RULES AND REGULATIONS GOVERNING COMMERCIAL INSECTARIES

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ABSTRACT

Natural enemies regulation by government is justified by the concept that society must actively protect health, agriculture and the environment, but this justification is too often interpreted in a negative way. Regulation should actively facilitate the use of biological control in order to promote healthy agriculture and a healthy environment. Regulation should not impede biological control except when dangers are clearly shown. California regulations support biological control by exempting them from permit required for intrastate movement of insects. Industry self-regulation is an ongoing process between supplier and customer and within organizations such as the Association of Natural Bio-control Producers via standards and ethics creation. States do have regulatory authority, but cede most of the regulatory activity to USDA Animal and Plant Health Inspection Service (APHIS), which acts in accordance with Federal Insecticide, Fungicide, and Rodenticide Act, National Environmental Policy Act, and the new Plant Protection Act. In addition, the Department of the Interior has jurisdiction over natural enemies that might pose a threat to endangered insect species under the auspices of the Endangered Species Act. Enforcement is carried about by intercepting product in transit. Changes in APHIS policy and procedures on international shipments have created havoc with importations in 2004. One day delays, additional customs and broker costs of $400-$1000 + per shipment have been standard this year. Commercial insectaries anticipate that APHIS will draft new federal regulations to carry out the new mandates in the Plant Protection Act and will closely monitor these activities. Insectaries will also continue to monitor international groups that are drafting recommendations on new policies and procedures for regulating multi-cellular natural enemies.

INTRODUCTION

Presently, commercial insectaries and their customers are suffering the effects of changes in regulatory practices for entry of beneficial insects, mites and nematodes into the United States. Enforcement procedures against natural enemies in transit exert harsh consequences on the insectaries: Delay movement of the highly perishable product for a few days and the product is rendered useless. Impact is felt mainly as a consequence of USDA APHIS and Fish and Wildlife transit delays. This paper gives an overview of the background and the impact of regulations that affect our industry, including the current situation on international shipments.

Reasons for regulations and regulating bodies

Society regulates behavior by setting up rules and then enforcing those rules. In the case of beneficial insects, mites, and nematodes, the main concerns of government entities are protecting human health, agriculture and the environment from introduction of new exotic pests or possible impact on endangered species. Some members of Canadian and European governments are attempting to add another layer of requirements to protect the consumer that demand efficacy data before issuing permits for beneficial insects, mites and nematodes to cross their borders. Rules regarding commercial insectaries are made and enforced by the insectaries and their customers, states, many federal agencies, and international consortia that create “guidelines” to foster harmonized legislation between nations. Enforcement is largely accomplished by deprivation. If the international permit is not correct, the international shipment is refused entry. If the customer is dissatisfied, they refuse to pay their bill. If the customer does not pay their bill, they are refused additional shipments.

Self regulation

A glimpse of self-regulation ethics and procedures may be viewed at the Better Business Bureau website (www.bbb.org). Even here, it is clear that the primary enforcers of ethical business practices are the partners in the business transaction: the supplier and the customer. Essential for the customer is the ability to go to a different supplier when a supplier does not give satisfactory service. The life-blood of the commercial insectary is stable and expanding customer demand that repeats annually. A satisfied and diverse customer base is the most reliable way to survive all the other variables that affect agriculture, such as the weather and the crop prices.

There is a concerted effort by members of the ANBP (Association of Natural Biological Control Producers) to build an ethical and technical framework that will foster excellence in the industry. The ANBP is the only professional organization representing the biological control pest control producers in North America. The ANBP Code of Ethics can be viewed at the ANBP website, www.anbp.org. Formed in 1990, ANBP has about 100
members, 37 of which are producers or suppliers. Primary goals are advocacy for the production and use of biological controls, work on regulatory issues facing the industry, communicating with the research community, and supporting quality assurance development.

ANBP supported the inception and its members actively work on ASTM subcommittee E35.30 on Natural Multi-Cellular (Metazoan) Biological Control Organisms, in an effort to create standards of quality that everyone believes to be fair in evaluating product (Glenister et al.). The scope of subcommittee E35.30 is the development of standard definitions, classifications, appropriate test methods, and recommended practices for quality, handling, distribution and use of natural multi-cellular biological control organisms.

ASTM is a non-profit international organization with the purpose of "the development of standards on characteristics and performance of materials, products, systems and services; and the promotion of related knowledge." More information is available at www.astm.org.

ANBP members are active in creating, commenting on, and voting on standards for commercial natural enemy products. Currently standards have been adopted for 3 species and are in progress for 15 species (Table 1 with updates available on the web at www.anbp.org). To date, quality standards have focused on methods of product enumeration upon receipt by the buyer.

As a full consensus organization, all opinions on standards under development are valued and considered. Voting members are required to be balanced among Producers and others (Users, Government, and Academia). Please contact the task group leaders on standards that you wish to review and comment on.

ANBP members also work within the International Organization of Biological Control framework and contribute to the IOBC Quality Guidelines.

State regulations
States have the right to regulate beneficial macrobials, but in the words of the NYS Director of Plant Industry, Robert Mungari, the amount of oversight relates to staffing levels and abilities.

Table 1
Species and natural enemy groups for which ASTM task groups are drafting standards.

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<th>ASTM E35.30 Task Groups</th>
<th>Status March 2003</th>
<th>Technical Contact</th>
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<tr>
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<td><em>Cryptolaemus montrouzieri</em></td>
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This is best demonstrated by the Florida Department of Agriculture, which requires voucher specimens for all incoming product and issues 4 year permits to the primary producers. The Florida Department of Agriculture has 7 taxonomic entomologists on staff. A 1992 letter from one of these taxonomists, Avas B. Hamon, “Our object is to assure only clean properly identified organisms be introduced into Florida.”

Some states maintain regulatory authority over the movement of all insects but exempt beneficial insects from permit requirements through careful wording (see next paragraph), as with the California regulatory code. However, most states do not specifically regulate intrastate or even interstate movement of microbial biological controls and defer to USDA APHIS in determining which beneficials should be allowed to move into the state from other nations. In turn, APHIS no longer regulates interstate movement of beneficial insects, mites and nematodes. It only regulates movement of these beneficials into the United States.

In the 1998 CCBC, Larry Bezark explained the regulatory role of the California Department of Food and Agriculture (CDFA) towards beneficials, in this statement: “The CDFA regulates all live insects and plant pests under the statutory authority of the Food and Agricultural Code. Section 6305 requires a permit to import into or move within the state any live insect or plant pest, including those used for biological control purposes, except honey bees, weeds for identification, and beneficial or useful insects of common occurrence in the state. Section 3558, California Code of Regulations, was adopted to specify which beneficial and useful insects are of common occurrence and exempt from the permit requirements. The regulation specifies that, in addition to the species named in the regulation, insects which have been introduced and previously released in California for biological control are also exempted from permit requirements. The Department maintains a listing of those species which have been previously authorized for release and do not need a permit for California. However, the Department often issues courtesy permits, upon request, to facilitate movement of permit exempt species within the state (Bezark, 1998).

Federal regulations

The various statutes are briefly described below. Until the Plant Protection Act was adopted by Congress in 2000, the federal government’s regulatory authority over multi-cellular natural enemies was murky. This new Act explicitly recommends that biological control be facilitated, and explicitly states that APHIS jurisdiction over the biological controls is concerned with whether they pose a plant pest risk. However, the APHIS regulatory procedures have not been rewritten to meet the demands of this new Act. We are hopeful that new regulatory procedures will improve the movement of multi-cellular natural enemies through customs at border crossings.

It is essential to the greenhouse industry that international shipments of beneficials not be interrupted. Of the 45+ beneficial species used in United States agricultural pest management, approximately twenty are exclusively produced outside the United States but are necessary to the overall success of these pest management programs. Interruptions in the regular supply of these imported beneficials threaten entire programs that have taken years to implement.

Today, the major difficulties with international shipments being held too long by customs, Fish and Wildlife, and APHIS are that the regulatory staff very often set aside the packages until someone can figure out how to process them. This happened with a $20,000 package of Trichogramma that Beneficial Insectary was importing into the Unites States from their production facility in Canada via Fedex. Fish and Wildlife at the Fedex Customs brokerage facility accidentally got the package and held it, probably because insects were the listed contents. Beneficial Insectary has not had problems with Fish and Wildlife at the Fedex hub since they have listed the contents as Farm-raised Insects (Sinthyia Penn, personal communication, 2004).

FIFRA

The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 gave EPA the authority to regulate biological control agents as pesticides, but at the same time gave the EPA authority to exempt from regulation substances that are adequately regulated by other agencies. Under this authority, EPA exempted multicellular natural enemies such as arthropods and nematodes from regulation under FIFRA (Cook et al., 1998). Two agencies that have oversight over multi-cellular natural enemies are Fish and Wildlife, and USDA APHIS, although until the new Plant Protection Act, APHIS actually did not have statutory authority.

Endangered Species Act of 1973

Under this act, the Department of the Interior has jurisdiction over natural enemies that endanger endangered species. Permits for importation from Canada of Trichogramma ostriniae, a very effective parasite of European Corn Borer eggs, were at first issued but later refused renewal on the basis that it was not known if there was a hazard to endangered Lepidoptera. This species continues to be produced and disseminated by Cornell University using stock that is already within the United States.
**NEPA**

The National Environmental Policy Act of 1969 as amended requires that Federal agencies examine their actions for impact on the environment. Thus APHIS must conduct an Environmental Assessment and either record a Finding of No Significant Impact, or undertake an Environmental Impact Statement before it issues permits for new exotic natural enemies (Cook et al., 1998).

**Plant protection act**

(Public Law 106-224 - June 20, 2000, 7 U.S.C. 7701 et seq.): This act has several positive developments for biological control (below). We are hopeful that the regulations written to support this act will be favorable to biological control as well.

Section 402-2. [Congress finds that] biological control is often a desirable, low-risk means of ridding crops and other plants of plant pests and noxious weeds, and its use should be facilitated by the Department of Agriculture, other Federal Agencies, and States whenever feasible;

Section 412 a) In General.-The Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.

**International guidelines and international cooperation**

The international community works to foster harmonized legislation by creating documents that recommend policies and procedures for international trade. Two organizations that the ANBP has been closely monitoring for their recommendations on biological control regulation are NAPPO and OECD. Information from these organizations’ promotional material is summarized here.

**North American Plant Protection Organization (NAPPO) ([www.nappo.org](http://www.nappo.org))**

The stated mission of NAPPO is: “NAPPO coordinates the efforts among Canada, the United States and Mexico to protect their plant resources from the entry, establishment and spread of regulated plant pests, while facilitating intra/interregional trade.” NAPPO was created under the authority of the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization (FAO) of the United Nations.

**Organization for Economic Cooperation and Development (OECD) ([www.oecdwash.org](http://www.oecdwash.org))**

The OECD is a group of industrialized, market-economy countries from Europe, North America, and the Pacific that meets to harmonize policy as a means to maximize economic growth. They draft guidelines that can be used by member countries as templates for regulatory policy, but do not directly regulate.

NAPPO has a set of policies and procedures which has been adopted as the current standard for data required prior to importation of exotic natural enemies into the United States. Named NAPPO Doc. 001-001 NAPPO Guidelines for Petition for Release of Exotic Entomophagous Agents for the Biological Control of Pests. October 15, 2000., these are published on the APHIS website at:


The OECD Working Group on Regulatory Approaches to Invertebrate Biological Control Agents, chaired by Wendy Sexsmith of the pesticide regulatory branch of Health Canada has created a draft document that proposes harmonized data requirements for the importation and inundative release of macrobials. Most troubling to us was the inclusion of a requirement for efficacy data for importation of exotic natural enemies, but we have been assured that the requirement will be very light: only 10% reduction of the pest population will need to be demonstrated. However, I fear that once the term efficacy is included in such a document, the pesticide-style connotation of efficacy will eventually prevail. This draft guideline has not yet been presented to the OECD Secretariat.

**CURRENT SITUATION**

In 2004, APHIS Plant Protection and Quarantine (PPQ) changed its regulatory procedures for border crossings of multi-cellular natural enemies in order to address several needs including:

1) The Office of the Inspector General had issued a report that said they did not adequately monitor the use of the Plant Pest Permits associated with PPQ form 526 that they use to authorize movement of natural enemies as well as plant pests.

2) Most of APHIS PPQ’s agricultural inspectors had been shifted into the Department of Homeland Security, yet APHIS legally retained authority to inspect our product before it is allowed into the country.

3) APHIS PPQ claims that it is imperative that its entomologists inspect our shipments to confirm that bioterrorist agents are not being introduced into agriculture via these shipments.
The new procedures require that all shipments be inspected by one of the few remaining APHIS PPQ inspectors. The procedures have created chaotic difficulties with our weekly incoming product. Importers have suffered stalled shipments, dead shipments, shipments sent back to the country of origin, and additional costs of $400-$1000+ per shipment per week to cover additional customs brokers’ and bonded carriers’ fees.

ANBP has requested that APHIS deputize the Department of Homeland Security’s Agricultural Inspectors (formerly APHIS inspectors) to inspect our shipments, as made possible in the Homeland Security Act. APHIS is resisting that solution. Ultimately, APHIS needs to draft new regulations which treat multi-cellular natural enemies in a separate category from plant pests and actually facilitates their use in the United States in accordance with the provisions of the new Plant Pest Act.

**CONCLUSIONS**

Self-regulation is an ongoing process between supplier and customer and within organizations such as ANBP. Natural enemies regulation by government is justified by the concept that society must actively protect health, agriculture and the environment, but this justification is too often interpreted in a negative way. Regulation should actively facilitate the use of biological control in order to promote healthy agriculture and a healthy environment. Regulation should not impede biological control unless dangers are clearly shown.

Bill Metterhouse, a veteran of state regulatory affairs in the New Jersey Department of Agriculture drew this carefully worded conclusion regarding natural enemies regulation in 1992: “Any regulatory or statutory requirements that we develop should be in accordance with the principles of plant quarantine and be reasonable, biologically sound and enforceable….Regulations should…not discourage the science or deter the implementation of biological control programs” (Metterhouse, 1993). Bill was speaking from the perspective of one with experience in setting up and enforcing plant pest quarantines as well as setting up one of the few state-run biological control rearing facilities. His words will stand the test of centuries.

**ACKNOWLEDGMENTS**

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**REFERENCES**


