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

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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; Lourde 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-
necessary 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 (IBCAs)” (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 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-
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; Uhlmann et al. 2000; Mason et al. 1999; Sands 1998). However, biological control researchers are actively developing appropriate protocols (Bigler et al. 2006; Van D reische and Reardon 2004). The N A PPO guidelines used in North America are flexible in terms of the detail of host range data that are required for a petition for release.

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

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**REFERENCES**


