. The publication of the FAO Code of Conduct in 1996 for import and release of exotic biological control agents was the turning-point for the activities related to the import and release of biological control agents in Europe. An EPPO expert panel developed from 1998 to 2002 two guidelines on the safe use of biological control and established a list of biological control agents widely used in the EPPO region. An EU funded project with the goal to develop scientific methods for evaluating environmental risks of biological control introductions into Europe (ERBIC) was conducted from 1998 to 2002. In 1999, the OECD initiated a working group with the aim to develop a guidance document on appropriate regulation of invertebrate biological control agents. Biological control industry was very concerned about these developments and proposed to the International Organization for Biological Control (IOBC/WPRS) to co-ordinate harmonization among European countries. A commission of the IOBC/WPRS was put in place in 2003 with the aim to facilitate and harmonize regulation in Europe. In 2004, the EU released a call for project proposals with the aim to develop a balanced system for harmonized registration of biological control agents.

INTRODUCTION

In the past, Europe has generally been a source rather than a recipient of invertebrate biological control agents in comparison to other countries with extensive experience in classical biological control, such as Australia, Canada, New Zealand, South Africa and the U.S.A. These countries had legislation and procedures in place relatively early to regulate imports and to analyze risks of exotic biological control agents (Sheppard *et al.* 2003). Most classical biological control programs in Europe have focused mainly on controlling exotic pests in the Mediterranean region. Today, there is a growing interest in classical biological control of invasive weeds throughout Europe, especially in conservation areas (Waage 1997). Increasing international trade in agricultural products and growing accidental introductions of organisms related to tourism and global trade are nowadays important sources of new imports of exotic pest species into Europe, as demonstrated by Bin and Bruni (1997) for Italy. Many of these introduced organisms are candidates for classical biological control if they establish in conservation reserves where they may threaten native species and communities. Most if not all European countries are signatories of the Convention on Biological Diversity and, thus, have the obligation to prevent the introduction and, as far as possible, to control those alien species that threaten indigenous ecosystems and habitats. Because chemical and mechanical control of such organisms may have negative effects on ecosystems greater than those of the introduced alien species itself, classical biological control may offer adequate solutions.

Protected crops grown in glasshouses have developed rapidly in many European and Mediterranean countries, and the protected environment has favored the temporary or permanent establishment of imported pests. On the other hand, customers in most European countries are increasingly concerned about pesticide residues in food, and food quality regulations are becoming more stringent in Europe where most of the glasshouse crops are marketed. This situation offers new avenues for non-chemical pest control. Biological control by augmentation or inundation has developed during the last 35 years and is now a major component of pest control in protected crops. About 90 species of invertebrate biological control agents are presently on the EPPO list of widely used and commercialized biological control agents in the EPPO region (EPPO 2002), and many more are under investigation for future release. Some agents on this list may have disappeared from the market, but new ones have come up in the meantime. Europe leads the world in this activity, and national regulatory agencies have therefore an obligation to rule and facilitate international trade in an efficient and appropriate way.

Regulations for introductions of invertebrate biological control agents differ between European countries and some have yet to establish these (Bigler 1997; 2001). Obligations in international laws and agreements, and an increasing interest in the import and release of exotic biological control agents calls for harmonized and better regulation between European countries. In many cases introductions of invertebrate biological agents are administered under regulations which were established for other purposes, such as plant quarantine, wildlife conservation and genetically modified plants. The application of appropriate regulatory procedures is important in order to maintain public confidence in biological control and to facilitate introductions and the commercial use of exotic biological control organisms.

ACTIVITIES AND DOCUMENTS TO FACILITATE HARMONIZED REGULATION IN EUROPE SINCE 1995

THE FAO CODE OF CONDUCT

The FAO Code of Conduct for the Import and release of Exotic Biological Control Agents was adopted in 1995 by the FAO Conference and published in 1996 as the International Standard for Phytosanitary Measures No. 3 (IPPC 1996). One objective of the Code was to provide a standard for those countries that are lacking adequate legislation and procedures to regulate import and to analyze risks related to biological control agents. The document lists in a generic way the responsibilities of the authorities and importers and exporters of biological control agents. Furthermore, it recommends that governments already fulfilling the objectives of the Code may adapt their existing regulatory systems in the light of this guidance. This objective of the Code may be interpreted as being the first attempt to harmonize regulation of biological control agents worldwide. The revised version of this Code of Conduct has extended its range from classical biological control to inundative biological control, native natural enemies, microorganisms and other beneficial organisms, and also includes evaluation of environmental impacts (IPPC 2005). The publication of the FAO Code can be considered as the turning-point for a number of activities related to import and release of invertebrate biological control agents in Europe.

EPPO GUIDELINES AND 'POSITIVE LIST'

694

Shortly after the Code's publication, the European and Mediterranean Plant Protection Organization (EPPO) together with CABI Bioscience organized a workshop on safety and efficacy of biological control in Europe (EPPO 1997). In its recommendations, the scientific committee of the workshop noted that "...practices for the import of macrobiological agents at present vary greatly between European countries. These practices should be harmonized, with appropriate conditions recommended for importation for different purposes, e.g. research, classical, commercial biocontrol." The workshop suggested that an EPPO Panel should be established, and promote the adoption of harmonized practice for the import of invertebrate biological control agents. The workshop broadly endorsed the FAO Code and recommended that guidelines be drawn up to meet European needs with respect to the different legislations and regulations. It was stressed that the guidance on harmonized regulation should not slow the process of import of biological control agents, be it for first introduction for research or for release later on. The workshop concluded that a certification system should be put in place for Europe instead of a registration procedure, to ensure a 'light' regulatory system with efficient and rapid mechanisms.

The registration system for microbial biological control agents in place in the EU under Directive 91/414/EEC was given as a negative example of regulating biological control agents. This Directive accommodates the registration of microbiological control agents since 1992, and experience over the years has shown that the Directive and its implementation is so stringent that it is basically impossible to register a new microorganism in the EU countries. The workshop decided to establish an expert panel with the aim of drawing up more specific guidelines and to prepare a 'positive list' of invertebrate biological control agents that are

widely used in the EPPO region without any reports on adverse effects. The EPPO panel met a number of times between 1998 and 2002 and the results were published in two guidance documents and in a 'positive list' of organisms for safe use in EPPO countries. The first guideline recommends a system for the first import of exotic biological control agents for research under contained conditions (EPPO 1999). The second document gives guidelines for the import and release of exotic biological control agents, including information on how to prepare a dossier by the applicant for the national authority and on how the authority should examine the dossier (EPPO 2001). The two guidelines stress the importance of a two-step system for import and release, i.e., EU countries should first establish a regulatory process for import of exotic organisms for research under containment. The results of these investigations will provide the necessary data to make decisions on whether the organism can later be imported for release. The approval for release will be granted if further studies show that the organism is safe for the environment and humans. To facilitate and speed-up the use of invertebrate biological control agents in the EPPO region, a list of commercially available organisms was first published (EPPO 2002) with the idea to regularly adapt the list depending on new information.

THE ERBIC RESEARCH PROJECT

In parallel with the EPPO panel activities, the EU-funded research project ERBIC (Evaluating Environmental Risks of Biological Control Introductions into Europe) was executed from 1998 to 2002. Among the objectives, major aims were: 1) to ensure that the introduction and use of biological control agents is done in a way which does not put at risk non-target organisms, 2) to develop rapid and reliable methods to assess the potential risk of import and release of biological control agents in Europe, and 3) to design specific European guidelines to ensure that biological control agents are environmentally safe. One of the main outcomes of the project was the proposal for the environmental risk assessment of exotic natural enemies in inundative biological control (van Lenteren *et al.* 2003). This paper presents for the first time detailed criteria for risk assessment and a ranking system that is based on the quantitative evaluation of more than 30 invertebrate biological control agents used in inundative control in Europe.

THE OECD GUIDANCE DOCUMENT

An initiative starting from a meeting held in Canada in 1999 resulted in an activity of OECD (Organization for Economic Co-operation and Development) countries with the aim to develop a harmonized approach for regulation of invertebrate biological control agents. It was agreed that a harmonized regulatory system in the OECD member countries would be beneficial for biological control and that a 'light' form of regulation would be appropriate. The development of harmonized guidance for regulation requirements would enable companies to submit the same applications to many countries, and would allow regulatory agencies to benefit from each other's reviews. The document (OECD 2004) proposes guidance to member countries on information requirements for a) the characterization and identification of the organism, b) the assessment of safety and effects on human health, c) the assessment of environmental risks and d) the assessment of efficacy of the organism. It is however, the decision of member countries whether and how these organisms are regulated, and countries

may require additional information to meet national or international requirements. With native or established organisms and with those long in use in a country, substantially reduced information requirements may be appropriate.

A BOOK ON METHODS OF RISK ASSESSMENT FOR BIOCONTROL AGENTS

Attempts to implement the EPPO, ERBIC and OECD documents into national regulatory systems in a number of European countries have shown that the required information and data are in many cases not available and have to be produced prior to submission of a dossier to the national authority. It became also evident that the framework of environmental risk assessment that should be used for the preparation of the dossiers by the applicants and the evaluation by national authorities was not yet established in Europe. The lack of methodology for risk assessment of invertebrate biological control agents was recognized by the European biological control community, and consequently, 25 experts from across the world gathered for a workshop in Switzerland in 2004 to put together a synthesis of current knowledge, and to provide recommendations for further regulatory guidance in this area. The emphasis was on providing science-based guidance for those assessing and evaluating environmental risks, and on providing up-to-date information on existing methods and their application for evaluating non-target effects. The starting point was to address all the information requirements for environmental risk assessment laid out in the recent OECD publication (OECD 2004). A further aim was to compile all this information for a book, which is to be published by CABI Publishing (Bigler *et al.* 2006).

696

THE IOBC/WPRS COMMISSION FOR HARMONIZATION OF REGULATION

The European biological control industry was very concerned when the OECD guidance document was published as the information requirements were considered to be too stringent, and manufacturers feared that each national authority in Europe would establish their own regulatory system. As a consequence, the International Biocontrol Manufacturer Association (IBMA) proposed to the International Organization for Biological Control (IOBC/WPRS) to co-ordinate harmonization among the European regulatory authorities. A Commission of the IOBC/WPRS was put in place in 2003 with the objectives to 1) collect information on regulation in European countries and compile an overview, 2) organize a workshop with countries that have participated in the data compilation together with the biocontrol industry and regulators, 3) produce a document that gives detailed guidance on regulation procedures for exotic and indigenous biocontrol agents, 4) up-date EPPO's list of safe organisms, 5) propose a consultation procedure that will allow exchange and use of information and data on biological control agents between European countries and 6) propose a European expert group for invertebrate biological control agents. The first meeting of the Commission was held in 2004 with the participation of scientists, regulators and industry representatives from 15 European countries and resulted in fulfillment of objectives 1 to 3. The document on information requirements for import and release of invertebrate biological control agents in European countries (Bigler *et al.* 2005) gives more specific advice to applicants and national authorities on information required for risk assessment compared to the EPPO and OECD documents cited above, and it reduces data requirements for facilitating regulation, but still respecting concerns of human and environmental safety. Proposals for objectives 4 to 6 will be elaborated in a future workshop.

THE EU CALL FOR A BALANCED SYSTEM OF REGULATION

In October 2004, the Directorate-General for Research of the European Commission released a call for project applications with the aim to develop a balanced system for regulation of biological control agents (micro- and macro-organisms), semiochemicals and botanicals. The call specifies that, despite considerable research efforts on biological control, the number of microbiological products on the market in Europe is currently still low, compared to other countries, e.g., the U.S.A. and Canada. The aim of the task is to review current legislation, guidelines and guidance documents and to compare this with similar legislation in other countries where the introduction of new biopesticides has proven to be more successful. New appropriate and balanced regulatory systems should be designed, provided that no compromises are made to the level of safety. This is the first time that the EU has become involved in regulatory affairs of invertebrate biological control agents with the intent to harmonize national systems of EU countries and hence, it can be expected that in few years from now, the EU members and other European countries may regulate invertebrate biological control agents under uniform principles.

REGULATION REQUIREMENTS IN EUROPEAN COUNTRIES IN 2004

For the preparation of the workshop organized by the IOBC/WPRS Commission on the harmonization of regulation of invertebrate biological control organisms held in 2004, and in fulfillment of objective 1 of the Commission (see above), we have sent out questionnaires to regulatory authorities and biological control scientists in 19 European countries. Replies were returned by all countries, although the quality of information provided differed greatly between countries. Nevertheless, the questionnaires yielded interesting information and data which are presently being compiled and prepared for publication. All countries addressed by the questionnaires have national legislations in place. However, large differences exist in the degree of implementation of regulatory measures of invertebrate biological control agents in these countries as demonstrated in Figure 1. The present status of regulation has been assigned to three categories: a) regulation is implemented to some degree in eight countries (Austria, Czech Republic, Denmark, Hungary, Norway, Sweden, Switzerland, U.K.), b) five countries are working on the design and implementation of a regulation system (Finland, Germany, Netherlands, Slovenia, Spain) and c) six countries have no regulation implemented yet and will not have a regulatory system in place in the foreseeable future (Belgium, France, Greece, Italy, Poland, Portugal).

The results of the survey further demonstrated that the requirements differ largely between European countries. Examples of differences are:

- the assignment of a competent national authority (plant health, pesticide registration or environmental authority),
- the information requirements for evaluation of a dossier and subsequent level of risk assessment,
- whether native species have to be regulated as well; when regulation is required, native species usually follow a “short track” risk assessment, whereas exotic species are assessed more thoroughly,

- the system of regulation: by authorization, by permit, etc.
- listing of biological control species based on commercial availability or on risk based evaluation.

The survey also showed that there is a need for harmonization on a European level. Initiatives with respect to information requirements for import and release have already been taken (Bigler et al. 2005).

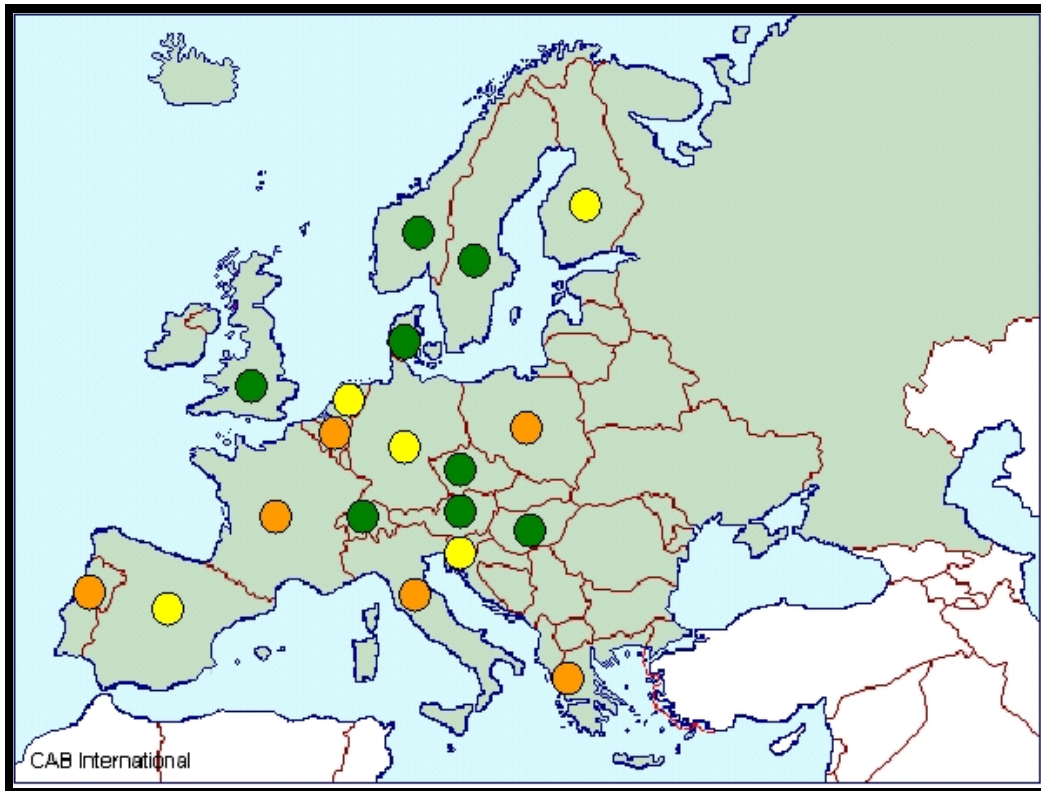


Figure 1. Present status of regulation of invertebrate biological control agents in 19 European countries. Countries where regulation has been implemented are indicated with green dots, countries where regulation is in preparation with yellow dots and those without regulation in place with orange dots.

CONCLUSIONS

Attempts to harmonize regulation of invertebrate biological control agents in Europe have been undertaken since the publication of the FAO Code of Conduct in 1996, and regulatory guidelines developed by international organizations, such as the EPPO and OECD during the last ten years, have been adopted and implemented by national authorities in a few European countries. Given that legislation for the regulation of invertebrate biological control agents differs among European countries and that laws are not yet in place in some countries, responsibilities are often not yet clearly assigned to ministries or government agencies on national levels. Different regulations among European countries may cause serious problems to the biocontrol industry as dossiers must respect national requirements and criteria in those

countries where regulation is in place. This makes applications more time consuming and costly, and can be a factor for a company to decide not to develop the organism to a product if the market potential is estimated low in comparison to the development costs. Past experience has shown that overregulation, i.e., rigid legislation with stringent data requirements may keep such products off the market for a long time or even prevent industry from submitting applications in some countries. This situation has been experienced in the EU since 1992 with the registration of microbial biocontrol agents that are regulated under the Directive 91/414/EEC which largely follows requirements developed for synthetic pesticides. Costly risk assessment studies and long term evaluation of dossiers has kept most products off the market and resulted for the few registered micro-organisms in an average evaluation period per product of over 70 months (Blum *et al.* 2003). Uncoordinated regulation of biological control organisms bear the risk that approval for release in one country may have impacts for others if the organism crosses borders and establishes in other countries. A recent example is the establishment of *Harmonia axyridis*, the Multicolored Asian Lady beetle, in European countries like Switzerland, where the application for release of this coccinellid was rejected in the nineties based on documented non-target effects. Releases in other European countries has resulted in the establishment of the lady beetle and in crossing borders and invading other countries. This and other examples demonstrate that Europe urgently needs a harmonized regulation of biological control agents which will prevent import and release of unsafe organisms, but which will not put an unnecessary burden on biological control.

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699

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HOW CAN LEGISLATION FACILITATE THE USE OF BIOLOGICAL CONTROL OF ARTHROPODS IN NORTH AMERICA?

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701

ABSTRACT

The use of biological control agents is an integral component of biologically-based pest management strategies. Although there have been many success stories and biological control became synonymous with environmentally friendly pest management, during the last 20 years an increased awareness of biodiversity interactions resulted in concerns being raised about potential negative effects. The outcome has been pressure to improve regulatory oversight of biological control and make the process transparent. In North America, oversight of biological control agents has fallen primarily under federal law and provincial/state laws have occasionally influenced release of biological control agents. Federal laws used are associated with Plant Protection Acts because these regulate plant pests and biological control agents have been viewed as indirect plants pests. In Canada and Mexico this has worked well for regulating entomophagous biological control agents whereas, in the United States there were legal concerns that have now been addressed by including a definition of a “Biological Control Organism” in the U.S. Plant Protection Act. Plant protection laws are appropriate for regulating biological control agents because they are designed to address movement of living organisms associated with plants. Canada, Mexico and the United States are intricately linked both geographically and economically, and efforts have been made to harmonize the data requirements for submissions. The North American Plant Protection Organization (NAPPO) document, “Guidelines for Petition for Release of Exotic Entomophagous Agents for the

Biological Control of Pests” was implemented as a North American standard. The guidelines act as a framework within which there is flexibility for reporting information based on continually improving scientific methods. Judgement of a petition is carried out through an international scientific peer-review process that includes experts in the areas under each heading. Comments are collated and a recommendation is made to the responsible agency in the country where release is intended. To date the process has been effective and this approach continues to provide opportunities for improving oversight based on science and ensuring that only effective agents are used. The future challenge is implementing a process that includes a wider stakeholder community while maintaining objective and scientifically sound assessment of entomophagous biological control agents.

INTRODUCTION

Biological control is a cornerstone of pest management in many parts of the world. Use of entomophagous biological control agents has resulted in important successes in reducing damage from pest species in a variety of manipulated systems and biological control has great value in sustaining environmental health, particularly through reductions in pesticide use. These attributes indicate that use of entomophagous biological control agents will continue and even grow. However, debate is increasing on the need for greater regulatory oversight of biological control agents, including entomophagous species.

Factors that contribute to the need for greater regulation of biological control agents include trade globalization and awareness of the importance of biodiversity. Expanded global trade has resulted in an astounding increase in the numbers of non-native species establishing in new habitats. Estimates suggest that invasive alien species are responsible for annual losses of US\$55-248 billion to worldwide agriculture (Bright 1999). More difficult to assess are environmental costs due to habitat loss or species extirpation or extinction caused by invasive alien species (Parker and Gill 2002). Biological control is an important strategy for combating invasive alien species and it has been viewed as being ‘environmentally friendly’ for more than 100 years. However, during the last decade as science and society have become increasingly aware of the importance of biodiversity to human well-being, a less positive view of biological control, particularly in island environments, has emerged especially with the introduction of generalist predators and non-specific herbivores (Howarth 1991; Simberloff 1992). This perspective is based on non-target/unintended impacts and has stimulated much debate (e.g., Follett and Duan, 2000; Louda *et al.* 2003; Schick *et al.* 1996; Wajnberg *et al.* 2001). Some have concluded that biological control regulation is archaic and Strong and Pemberton (2001) stated that in the United States “In the absence of reform, rational as well as irrational opposition to biological control will grow. Only sensible reform will maintain public support for this powerful tool.” There is now a growing consensus that all deliberate introductions of non-indigenous species should be subject to impact risk assessment (Wittenberg and Cock 2001). Furthermore, regulations for biological control agents “... are needed to provide clear guidance as to what introduction can be made legally and to define procedures to resolve any conflicts of interest that may arise.” (Van Driesche and Bellows 1996). As Mason and Kuhlmann (2002) concluded, it is clear that regulations for biological control agents are nec-

essary not only for the preservation of biodiversity but for the protection of biological control as a pest management strategy. Messing (2000) suggested that regulations would also help allay some of the concerns about introductions of exotic species that result in exaggerated estimation of the risks in doing so. The challenge is how legislation can facilitate rather than impede entomophagous biological control.

EXISTING REGULATIONS

Regulation of entomophagous biological control agents varies greatly around the world from jurisdictions where there is no regulation to those where specific laws have been enacted and are strictly enforced. Others (e.g., Barratt *et al.* 2003; Hoddle 2003) summarized the status of biological control regulations up to 2002. Since then, new developments have taken place and these will be outlined as they pertain to entomophagous biological control activities in North America. Of particular note are the combined efforts to harmonize the information requirements for submissions to regulatory agencies for approval to release biological control agents.

INTERNATIONAL

Globally, the International Plant Protection Convention (IPPC) provides guidance for “securing common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control” (FAO 1999). A ‘Code of Conduct for the Import and Release of Exotic Biological Control Agents’ (FAO 1996) and recently updated (Nowell 2005) serves as a framework for regional and national plant protection organizations to develop guidelines/regulations that are appropriate for their jurisdiction. Under this International Standard for Phytosanitary Measures (ISPM No. 3) regional plant protection organizations, such as the North American Plant Protection Organization (NAPPO), are charged with ensuring that appropriate measures are implemented and that proper documentation of movement of biological control agents is made.

Recently, an OECD initiative resulted in the document “Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCA)” (OECD 2004). This document purports to harmonize data requirements to enable the use of the same data in the approval process among member countries. The OECD document is intended primarily for commercial biological control agents. Such harmonized regulations, by lessening registration requirements amongst members, would minimize costs for developing new agents. While the detailed information requirements set out in the document are helpful, there is concern that in some areas the requirements may be impossible to meet. This is especially the case for risk assessment where the methodologies are largely experimental. It is clearly stated in both the FAO and OECD documents that individual jurisdictions (i.e., countries and their states) may require more detailed information than outlined in the Codes, to meet their own regulations.

North America, Canada, Mexico and the United States do not regulate entomophagous biological control agents under specific biological control acts. Rather, each country regulates these agents under one or more legislative acts, the primary one being a plant protection act.

CANADA

Biological control agents in Canada have been regulated through the Plant Protection Act (PPA) of 1990 (Department of Justice Canada 2005) which is administered by the Canadian Food Inspection Agency (CFIA). In accordance with this Act, an import permit is required for importations of all exotic arthropods into Canada. Conditions attached to the permit may include such restrictions as 'for experimental use in a containment facility only'. Permits are generally valid for a 3-year period and are renewable. The permitting process is based on the provision of information relating to the source, the organism and the end-use (destination). Entomophagous biological control agents are regulated under the PPA with respect to their potential to be indirectly injurious to plants, because plant pests are loosely defined under the Act (Parker and Gill 2002). Furthermore, commercial entomophagous agents are regulated in a similar manner to classical agents and those species with a history of importation without negative effects are generally admitted under permit.

For release of a classical biological control agent or a first release of a commercial biological control agent submission of a petition (based on the NAPPO standard) justifying the release is required. The petition is reviewed by experts and representatives of other agencies, including Environment Canada (EC) and the Pest Management Regulatory Agency (PMRA) and where feasible, provincial government representatives. The review is carried out through a Biological Control Review Committee (BCRC) and depending on the comments, a recommendation is made for or against release to the regulatory entomologists of the CFIA who review all the comments and make a recommendation to the Director of the Plant Health Division (Fig. 1). The process generally takes about 6 months from submission to notification that release is approved or not approved.

The process has worked very well because recommendations are based on the scientific merit of the petition submitted, and although reviews are done mostly on a volunteer basis, these have been completed in a timely manner. A weakness of the Canadian regulatory process is the lack of public participation. Such participation may be warranted and would make the process truly transparent, but the way to accomplish this is not clear.

MEXICO

In Mexico, the importations of biological control agents are regulated through the Plant Health Act of the Mexican States (SARH 1980). In these regulations the Sanidad Vegetal (Ministry of Agriculture) is mandated to authorize the introduction of exotic arthropod species or the mass production of arthropods in insectaries, for use in the biological control of pests, according to requirements set out in Articles 101 and 102. As part of the importation requirements, the organisms must be accompanied by a certificate of biological purity and a certificate of origin provided by the phytosanitary authorities of the exporting country. The permit is granted for one year, and as in Canada, it is renewable.

The importer must submit an application to the General Director of Plant Health of the Ministry of Agriculture. A copy of the application is sent to the Nacional de Referencia de Control Biológico (National Center of Biological Control Reference [NCBCR]), where it is reviewed taking into account phytosanitary and environmental risks. After the review the

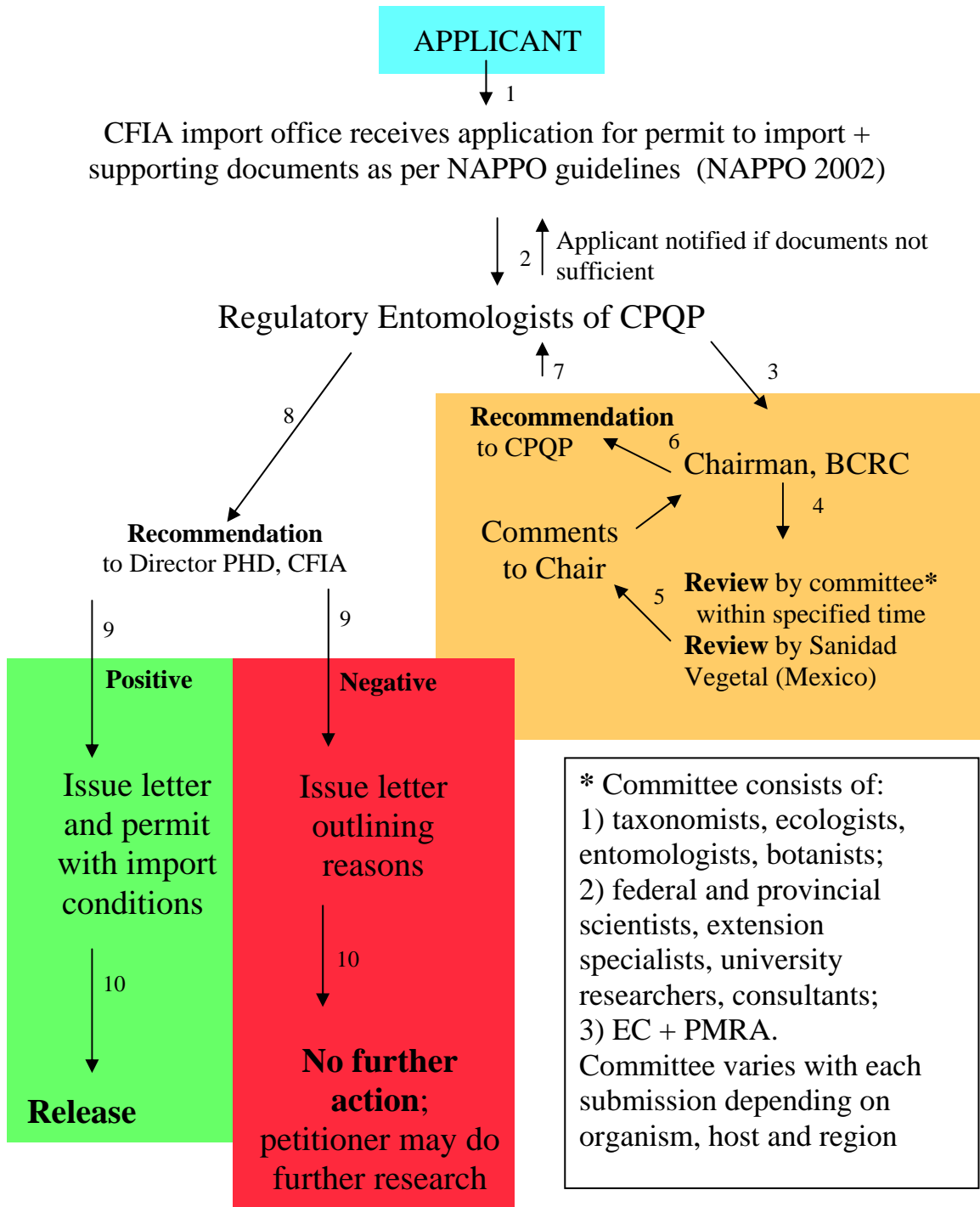


Figure 1. Canadian review process (9 steps) for import and release of new entomophagous biological control organisms. BCRC = Biological Control Review Committee; CFIA = Canadian Food Inspection Agency; CPQP = Centre for Plant Quarantine Pests (CFIA); EC = Environment Canada; NAPPO = North American Plant Protection Organization; PHD = Plant Health Division (CFIA); PMRA = Pest Management Regulatory Agency (adapted from and courtesy of CFIA).

NCBCR issues the authorization or denial through an official letter from the General Director of Plant Health to the applicant (Fig. 2).

In the case of exotic agents (for classic biological control), it is essential to justify the introduction. This includes providing information according to the NAPPO standard on the specificity, biology and behavior of the agent, natural enemies of the biological control agent, results from other countries on the biology and implementation of the agent. For commercial biological control agents information must be provided on the behavior, geographical distribution and any phytosanitary problems associated with the prey or hosts utilized for the rearing; if there are any doubts, an opinion is requested from the Consejo Nacional Consultivo Fitosanitario (National Consultative Phytosanitary Advisory Group) that consists of professionals from academic institutions, research and the government. The processing time is three months for applications for exotic biological control agents and 10 days for beneficial organisms, naturally present or previously introduced and established in Mexico that are mass reared in insectaries.

UNITED STATES

In the United States, biological control agents of plant pests and noxious weeds are regulated by Plant Protection and Quarantine (PPQ), Animal and Plant Health Inspection Service (APHIS) of the USDA (USDA) under the Plant Protection Act of 2000 (APHIS 2005a). This recently enacted legislation provides APHIS the authority to regulate organisms that may directly or indirectly harm plants or plant products. Unlike the previous Federal Plant Pest Act of 1957, the Plant Protection Act also broadly defines biological control agents and recognizes their potential to control plant pests. APHIS is authorized to regulate the importation, interstate movement and environmental release of biological control agents, but may deregulate the interstate movement and environmental release of those agents that APHIS has determined not to be plant pests. APHIS is now in the process of revising its regulations to fully implement this new Act and the following discussion only describes the current regulatory processes for the movement and release of entomophagous biological control agents that were developed under the older Federal Plant Pest Act.

For classical biological control research endeavors involving entomophagous agents, PPQ requires separate permits for importation to containment facilities, domestic movement to other containment facilities, and release to the environment (APHIS 2005b). In general, all movements of entomophagous agents originating from outside the United States are assumed to actually or potentially pose some risk to plants (e.g., pest host contaminants, hyperparasites, unevaluated impacts on plant communities, etc.) or to nontarget species, including endangered or threatened species. Permits for all movements are consequently restricted to Federally inspected containment facilities to prevent the irretrievable release of the organisms to the environment. The permits for containment facilities are issued to facilitate the removal of contaminants from foreign sources, to confirm the identity and purity of the agents, and to develop documentation that can be used to support future applications for release to the environment (i.e., release from containment). We do not anticipate changes to this approach when new regulations are proposed under the Plant Protection Act.

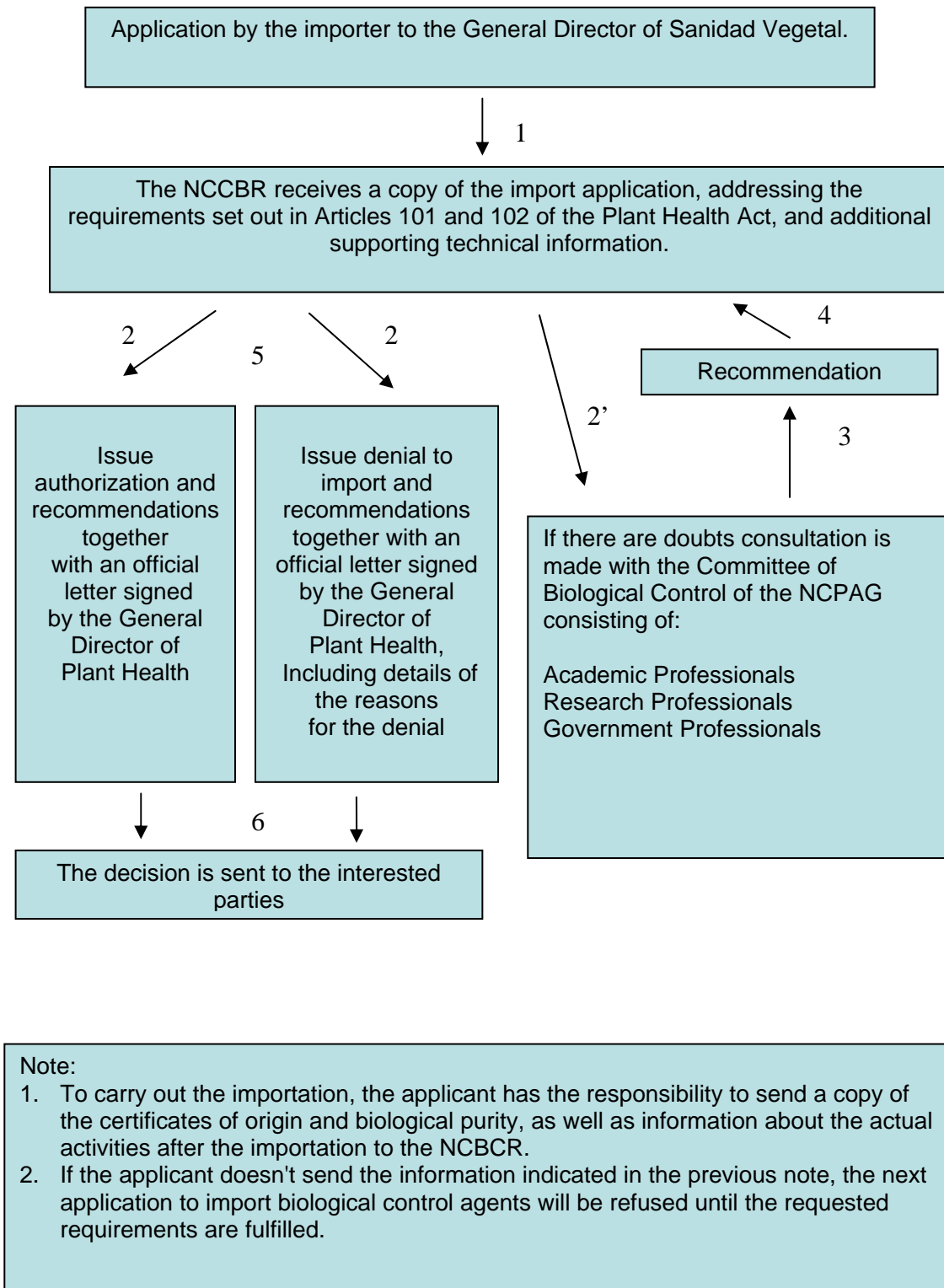


Figure 2. Steps for import and release biological control organisms in Mexico. NCBCR = National Center of Biological Control Reference. NCCPG= National Consultative Phytosanitary Advisory Group.

Following processing of agents and conducting basic biological studies (including host specificity evaluations) in containment, researchers may submit an application to PPQ for environmental release. A supporting document must accompany the application with information equivalent to the NAPPO petition discussed in the Canadian process. PPQ will review the supporting documentation and may request additional reviews with input by Canadian and Mexican counterparts to make a decision on whether or not the agent can be safely released to the environment. Decisions are made based on anticipated indirect or direct plant pest risks including potential impacts on nontarget species, especially endangered and threatened species. Any potential impacts on endangered and threatened species would trigger the Endangered Species Act of 1973 and would require consultation with the United States Fish and Wildlife Service in the Department of Interior. If PPQ determines that the release of the agent will not likely result in adverse impacts to plants and/or nontarget species, a determination of no further regulatory jurisdiction is documented on the permit application and sent back to the applicant. Otherwise the application is denied. When a determination of no jurisdiction is made, the agent may be moved and released throughout the contiguous United States without PPQ permits. Federal permits are still required for movements to and releases in Hawaii, Alaska, Guam, Puerto Rico, American Samoa, and the U.S. Virgin Islands. When PPQ makes a determination of no jurisdiction, individual States may require their own permits under State laws and regulations. This current regulatory process for environmental release of entomophagous agents does not trigger the National Environmental Policy Act of 1972 (NEPA), and no formal environmental assessments are produced to document these determinations of no jurisdiction (technically no Federal permit is issued). However, all subsequent Federal actions, including releases by Federal employees, on Federal lands, or under Federal funding may require compliance with NEPA. We anticipate that PPQ will begin issuing permits for release of entomophagous agents with new regulations under the Plant Protection Act. Such a change will require PPQ to develop formal environmental assessments to document for the public record the information used to make the Federal decision. However, the information currently provided as part of the NAPPO decision is largely what is required to develop a more formal environmental assessment. In addition, we anticipate that PPQ will begin requiring permits for the domestic movement of all entomophagous biological control agents except those formally deregulated by an official listing in the Federal Register. Listing will require an environmental assessment as well as a continuing safety record following establishment in broad areas of the United States.

PPQ permits are required for the importation of entomophagous biological control agents commercially produced outside the United States, including in Canada and Mexico. Commercial import permits restrict the species allowed entry to those agents that are indigenous to and widely distributed in the contiguous United States. All such imports are received and inspected at PPQ inspection stations where identity and purity are evaluated. The inspection process confirms the absence of plant pest risk and Federal permits are not required for subsequent movements within the contiguous United States. As with research releases, State permits may be required for releases in individual states. Equivalently, commercial movements and releases of domestically produced entomophagous biological control agents within the contiguous United States do not require PPQ permits as long as the shipments contain only approved indigenous species and are clear of plant pest host materials and other con-

taminants (e.g., hyperparasites). As with research releases, we anticipate that PPQ will begin requiring permits for the domestic movement of all entomophagous biological control agents except those that are formally listed as deregulated.

It is apparent that in the U.S., several levels of regulations apply to entomophagous biological control agents. As Messing (2000; 2005) has stated, establishment of clear, coherent, and streamlined regulations at the national level will be important to ensuring objective assessment of the risks and benefits of biological control in the U.S.

HARMONIZATION

In North America, there has been important progress in harmonizing the data required for release of entomophagous biological control agents. Petitions submitted to the regulatory agencies (CFIA, APHIS and Sanidad Vegetal) must conform to the standards set out in the NAPPO guidelines (NAPPO 2002). These guidelines were developed by representatives of Canada, Mexico and the United States and are a first attempt to harmonize the data requirements for the three countries. In the case of entomophagous biological control agents the NAPPO guidelines are dynamic and can be changed with the advent of new knowledge.

ARE THESE REGULATIONS AND THEIR OVERSIGHT APPROPRIATE FOR BIOLOGICAL CONTROL AGENTS?

The key to ensuring that arthropod biological control agents are appropriately assessed will be the expertise of the agency (or agencies) in each country that oversees regulation. Depending on the agency mandated with this responsibility, requirements and risk assessments could be based on models used for pesticides (as is the case for microbial agents) or even human pathogens. For entomophagous biological control agents, the most appropriate regulatory models are those already in place for regulating classical biological control agents of weeds. In North America these models are based on ecological theory and assessments are done mainly by scientific experts reporting to regulatory agencies. In addition, they are linked to IPPC standards and thus are in step with regulation of biological control agents in other jurisdictions.

In the context of plant protection, biological control agents are either direct (phytophagous) or indirect (entomophagous) plant pests depending on trophic relationships and the pest status of the associated plant (Fig. 3). Herbivores that feed on weeds are considered to be beneficial plant pests as are natural enemies of herbivores that feed on native endangered and/or important plant species. Similar patterns are apparent for pollinators and decomposers. The biological relationships at each trophic level remain the same regardless of whether the plant is a weed, native species or crop. Because of these complex relationships regulation of entomophagous biological control agents would thus be most appropriate under plant protection acts.

The entomophagous biological control agents that have come under the regulations outlined above are beginning to be carefully scrutinized. For example, based on petitions reviewed in Canada, 64% (7/11) of the biological control agents recommended by the BCRC and CFIA regulatory entomologists have been approved for release since 2000. Those submissions that were not approved were for agents for which host specificity could not be dem-

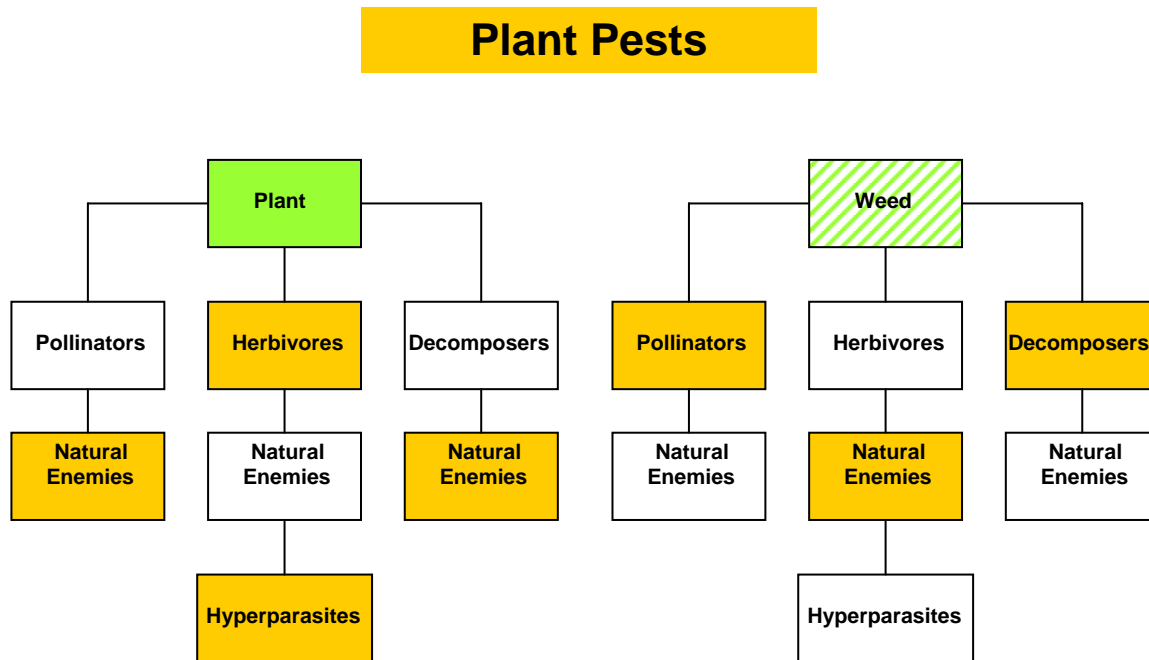


Figure 3. Pest status of trophic groups associated with 'valued' and 'non-valued' (=weed) plants. Shaded boxes indicate 'pest' groups.

onstrated or for targets for which a native North American species might be more suitable for biological control. The arguments in support of release have been based on scientific studies and have been peer reviewed. Turnaround from the time of petition submission until approval or rejection of the agent for release is six months.

There are several limitations to the current system in North America. There is a perceived lack of transparency of the approval process. Public input is not yet incorporated into the review of petitions, nor is it a required part of the justification for initiating biological control projects. Reviews should incorporate comments from all interested parties in all three countries.

Another shortcoming of the current process is the availability of appropriate methodology for assessing impacts of entomophagous biological control agents. Risk assessment is usually interpreted as meaning the greater the specificity of a biological control agent, the less the risk for non-target impacts. However, for arthropod biological control agents, host specificity testing has lagged behind that for weed biological control agents because historically the concerns for non-target impacts on invertebrates has not been as great (Waage 2001). Furthermore, the sheer complexity of raising arthropods for testing has created a research bottleneck. Historical published data and collections continue to be an important source of host range determinations. Protocols used for assessing host range of weed biological control agents are well-defined but these are not necessarily appropriate for entomophagous biological control agents (Barratt *et al.* 1999; Kuhlmann *et al.* 2000; Mason *et al.* 1999; Sands 1998). However, biological control researchers are actively developing appropriate protocols (Bigler *et al.* 2006; Van Dreische and Reardon 2004). The NAPPO guidelines used in North America are flexible in terms of the detail of host range data that are required for a petition for release

of an entomophagous biological control agent. This flexibility was intended to facilitate continued release of safe agents while screening methods and interpretation of results are being developed. As this knowledge becomes more sophisticated, the guidelines can be updated.

COMPLIANCE

A major challenge for regulation of entomophagous biological control agents is to ensure compliance on the part of biological control practitioners. The present process relies on an honour system where submissions are made voluntarily by ethical individuals/agencies. Like inspection of international shipments and detection of inappropriate commodities, ensuring that all entomophagous biological control agents released are approved may be impossible. The best strategy to promote compliance will be timely review of submissions and fair assessments.

CONCLUSIONS

Increased regulation of entomophagous biological control agents in North America is inevitable. While no comprehensive legislation such as a 'Biocontrol Act' exists in Canada, Mexico or the United States, exotic invertebrates imported for release as biological control agents are being regulated under existing plant protection and associated acts. As demonstrated by the regulatory processes in Canada and Mexico, review of submissions for release of entomophagous biological control agents is timely and scientifically based. This encourages compliance by practitioners and safety of the agents based on best available knowledge. While the future of using entomophagous biological control agents will be that of greater scrutiny, appropriate legislation and regulation will ensure continuing effectiveness and increased safety.

711

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

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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.

715

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 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 Māori (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 Māori 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 body¹ 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 1998³.

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 Māori 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).

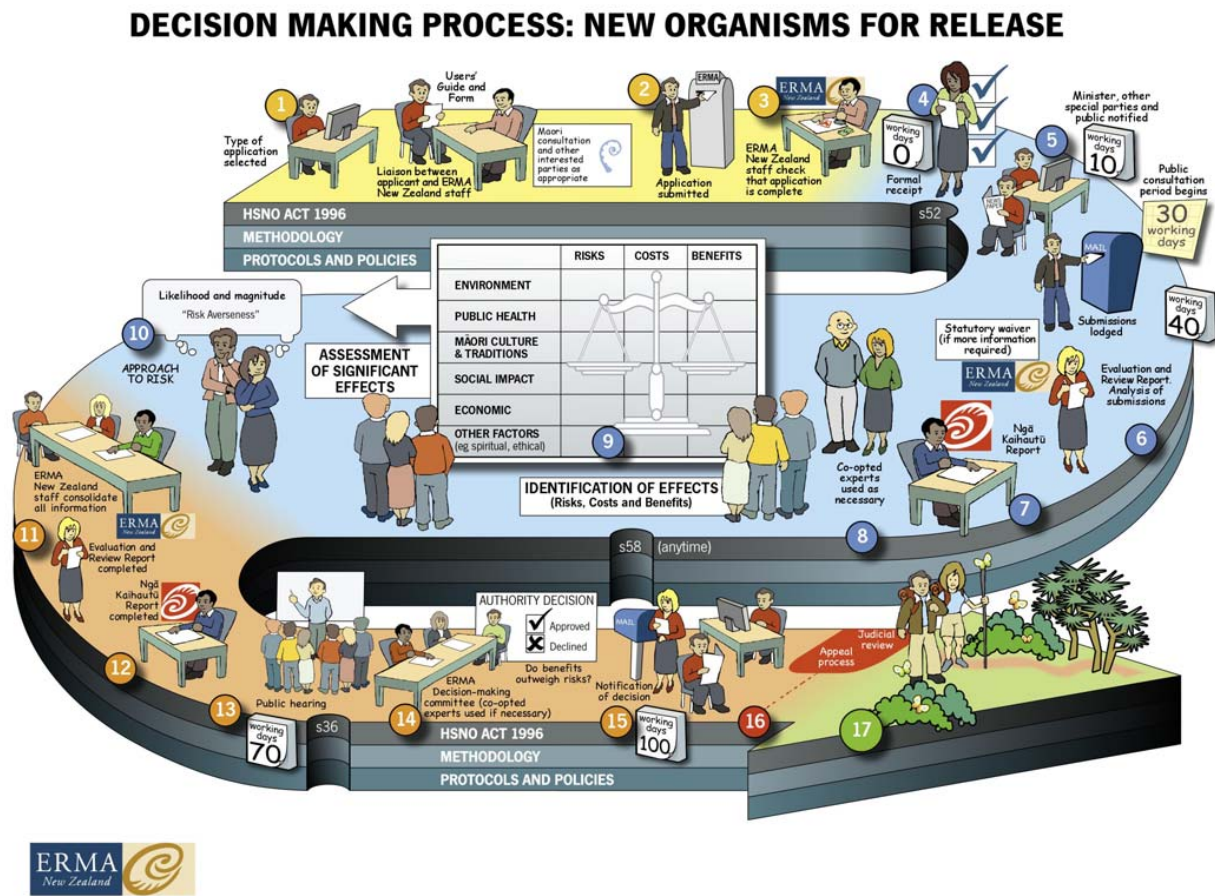


Figure 1. A diagrammatic representation of the application process for the full release of a biological control agent in New Zealand.

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:

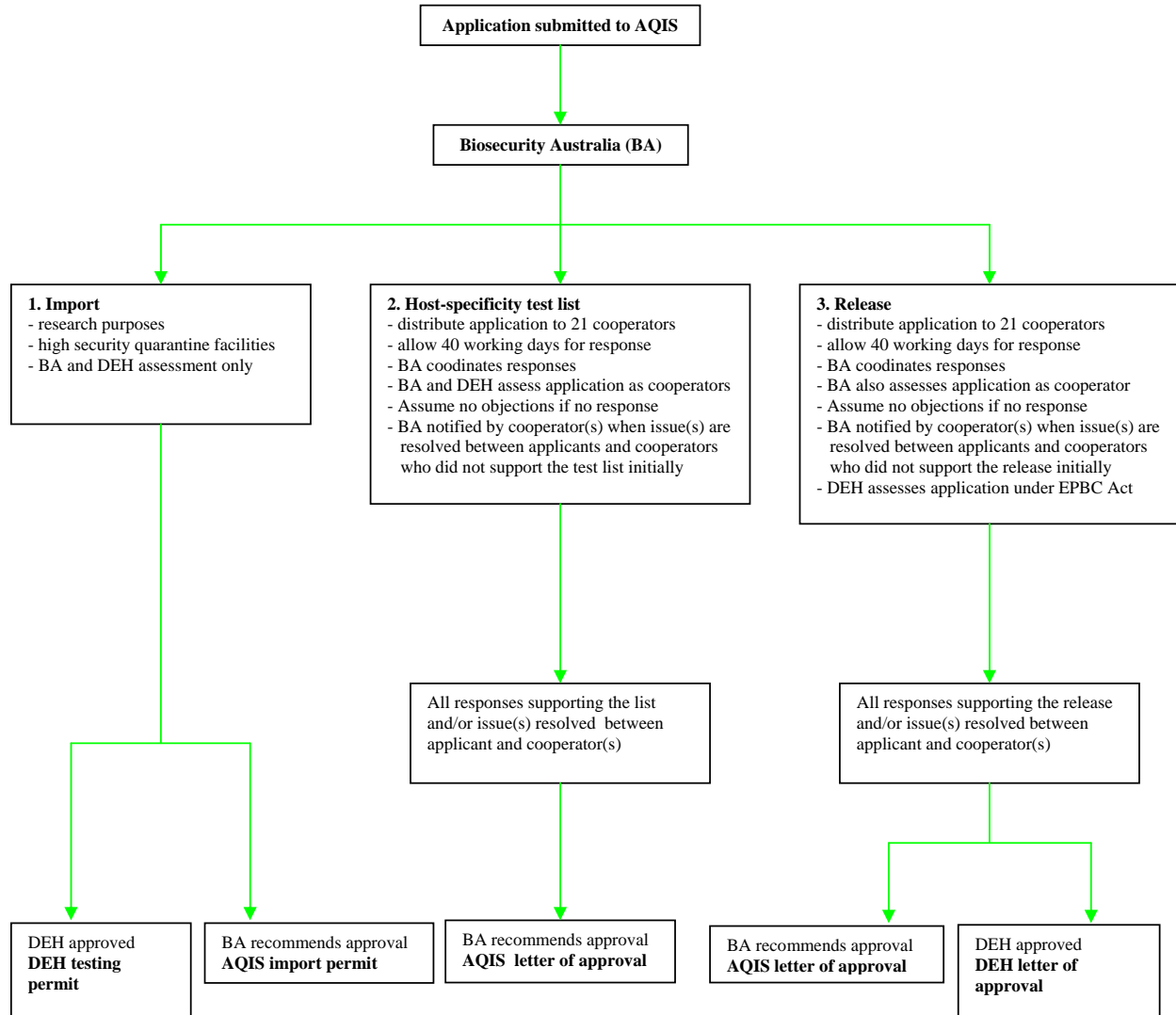
1. A potential BCA is identified and approval is sought to import into containment.
2. Application submitted for acceptance of list of species against which the potential agent will be tested for specificity
3. Application submitted to release biological control agent
4. The applicant reports on BCA 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 host specificity test list only needs to be submitted to AQIS. Credit: Australian Government, Department of Agriculture, Fisheries and Forestry, <http://www.affa.gov.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 application⁴ 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).

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 Māori 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 Māori



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

- 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 Māori
- 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.

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INTERNATIONAL GUIDELINES FOR THE EXPORT, SHIPMENT, IMPORT, AND RELEASE OF BIOLOGICAL CONTROL AGENTS AND OTHER BENEFICIAL ORGANISMS (INTERNATIONAL STANDARD FOR PHYTOSANITARY MEASURES NO. 3)

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ABSTRACT

This paper describes the development and review of the International Standard for Phytosanitary Measures (ISPM No. 3) which provides guidelines for risk management relating to the export, shipment, import and release of biological control agents and other beneficial organisms. The standard lists the related responsibilities of contracting parties to the International Plant Protection Convention (IPPC) ('contracting parties'), of National Plant Protection Organizations (NPPOs) or of other responsible authorities, importers and exporters. ISPM No. 3 addresses biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), including those packaged or formulated as commercial products. Provisions are also included for importation of non-indigenous biological control agents and other beneficial organisms for research in quarantine facilities.

INTRODUCTION

Phytosanitary standards (ISPMs) are developed under the auspices of the International Plant Protection Convention (IPPC) and provide a framework within which national plant protection organisations (NPPOs) can develop regulations to provide for plant protection. The level of phytosanitary protection that is considered appropriate for any given country, is for that particular country to decide. The finalization and adoption of the IPPC occurred after the first publication of ISPM No. 3 (FAO 1996b). In the 1980's onwards there was an increasing volume (both number of species and number of individual specimens) of biological control agents moved internationally, particularly classical biological control agents and those

used for inundative release. Prior to 1995, there was no agreed international guidance for the trans-boundary movement of these live organisms, hence FAO developed ISPM No. 3 to address a specific need. It was decided that the most appropriate place for such an international guideline was within the framework of the IPPC. The FAO Conference adopted ISPM No. 3 in 1995, before the revision of the IPPC (which was adopted in 1997) and the finalization of the World Trade Agreement on the Application of Sanitary and Phytosanitary Measures. There have also been many scientific developments in the knowledge of biological control agents since 1995. It is within this context that ISPM No. 3 was developed and now been revised.

The primary support standard to ISPM No. 3 was ISPM No. 2 (FAO 1996a). More detailed guidance on Pest Risk Analysis is provided in other ISPMs, particularly ISPM No. 11 (FAO 2004a) and ISPM No. 21 (FAO 2004c).

At the second session of the ICPM (October 1999) issues wider than agriculture, such as the impact on the environment and other relevant international agreements, were considered in the context of the IPPC (e.g., the Convention on Biological Diversity). The ICPM established an expert working group to consider this and other relevant issues. An output of the working group was that the recommendation that ISPM No. 3 be amended “to include consideration of risk of spread of biological control organisms to other countries”.

Prior to revision, the scope of ISPM No. 3 was relatively narrow and primarily applicable to classical biological control agents. Although conceptually it encompassed the principles of the IPPC and SPS Agreement and could in practice be applied more widely, it was not explicit on a number of important phytosanitary issues e.g. pest risk analysis. Therefore, the scope of ISPM No. 3 was broadened to encompass the principles and articles of IPPC, in particular Article VII 2 (g) “*Contracting parties may make provisions, with adequate safeguards, for the importation for purposes of scientific research or education, of plants and plant products and of specimens of plant pests. Adequate safeguards likewise need to be taken when introducing biological control agents and organisms claimed to be beneficial.*” Hence the revised standard has incorporated guidelines that cover other beneficial organisms with particular reference to sterile insects as well as biological control agents.

In addition, ISPM No. 3 was considered by the ICPM for possible review in 2001 (five years after adoption, as is standard for all adopted ISPMs) and issues such as the rapid increase in the use of, and trade in biological control agents, as well as developments in biological control practices meant there was a need to update this standard. The standard also needed to be made consistent with other more recently developed ISPMs and phytosanitary concepts within the framework of the IPPC. The revision of ISPM No. 3 was placed on the IPPC work programme and the revision commenced as soon as funding became available.

REVIEW OF ISPM NO. 3

Given the above context and to ensure that all relevant issues were addressed in this process, the ICPM Standards Committee drafted specifications for the review of ISPM No. 3. According to IPPC Specification No. 4 the review needed to include the consideration of:

- Revision of title and text;
- Pest risk analysis procedures appropriate for biological control agents;
- Regulatory guidance developed by the OECD since publication of the standard;
- Issues relating to the transport and handling of biological control agents;
- Possibilities for clarification and emphasis with regards to invasive species and other impacts on the environment, and
- Issues relating to pre and post release monitoring.

Other matters to be considered and addressed where appropriate were:

- Sterile insect technique (SIT) issues;
- Beneficial organism issues, and
- The use of biological control agents that had been genetically modified using modern biotechnology techniques.

An expert working group (including nine independent experts plus the IPPC Secretariat) met in December 2003 at FAO Headquarters in Rome to revise ISPM No. 3. The outcome was a revised draft ISPM No. 3 that was reviewed by the Standards Committee in May 2004. The draft ISPM No. 3 was released for country consultation in June 2004. Many comments were received and all comments from all interested parties had to channel their comments through the NPPOs. Comments provided by the NPPOs were considered by the Standards Committee and the necessary adjustments made to the draft. The final version of the standard was submitted to the seventh session of the ICPM (in April 2005) for consideration. After minor modifications it was adopted as ISPM No. 3 (FAO 2005a and 2005c).

The Standard states that it is “*intended to facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms. Responsibilities relating to this are held by contracting parties, NPPOs or other responsible authorities, and by importers and exporters.*” However it does not include reference to living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control.

“Contracting parties, or their designated authorities, should consider and implement appropriate phytosanitary measures related to the export, shipment, import and release of biological control agents and other beneficial organisms and, when necessary, issue related import permits.”

As described in this standard, NPPOs or other responsible authorities should:

- *“Carry out pest risk analysis of biological control agents and other beneficial organisms prior to import or prior to release;*
- *Ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with;*

- *Obtain, provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biological control agents and other beneficial organisms;*
- *Ensure that biological control agents and other beneficial organisms are taken either directly to designated quarantine facilities or mass-rearing facilities or, if appropriate, passed directly for release into the environment;*
- *Encourage monitoring of release of biological control agents or beneficial organisms in order to assess impact on target and non target organisms.*

Responsibilities of, and recommendations for, exporters include ensuring that consignments of biological control agents and other beneficial organisms comply with phytosanitary import requirements of importing countries and relevant international agreements, packaging consignments securely, and providing appropriate documentation relating to biological control agents or other beneficial organisms.

Responsibilities of, and recommendations for, importers include providing appropriate documentation relating to the target pest(s) and biological control agent or other beneficial organisms to the NPPO or other responsible authority of the importing country.”

DISCUSSION

A primary objective of the revision of ISPM No. 3 was to ensure consistency with the IPPC (FAO 1997) and that it was harmonized with relevant IPPC phytosanitary terms (FAO 2005b).

729

OBJECTIVES OF THE STANDARD

The objectives of the standard are to:

- *“Facilitate the safe export, shipment, import and release of biological control agents and other beneficial organisms by providing guidelines for all public and private bodies involved, particularly through the development of national legislation where it does not exist;*
- *Describe the need for cooperation between importing and exporting countries so that:*
 - i. benefits to be derived from using biological control agents or other beneficial organisms are achieved with minimal adverse effects;*
 - ii. practices which ensure efficient and safe use while minimizing environmental risks due to improper handling or use are promoted.”*

Guidelines in support of these objectives are described that:

- *“Encourage responsible trade practices*
- *Assist countries to design regulations to address the safe handling, assessment and use of biological control agents and other beneficial organisms*

- *Provide risk management recommendations for the safe export, shipment, import and release of biological control agents and other beneficial organisms*
- *Promote the safe use of biological control agents and other beneficial organisms.*”

SCOPE OF THE IPPC

The International Plant Protection Convention (IPPC) is based on securing common and effective action to prevent the spread and introduction of pests of plants and plant products, and the promotion of appropriate measures for their control. In this context, the provisions of the IPPC extend to any organism capable of harbouring or spreading plant pests, particularly where international transportation is involved (Article I of the IPPC, 1997). A pest is defined as “*any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products*”.

The IPPC (1997) contains the following provision in relation to the regulation of biological control agents and other beneficial organisms. Article VII.1 states:

“With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:

- d) prohibit or restrict the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into their territories.”*

Section 4.1 of ISPM No. 20 (FAO 2004b) contains a reference to the regulation of biological control agents; it states:

“Imported commodities that may be regulated include articles that may be infested or contaminated with regulated pests. ... The following are examples of regulated articles: ... pests and biological control agents.”

The revised ISPM No. 3 provides international guidelines relating to phytosanitary measures, as well as recommending guidelines for the safe use of biological control agents and other beneficial organisms claimed to be beneficial. Phytosanitary concerns with regards to biological control agents include the possibility that newly introduced biological control agents, or organisms claimed to be beneficial may introduce pests or diseases which affect the agent, hence reduce the effect of a biological control program or may severely disrupt an existing biological control program; or may significantly affect non-target organisms, such that there are harmful effects on plant species or plant health. This standard does not alter in any way the scope or obligations of the IPPC itself as contained in the New Revised Text (1997) or conflict with any of the other ISPMs.

Most of the standard is based on the premise that a biological control agent or other beneficial organism may be a potential pest itself, and in this sense Article VII.1c of the IPPC (1997) applies because contracting parties may prohibit or restrict the movement of regulated pests into their territories. In some situations, biological control agents and other beneficial organisms may act as a carrier or pathway for plant pests, hyperparasitoids, hyperparasites

and entomopathogens. In this sense, biological control agents and other beneficial organisms may be considered to be regulated articles as described in Article VII.1 of the IPPC (1997) and ISPM No. 20 (FAO 2004b).

ISPM No. 3 does not specifically cover genetically modified organisms (GMOs). Although GMOs are specifically excluded, the principles of pest risk analysis for assessment of risk and implementation of an appropriate level of protection are still applicable. In addition, this standard does not cover pesticide registration. Pesticide registration is an independent set of processes that differ between countries. The extent to which organisms covered in ISPM No.3 are involved in these registration processes depends on individual countries. In some instances the processes and information required are coincident with the requirements of ISPM No.3. However, the objectives of pesticide registration are different as a whole from those of the IPPC/ISPM No.3, although there may be similar elements.

STRUCTURE

The structure of this revised standard broadly follows that of the original ISPM No. 3, and its content is based primarily on risk management relating to the use of biological control agents and other beneficial organisms. Based on in-country experience, the previous format of ISPM No. 3 was very easy to understand and popular in the field, and so as much of the content and format as possible was retained.

PEST RISK ANALYSIS

The existing standards on pest risk analysis (ISPM No. 2 (FAO 1996a), ISPM No. 11 (FAO 2004a) and ISPM No. 21 (FAO 2004c)) provide the appropriate fundamental processes for carrying out pest risk assessments for biological control agents and other beneficial organisms. In particular, ISPM No. 11 includes provisions for pest risk assessment in relation to environmental risks, and this aspect covers environmental concerns related to the use of biological control agents. Implicit in the development of the output of a risk analysis is the development of risk management plans for organisms being considered.

The IPPC (1997) takes into account internationally approved principles governing the protection of the environment (Preamble). Its purpose includes promoting appropriate phytosanitary measures (Article I.1). Therefore, in carrying out pest risk analyses in accordance with this and other appropriate ISPMs, and in developing and applying related phytosanitary measures (i.e., pest risk management), contracting parties should consider the potential for broader environmental impacts resulting from releasing biological control agents and other beneficial organisms (e.g., the impact on non-target invertebrates).

ISSUES/CHANGES

The content of ISPM No. 3 was not consistent with that of more recent ISPMs in that it included a significant amount of technical implementation details, as well as having a significantly different functional layout and terminology (e.g., see Table 1 for a summary of terminology changes). The revision removed the technical details and adjusted the layout of the text to align more closely with that of other standards.

Table 1. A summary of ISPM No. 3 terminology changes.

Term	New	Modified	Deleted
Authority		x	
Beneficial Organism	x		
Biological Control		x	
Biological Control Agent		x	
Biological Pesticide (biopesticide)		x	
Classical Biological Control Agent		x	
Contamination	x		
Control (of a pest)	x		
Ecoarea			x
Entry (of a consignment)	x		
Establishment		x	
Exotic			x
Import Permit (of a biological control agent)			x
Host Range	x		
Infestation (of a commodity)	x		
Introduction		x	
Inundative Release		x	
Natural Enemy		x	
Organism		x	
Parasitoid		x	
Pathogen		x	
Phytosanitary Measure	x		
Quarantine		x	
Reference Specimens	x		
Regulated Organism	x		
Specificity		x	
Sterile Insect	x		
Sterile Insect Technique	x		

It is recognized that much of the information removed was useful to various parties involved in the practical processes of import and release of biological control agents and other organisms claimed to be beneficial. It is intended that the technical implementation details will be compiled into a set of technical explanatory documents in support of the standard. These documents will not be obligatory, have no official status under the ICPM, and will not be considered official interpretations of ISPM No. 3. However, they may provide examples

of processes and methodologies that could be followed when implementing the standard. According to the IPPC, such explanatory documents need to be developed under the auspices of the IPPC secretariat (otherwise they do not have ISPM explanatory document status).

The general arrangement of ISPM No. 3 (FAO 2005a) is as follows: “designation of responsible authority and description of general responsibilities; pest risk analysis; responsibilities of contracting parties prior to import, documentary responsibilities of importer prior to import; responsibilities of exporter; responsibilities of NPPO or other responsible authority of the importing contracting party upon import; responsibility of the NPPO or other responsible authority before, upon and following release.

The implementation of the guidelines is the responsibility of the contracting parties (usually the NPPO's) or other responsible authorities. Previously, ISPM No. 3 included details and obligations for organisations (e.g., exporters, researchers and importers) that are beyond the scope of the IPPC.

These guidelines are not legally binding under the IPPC, but are indirectly binding through the WTO/SPS Agreement. Advice for parties other than NPPOs, such as exporters, is provided. This advice is for guidance on appropriate process and is not obligatory. The obligations of non-NPPO parties are those contained in the regulations of countries within which they operate. These regulations should have been developed by the NPPO within the framework of ISPM No.3, hence align with the ISPMs objectives.

Reference is made to other international agreements where appropriate, but such references are intentionally vague to ensure it is not implied the IPPC is infringing or interpreting such agreements.

The revision of ISPM No. 3 should improve the understanding of the processes associated with the import and release of biological control agents and/or beneficial organisms, and facilitate the safe trade in such organisms while protecting the environment. This ISPM continues to provide a framework for countries to establish their own phytosanitary measures for biological control agents and/or beneficial organisms i.e., it is not a prescriptive standard that details phytosanitary measures that should be applied in all countries around the world.

Further information on ISPM No. 3 (or any other ISPM or the IPPC) can be obtained from the IPPC Secretariat (ippc@fao.org) or: IPPC Secretariat, FAO-AGPP, Viale delle Terme di Caracalla, 00100 Rome, Italy.

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