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Review Article

A global review of risk-benefit-cost analysis for the introduction of classical biological control agents against weeds: a crisis in the making?

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Abstract

Risks of non-target effects resulting from releases of exotic organisms for the biological control of alien pests are a growing major concern because: (a) previous releases (<1%) are having significant negative impacts on rare native species, (b) alien organisms are a recognized global threat to sustainable agriculture and biodiversity, (c) risk analysis, as applied to environmental threats of species invasions and harmful effects of releases of genetically modified organisms, is a burgeoning field, and (d) biological control is increasingly being used in complex natural ecosystems where indirect impacts are harder to predict. As a result, governments are adopting a more risk-averse attitude to biological control as they assess such releases from an environmental and an economic standpoint. This is leading to more expensive and fewer successful release applications. In this paper we review the processes of risk analysis used by regulatory bodies around the world to pre-judge biological control releases against weeds. The aim is to publicize both strengths and weaknesses and to help encourage existing assessments to be fair to all without blunting the value of biological control as an effective tool against invasive alien weeds. The review, based around the five components of formal risk analysis (comparative analysis, risk assessment, risk management, risk evaluation, and risk communication), also focuses on how well the benefits and costs of biological control releases are evaluated in addition to the traditional analysis of the hazards. Currently only the New Zealand approach closely matches a full ecological risk-benefit-cost analysis of biological control releases with a precautionary approach, open consultation, a broad hazard/benefit definition in the release application and a judicial basis to the decision, but it comes at a high cost. Improving the analytical approaches used by countries runs a high risk of grinding biological control releases to a halt in a world where the precautionary approach has been adopted with respect to threats from exotic organisms on biodiversity (in line with the 'precautionary approach' set forth in principle 15 of the 1992 Rio Declaration on Environment and Development). The benefits of biological control remain poorly understood by the public, allowing the risks to attain disproportionate attention. We make recommendations to address this crisis in the making and discuss the outcomes of the review with respect to the inherent social risks of making analysis of biological control releases an overly protracted process.

Introduction

Alien invasive species remain the second most significant threat to biodiversity after habitat destruction, threatening significant percentages of listed rare and endangered native plant species (Pimentel, 2002). Of these, alien weeds are the most costly causing more than a third of the estimated US$350 billion worldwide annual economic damage from all introduced pests. Classical biological control of weeds, based on the introduction of exotic natural enemies as biological control agents to control alien invasive plants, has a long history including highly successful programmes and remains the only tool capable of reducing densities of our worst alien weeds. Despite this, the current perception of biological control in the broader community is orientated more towards the threat to agriculture and biodiversity than towards possible benefit through control of the target pest. Many consider this to be driving the discipline towards a crisis. The legislative risk assessment process for biological control agents prior to permissions being granted for release continues to increase in complexity in most countries as the regulatory responsibilities for releasing exotic organisms now concern both agriculture (the traditional arena) and the natural environment. 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"[a], designed to protect against such invasions, adopts the 'precautionary approach' within it. This in turn has led to increasingly precautionary attitudes towards classical biological control releases. Under such legislation environmental protection agencies meticulously deliberate over the controllable new threats biological control organisms might pose to native species, in a world where of the order of only 1–4% of exotic arthropods are deliberately introduced (Emberson, 2000; Pimentel, 2002). Such environmental assessments can delay agent release by years, multiplying programme costs. Public support is therefore dwindling and agencies that traditionally fund biological control research are experiencing donor fatigue. Meanwhile the threats and damage from the target alien weeds themselves are left to increase. Furthermore weeds, however damaging, are starting to be avoided as potential biocontrol targets when there is a close native relative. These precautionary attitudes result from a number of historical and scientific factors.

Undesirable direct or indirect non-target impacts of biological control agents are the greatest current concern. This has grown out of an ecological literature that has discussed many potential negative non-target impacts associated with deliberate biological control releases. This has been a popular topic of discussion and speculation as the global society itself becomes increasingly risk averse, particularly with regard to the remaining natural environment and biodiversity.

The context of the discussion, with respect to weed biological control, however, is that of 352 biological control agent species deliberately released up until 1998 (Julien & Griffith, 1998), 0.6% (two cases) have been observed causing significant non-target population suppression in one or two countries where released (Louda *et al.*, 2003), 10% of releases have been observed feeding on (with one exception) anticipated closely related non-target plants (Pemberton, 2000), while between 20% of releases (Crawley, 1989) and 34% of species (Julien *et al.*, 1984) were observed to significantly suppress their target weeds. These figures are clouded by relatively poor historic evaluation of releases against either targets or non-targets, but current ecological discussion surrounding biological weed control focuses relatively little attention on the historical success or the potential future environmental benefits from highly targeted and regulated modern biological control practices.

Nonetheless recent ecological understanding of the intricate and reticulate nature and function of food webs and how complex natural communities are structured suggests that the introduction of new organisms into the environment may cause more far reaching changes than previously thought on the forces that hold together natural communities (Strong & Pemberton, 2001). Biological control is increasingly being used for pest management in natural ecosystems. This leads to the introduction of exotic organisms into much more complex food webs than found in the more traditional agricultural arena of biological control. This has generated legitimate concern about future biological control releases into such complex systems.

Releases and proposed releases of genetically modified organisms (GMOs) have also instigated general concerns about releasing novel genotypes into the environment recognized internationally through the Cartagena Protocol on Biosafety. This has led, in turn, to increased awareness of critical issues in ecological risk analysis of such introductions.

Not all biological control organisms have been traditionally given the same degree of risk assessment. This has traditionally developed in parallel with quarantine legislation linked to plant protection. As a result, natural enemies used to target alien weeds also pose threats to economic plants and have always been subject to a stringent legislative framework compared to biological control agents targeting other sorts of pest organisms. The relatively low number of economically important invertebrates and the lower perceived societal value of native invertebrate species have also created this difference. As such, biological control agents against non-plant pests have, until recently, required very little quantitative assessment (Hopper, 2001).

That the broader society considers biological control to be 'risky', however, also results from poor public and political perceptions of the benefits biological control has provided and can provide. For biological control to achieve its full potential, agencies responsible for its practice should consider redressing this to ensure policy discussions relating to improved risk analysis lead to fair and open assessment processes balancing risks to benefits in the future.

As a starting point this paper reviews the current procedures used in analysing the risks of potential biological control agents targeted against weeds in all countries that have a long history of significant activity in this discipline. (The acronyms of organizations, conventions and government acts used in this review are summarized in Table 1.) The aim is to evaluate existing procedures in each country against the widely accepted model for conducting risk analysis in general and ecological risk assessment in particular. Such procedures have developed more or less in parallel between countries based on streamlined plant protection and quarantine legislation; however, the precise approaches adopted vary significantly between countries, based on local biases, issues and vested interests. This review aims to identify strengths and weaknesses across these systems. The International Plant Protection Convention (IPPC) Code of Conduct for the Import and Release of Exotic Biological Control Agents (IPPC, 1996a) is also included in this review. Identified strengths may be usefully considered by other countries, while identified weaknesses might suggest ways that current procedures in risk analysis might be improved. The results of this review are discussed

[a] www.biodiv.org/decisions/default.asp?lg=0&dec=VI/23

Table 1. Acronyms of organizations, conventions and government acts* used in this review.

Acronym	Agency
AAFC	Agriculture and Agri-Food Canada
AFFA-AQIS	Agriculture Fisheries and Forestry Australia – Australian Quarantine Inspection Service
AFFA-BA	Agriculture Fisheries and Forestry Australia – Biosecurity Australia
APHIS-PPQ	USDA Animal and Plant Health Inspection Service – Plant Protection & Quarantine Program
ARC-PPRI	South African Agricultural Research Council – Plant Protection Research Institute
BLM	USDI Bureau of Land Management
BCRC	AAFC Biological Control Review Committee
BIA	USDI Bureau of Indian Affairs
CFIA-PHPD	Canadian Food Inspection Agency, Plant Products Directorate, Plant Health and Production Division
CBD	Convention on Biological Diversity
DEAT	South African Department of Environmental Affairs and Tourism
DEH	Australian Department of the Environment and Heritage
EPA	US Environmental Protection Agency
EPBC	Australian Environment Protection and Biodiversity Conservation Act (1999)
EPPO	European and Mediterranean Plant Protection Organization
ERMA	New Zealand Environmental Risk Management Authority
ESA	US Endangered Species Act (1973)
FWS	USDI Fish and Wildlife Service
HSNO	New Zealand Hazardous Substances and New Organisms Act (1996)
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
NAPPO	North American Plant Protection Organization
NDA	South African National Department of Agriculture
NEPA	US National Environmental Policy Act (1969)
NMFS	US National Marine Fisheries Service
NPS	USDI National Parks Service
TAG	USDA-APHIS Technical Advisory Group
USDA	US Department of Agriculture
USDA-APHIS	USDA Animal and Plant Health Inspection Service
USDA-ARS	US Department of Agriculture – Agricultural Research Service
USDI	US Department of the Interior
WGBICW	South African Working Group on Biological and Integrated Control of Weeds

* Further information on the government acts cited in this review is given in footnotes and/or the references.

in a broader context of risk-benefit-cost analysis leading to recommendations on how research agencies might act in the future to encourage a healthy future for biological control.

Definitions

Terminology associated with evaluating the risks, costs and benefits of releasing a new organism into the environment suffers from inconsistency in usage by users across different countries. In this review, risk-benefit-cost (RBC) analysis refers to a complete process of deciding whether a new organism will be released and managed. The term 'risk analysis' is more traditionally used for this, as risk can be defined as the product of the likelihood and the level of consequence of an outcome, be it bad (a hazard) or good (a benefit). Risk is now, however, invariably associated with undesirable outcomes masking the equal importance of the benefits (and costs) associated with releasing new organisms as recognized in the relevant New Zealand legislation (the Hazardous Substances and New Organisms Act (1996)). The best recognized practice of RBC analysis consists of five components: comparative analysis, assessment, management, evaluation and communication (Lonsdale *et al.*, 2001). Comparative analysis defines the context of the required analysis relative to level of perceived risk associated with the type of action. Should, for example, biological control releases with measurable outcomes available for over 100 years be treated with the same level of uncertainty as GMO releases? RBC assessment is the core of RBC analysis and is subdivided into (a) identifying the hazards, benefits and costs that might result from releasing the biological control agent or not, and (b) analysing the risks of exposure to all identified hazards, benefits and associated costs (frequency of occurrence and consequences should it occur) and quantifying the uncertainty associated with each. Risk-benefit management identifies what can be done to manage the hazards and benefits should they occur. Risk-benefit evaluation provides a procedure for evaluating the RBC assessment following release. Communication ensures broad consultation on hazards, benefits and costs in the other four components allowing fair treatment of possible conflicts of interest and a democratic basis to the final decision-making process. Most countries included in this review tend to use 'assessment' rather than 'analysis' to describe the process used. To avoid confusion, therefore, we adopt the terminology used by each country when referring to their procedures.

Summaries of National Procedures

Australia

Organizations wishing to undertake biological control of a particular weed for the first time must submit a 'Nomination of Target Weeds for Biological Control' to the Australian Weeds Committee (which reports indirectly to the Natural Resources Management and Primary Industry Standing Committees) in a format that includes the weed's pest status across each state, possible implications of biological control for industry (e.g. the horticultural industry) and other control methods available. This allows possible conflicts of interest to be aired. The nomination must normally be accepted prior to any applications to introduce biological control agents.

Australia is the only country with biological control legislation: the Biological Control Act (1984) (Cullen & Delfosse, 1985). Under the process largely in place since 1987, applications to import and release biological control agents must be made for separate permits from Agriculture Fisheries and Forestry Australia – Biosecurity Australia (AFFA-BA) and Department of the Environment and Heritage (DEH). In addition to having different agency perspectives, AFFA-BA manages peer-reviewed risk assessment of non-target

impacts through state and federal agencies, while DEH requires a risk-benefit assessment involving public consultation of the likely impacts on the environment. In practical terms, most aspects required for applications to AFFA-BA are also suitable for applications to DEH.

For AFFA-BA, release applications are preceded by applications for the approval of test plant lists and applications for introduction into quarantine. Fully justified official formatted applications for the approval of test plants are submitted to AFFA-BA and sent out to 21 cooperating agencies: state and federal agriculture and conservation agencies and the Australian Quarantine Inspection Service (AFFA-AQIS). Agencies have 40 days to comment on the application. Requests for additional test plants to be added to the list also need justification. Additions may be negotiated directly between the applicant and the cooperator facilitated by AFFA-BA. Import applications made to AFFA-BA are not peer reviewed and are normally issued within 10 days if suitable quarantine facilities are available. Release applications based on a standard format are submitted to AFFA-BA. These applications only address direct risk of agents on non-target organisms and are almost entirely built around evidence and test results for agent specificity. The applications are again sent out to the 21 cooperating organizations for comment within 40 days. Comments usually address the test methodology and the test results and may request further testing, should the evidence be inconclusive. Once agreement has been reached by the 21 cooperators, AFFA-BA can issue a release permit under the Quarantine Act (1908) in the form of a letter changing the conditions on the importation permit.

Under the Wildlife Protection Act (1982) until 2001 and then under the Environment Protection and Biodiversity Conservation Act (1999) (EPBC) following repeal the import application to DEH is an application to amend the list of legally importable species allowed by DEH to include the biological control agent. It is the responsibility of the importer to outline draft terms of reference for an assessment of potential impacts of the proposed amendment on the Australian environment. The main aim of the assessment is to provide a summary analysis of key information (including costs and benefits), and a detailed evaluation of the risks of the proposed release. The draft terms of reference are posted on DEH's website[b] for 10 business days to allow for public comment. Any comments that are received are considered by the applicant, and appropriately incorporated into the terms of reference. When the final terms of reference are agreed, a testing (import) permit is issued by DEH that allows testing in a quarantine facility, if necessary, to meet the terms of reference and to produce a draft of the required assessment. Voucher specimens of all tested agent material are lodged at a recognized institution. The draft assessment is then published on the DEH website for 20 business days. Any public comments received are appropriately addressed with justification by the applicant in the assessment. Once the final assessment has been accepted, the Commonwealth Minister for DEH tables it in parliament for consultation by other federal, state and territory ministers considered appropriate and may also consult with other organizations or individuals before making a decision to amend the list. If the Minister approves the amendment, the list will be formally amended to include the agent species through publication in the Australian Government Gazette, a change which may be reviewed within 5 years. Once the agent appears on the live import list, importers of biological control agents can apply to DEH for the release permit. Public negatively affected by the decision may request a written explanation.

[b] www.ea.gov.au/biodiversity/trade-use/publicnotices

The number of release permits issued per year since 1950 is given in Figure 1(a). While this varies a lot between years the numbers have been in decline over the last 3 years since the enforcement of the EPBC Act brought in a more protracted assessment process.

South Africa

Invasive plant species suitable for biological control are declared under the Conservation of Agricultural Resources Act (1983). The selection of weeds for biological control is determined by the 'clients' (largely government agencies) that fund the research in consultation with the biological control research providers. The Agricultural Research Council – Plant Protection Research Institute (ARC-PPRI) is the dominant research provider but works closely with university research groups that are all part of a Working Group on Biological and Integrated Control of Weeds (WGBICW) (Olckers, 1999). Public consultation starts early in project development with advertisements for interested parties to participate in the process. If threats to economically important species are identified, a continual risk assessment process is undertaken with affected parties (Zimmermann & Neser, 1999). The National Department of Agriculture (NDA) through its Directorate of Plant Health & Quality regulates the release of biological control agents under the Agricultural Pest Act (1983), while the Department of Environmental Affairs and Tourism (DEAT) also needs to independently approve releases once a formalized Environmental Impact Assessment (EIA) has been completed. This EIA evaluates threats to biodiversity and endangered species and other relevant conflicts of interest, even at a local level, under the Environment Conservation Act (1989).

Release applications are only submitted when WGBICW is convinced about the credibility of the testing and the merits of a release. Under the NDA process, release applications justify the relevance and safety of release of the proposed biological control agent. These applications address risk through host specificity assessments, assess costs using quantitative data on the impacts of the target weed, and evaluate potential benefits of successful control to industry and the environment. Applications are evaluated by a review panel of four government and university scientists with experience in biological control. NDA may select specific scientists to suit particular applications. They may include conservation ecologists or overseas scientists with no vested interests. The panel conducts its review, mainly of the specificity work, which may involve direct exchanges with the applicants before it makes a recommendation "preferably within 3 months" to NDA. If the recommendation is favourable, then NDA will issue the release permit subject to certain conditions (e.g. subsequent approval from DEAT).

In the DEAT process, which is independent of the NDA process and usually takes upwards of 12 months, biological control is treated in the same way as other activities that may alter the environment. The EIA contains all the research and host specificity testing results and includes input from other experts and taxonomists. An invitation to register as an interested party is placed in two national newspapers. Evidence that all registered interested parties (not just environmentalists) have been kept informed of progress towards a release proposal is included in the EIA. Where there are conflicts of interest, results are presented at workshops held with all stakeholders, and the minutes of these workshops or meetings are added to the EIA. Prior to the EIA, a Plan of Study for Scoping, which constitutes a declaration of intent to initiate biological control research, is circulated to nine provinces for information and comments. The EIA (Scoping Report) is submitted to DEAT, which

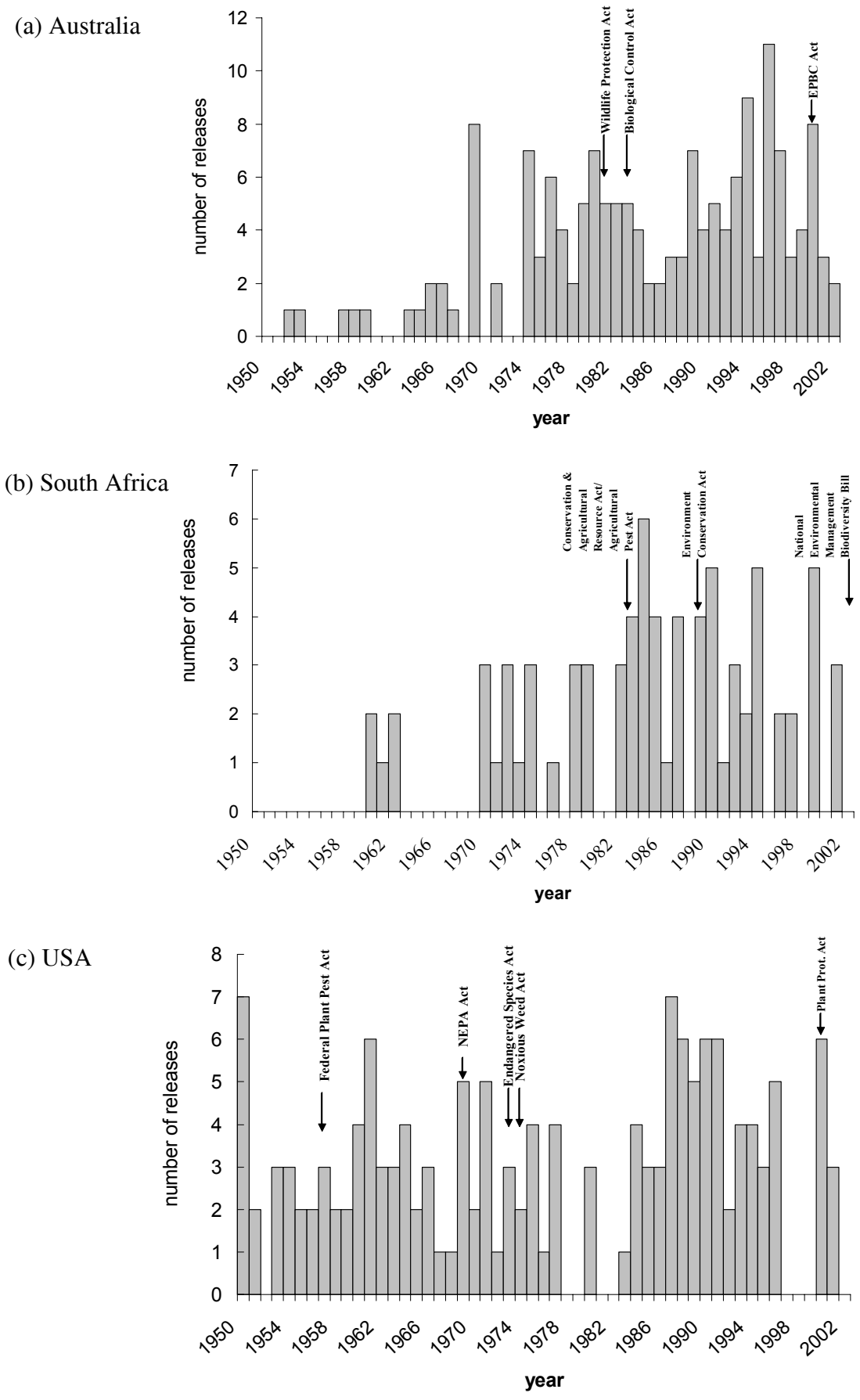

Figure 1. Number of release permits for classical biological control agents against weeds provided per year in (a) Australia, (b) South Africa, (c) USA, (d) Canada, and (e) New Zealand in relation to key associated government acts.

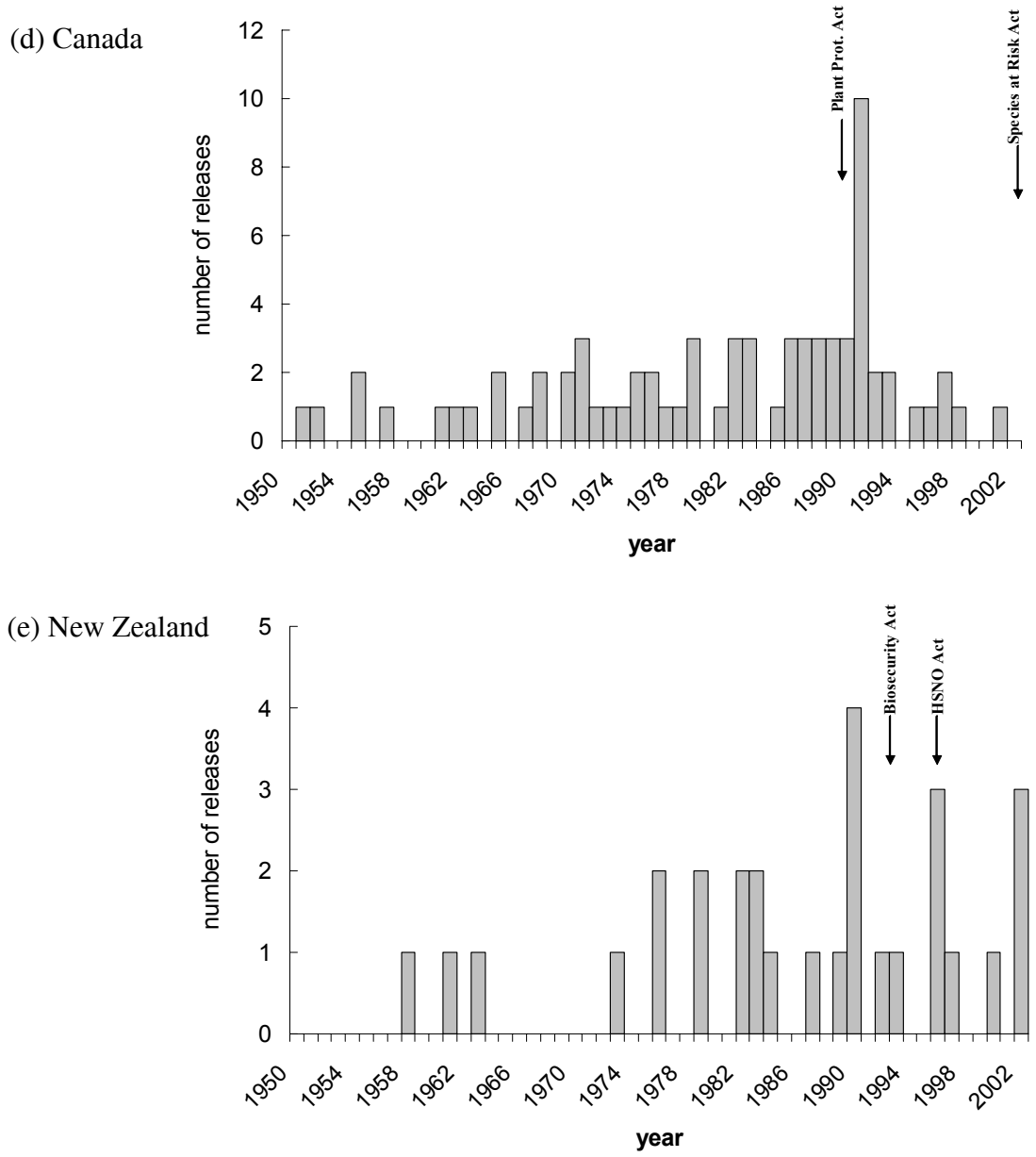

Figure 1 (continued).

circulates it back to the nine provinces for review. The decision by DEAT legally requires release approval from all nine provinces but can ignore inappropriate or non-responses and DEAT may reconsider previous decisions.

The number of release permits issued per year since 1950 in South Africa is given in Figure 1(b). It has taken a while since 1989 for the implications of the Environment Conservation Act to take effect, but releases now appear to be declining with releases permitted in only 2 of the last 5 years. A new National Environmental Management Biodiversity Bill is also being formulated in which biological control agents have been included with other alien and invasive species. This bill may also pose restrictions on surveys in South Africa for natural enemies of weeds of South African origin.

United States of America

Introductions for the classical biological control of weeds in the USA are guided by the Plant Quarantine Act (1912), the Federal Plant Pest Act (1957), the Noxious Weed Act (1974), the Agricultural Risk Protection Act (2000) and the Executive Order 13112 for Invasive Species, while threats to native species are covered under the Endangered Species Act (1973) (ESA), the National Environmental Policy Act (1969) (NEPA) and the Coastal Zone Management Act (1972).

Petitions for the release of phytophagous arthropods or obligate plant pathogens for classical biological control are built up through a consultation process under guidelines maintained by the US Department of Agriculture (USDA) — Animal and Plant Health Inspection Service — Plant Protection & Quarantine Program (APHIS-PPQ). APHIS-PPQ has regulatory responsibility for import and release permits for agents for the biological control of weeds and is assisted in this process by the Technical Advisory Group (TAG).

TAG is made up of representatives of 13 federal agencies that either support, or conduct research on, or use weed biological control as part of their activities. TAG functions under APHIS-PPQ procedures. Five USDA agencies (including the Natural Resources Conservation Service), six US Department of the Interior (USDI)

agencies (including the Fish and Wildlife Service (FWS), the National Park Service (NPS), the Bureau of Land Management (BLM) and the Bureau of Indian Affairs (BIA)) and the US Environmental Protection Agency (EPA) and Department of Defense are represented on TAG.

Through this consultation process, TAG assists by making recommendations on target suitability and test plant lists for specificity testing. List development requires at least informal independent consultation with FWS and/or the National Marine Fisheries Service (NMFS) on threats to federally listed endangered species (FWS must respond within 30 days). Import permit applications are also submitted to APHIS-PPQ and voucher specimens are lodged.

TAG provides a science-based link between the research community and the regulatory agencies involved in weed biological control. Its advisory role to APHIS-PPQ covers: (a) reviewing petitions with the aim of making conservative recommendations to APHIS-PPQ, (b) assessing risk and benefit associated with release and recommending specific actions for the petitioner before a release application is written to APHIS-PPQ, (c) incorporating member agencies' concerns and perspectives into planning biological control programmes, and (d) assisting in defining a course of action when there might be a conflict of interest. A reviewer's manual defines the requirement of petitions, petitioners and reviewers[c].

The elected chair of TAG builds consensus amongst the TAG members although there is no strict need for unanimity for a positive TAG recommendation. TAG, therefore, only recommends a release petition to APHIS-PPQ if there is sufficient justification that a weed should be a target for biological control and the benefits of possible successful biological control outweigh the risks and, perhaps most importantly, that the activities undertaken will not directly or indirectly jeopardize the continued existence of an endangered species. When a positive recommendation is received from TAG, APHIS-PPQ invites the petitioner to submit another permit application.

Release permits issued by APHIS-PPQ invoke compliance with NEPA and ESA. NEPA requires an 'Environmental Assessment', drafted by the applicant. An Environmental Assessment is a non-scientific document (of some 15 pages) for public consumption that presents a balanced account of the likely positive and negative direct or indirect impacts on the environment of the release. ESA requires a 'Biological Assessment' on the risks to any listed endangered species or critical habitats, the areas likely to be affected and the manner (including a cumulative effects analysis) in which these are likely to be affected. This report is submitted to FWS as part of the consultation process conducted independently of FWS's role on TAG. Where such effects have not been identified, and FWS concurs through informal consultation, this report is less substantive. Approval becomes a substantive process if the Biological Assessment indicates effects on endangered species or critical habitats are likely to occur. DeLoach *et al*. (2000) is an example of a substantive Biological Assessment.

Once FWS and/or NMFS agree to the release, both following informal or formal consultation, then their report is added to the Environmental Assessment and the Environmental Assessment is then published for at least 30 days on the Federal Register for public comment. APHIS-PPQ considers the comments and consults with the relevant state plant regulatory official and then issues a release permit or asks the applicant to produce an Environmental Impact Statement when significant negative impacts are expected or advises that the project be discontinued.

The number of release permits issued per year since 1950 is shown in Figure 1(c). The ESA became effective after 1973 and there was a clear decline in release permits from 1978 to 1982. The implications of the CBD in the 1990s may now be starting to show. An increasingly precautionary approach by the FWS is at least in part responsible for release permits only having been issued in 2 of the last 6 years.

Canada

Most introductions of agents into Canada for classical biocontrol purposes have historically been conducted by federal scientists, working for the Research Branch of Agriculture and Agri-Food Canada (AAFC). Releases of weed biological control agents in Canada are regulated in the same way as pests under the Plant Protection Act (1990) and associated regulations. Importation and release permits are issued by the Canadian Food Inspection Agency, Plant Products Directorate, Plant Health and Production Division (CFIA-PHPD) following recognized guidelines[d]. The only regulatory reference to biological control agents is the need for additional information on survival and environmental impact information in applications to import and release biological control agents.

Host plant test list approval and release petitions, in the same basic format as defined by APHIS-PPQ (including a basic risk-benefit assessment compiled by the applicant), are submitted to the AAFC Biological Control Review Committee (BCRC). Petitions must conform to the format and substance of the North American Plant Protection Organization's (NAPPO) Standards for the import and release of phytophagous and entomophagous biocontrol agents. BCRC is made up of entomological and botanical scientists from several federal and provincial government agencies (including Environment Canada). Anonymous reviewers are added to BCRC from a broader group including unaffiliated experts and universities for each petition depending on the agent organism, target and region.

There is no formal process for public consultation during petition evaluation. Petitions received are also submitted to TAG in the USA for comment. Although BCRC and CFIA-PHPD pay particular attention to non-target issues, there is currently no requirement to directly design and assess petitions, in the way that TAG and FWS do, with respect to listed endangered species (this is likely to change when the recently passed Species at Risk Act (2002) comes into force following development of associated regulations). The Chair of BCRC makes a recommendation to the Director of CFIA-PHPD and provides all parts of the petition and the reviewers' comments. The petition is then reviewed by the regulatory entomologists of the Centre for Plant Quarantine Pests of CFIA. Based on comments from BCRC, TAG and its own staff entomologists, CFIA-PHPD makes the decision about the release of the agent under the Plant Protection Act (1990) within 6 months. Voucher specimens must be deposited. CFIA-PHPD does not approve releases without comments from TAG, but is not obliged to follow TAG and FWS recommendations, so agents may be approved for release in Canada before being approved for release in the USA (e.g. some agents against *Cynoglossum officinale*). Release of biological control agents may also regulated by some Provinces.

[c] www.aphis.usda.gov/ppq/permits/tag/tag.pdf

[d] www.inspection.gc.ca/english/plaveg/protect/dir/d-96-14e.pdf

The number of release permits issued per year since 1950 is shown in Figure 1(d). Canada has seen a decline in the number of release permits issued over the last decade, although the reasons for this do not appear to be legislative.

New Zealand

The system for releasing biological control agents in New Zealand was revolutionized by the Hazardous Substances and New Organisms Act (1996) (HSNO). This Act initiated a new environmental risk evaluation procedure to address proposed new chemicals and novel organisms[e] under the Environmental Risk Management Authority (ERMA). ERMA has the responsibility of assessing and making decisions on standardized import and release applications. This is 'enabling' legislation meaning that the introduction of any organism is possible as long as ERMA can be convinced of low impact and risk. ERMA is a semi-judicial body corporate of 6–8 members appointed by the Minister for the Environment to represent a "balanced mix of [relevant] knowledge and experience". Two members of ERMA have research experience in ecology and entomology and staff are changed frequently to ensure objectivity. Suitability of target weeds is judged through the risks, costs and benefits assessed in the ERMA process. Permits are then issued by the Ministry of Agriculture and Forestry under the Biosecurity Act (1993).

An application for importation into quarantine requires a full risk analysis including an eradication strategy should escape occur. ERMA must respond to the application in 14–80 business days and there is no public consultation. ERMA describes some of the ways available to address the principles of the HSNO Act. This methodology recommends the applicant identify interested groups associated with proposed releases and engage them in discussions and in the assessment process. The defined risk, cost and benefit categories are ecosystem health and intrinsic value, species conservation, social well-being now and in the future, spiritual and cultural values, and public health. The Act states, "Identifying risks and benefits requires a systematic consideration of all significant impacts of the organism on the natural environment, people and communities". The applicant is required to develop a full environmental risk assessment and a full benefit assessment and cost analysis by identifying and analysing all reasonable potential hazards, risks, benefits and conflicts of interest. Evidence of support from stakeholders, including indigenous people, is also required. Host specificity testing is not in itself a requirement, but it has been quickly adopted as a standard for agents proposed for release against weeds. Adequate consultation on the test list helps prevent ERMA insisting on further testing, which would require a new submission and associated costs.

Once the application is submitted, ERMANZ (ERMA's administration) notifies the public through advertisements in four national newspapers and placing the submission on its website[f] for 90 business days. In the meantime ERMANZ prepares an 'Evaluation and Review' report of the application with the help of expert advice and peer review and feedback from the applicant as required. Independent submissions from public or private sources are also received and handled by ERMANZ. ERMA then convenes a public hearing. This is not always a requirement, but appears to be the current *modus operandi*. ERMA applies the 'precautionary approach' in its review of the risks, costs and benefits in the application if full agreement is not reached and with respect to direct or indirect impacts on native species and communities (a legislative requirement). A typical ERMA approach is to suggest that even if the risk is small, if the benefits are small then why take the risk? ERMA's decision is final and is made without restrictions. There is an opportunity for ministerial intervention in certain cases, and a judicial review of the process (but not the decision) can be undertaken. In theory the semi-judicial process should allow precedent to determine future ERMA attitudes; however, the current political climate and frequent ERMA staff turnover have not encouraged this.

The number of release permits issued per year since 1950 in New Zealand is provided in Figure 1(e). An average number of releases of one a year has not declined since the HSNO Act came into effect in the late 1990s. This suggests the improved ERMA risk analysis procedures adopted have not as yet become too restrictive in New Zealand despite increased associated costs.

IPPC Code of Conduct

Also referred to as the FAO Code of Conduct, this code sets out the responsibilities of the authorities of governments and importers of exotic classical biological control agents (IPPC, 1996a). It encourages governments to adopt specific legislation and regulations and designate an authority to administer such activities recognizing that a specific code is required for classical biological control. It recommends that both hazard identification and exposure analysis of risks (no mention of benefits) should be carried out following International Standards for Phytosanitary Measures (ISPM) guidelines for pest risk analysis (IPPC, 1996b). Stipulated risks include contaminants, non-target and environmental impacts, handling of agents, and human and animal health. Voucher specimens should be deposited. The suitable decision maker might be the relevant national plant protection organization, which should define a level of appropriate risk on which to base its decision (which implies that the Code is somewhat risk accepting). Identification of risk mitigating procedures is also recommended. Monitoring of releases to evaluate risks is encouraged. The environmental and economic impacts of the releases should be assessed and published. Information on the safety and environmental impact of agents should be made publicly available after release. Notification of relevant interested parties should be made following unexpected deleterious incidents.

This code is being used as a basis for developing standards for the "safe use of biological control" by the European and Mediterranean Plant Protection Organization (EPPO). Required improvements in the current code of conduct have been discussed and documented which would tend to make the code more risk-averse (Quinlan *et al.,* 2003). These include stronger guidelines for formalized risk analysis via effective (a) assessment of non-target hazards and economic consequences of releases, (b) risk management including quarantine standards, (c) post release monitoring and evaluation procedures, and (d) conflict resolution, participation, consultation and transparency in the decision-making process. A need was also recognized to emphasise relevance to movements between geographically isolated ecosystems within countries as well as across borders.

Risk-Benefit-Cost Analysis and Measuring Uncertainty in Biological Control

Using risk analysis to quantify uncertainty associated with a particular hazard is difficult in ecological systems that are inherently

[e] Including GMOs, subspecies, infraspecies, varieties, strains or cultivars prescribed as a recognized 'risk species' (=noxious species), where that organism was not present in New Zealand at the time the act came into force or organisms that entered New Zealand illegally.

[f] www.ERMANZ.govt.nz

variable. Biological control has many characteristics of a high risk activity. The outcomes are persistent, and spread of biological control agents is uncontrollable following release so the effects of such releases are irreversible. In addition public awareness of the risks of hazards associated with biological control is limited and there is little experience or understanding of managing adverse impacts of biological control. Public concerns, therefore, are based on significant levels of uncertainty. Public assurance of the safe practice of biological control therefore requires formalized best practice RBC analysis. The following sections follow the main and sub-components of RBC analysis. In each section we assess how each of the national procedures already outlined compares and performs in relation to best practice RBC analysis. RBC analysis requires a quantitative approach. Qualitative risk assessment is relatively quick requiring few data, but tends to be subjective, and fails to effectively analyse uncertainty or adequately compare alternative outcomes or risk and benefit. Scientifically testable predictions or predictions that the public will easily understand are also rarely produced. RBC analysis's quantitative approach encourages uncertainty to be expressed in terms of probability and provides testable predictions across multiple risks and benefits. This forces analysts to think hard about what is and is not known about identified hazards, and to be more precise about inferences drawn. RBC analysis requires data analysis skills, particularly for risks that are likely to be rare, but of high concern.

Comparative Analysis

Some types of activity are more hazardous than others. This is known from quantitative measurement, but also from experience. Comparative analysis is the process by which different courses of action are compared. For example, history tells us that biological control introductions lead to fewer negative impacts than occur with other pathways by which exotic organisms gain entry (Emberson, 2000). The historical evidence of success, failure and negative impacts of classical biological control has generated an inherent level of accepted risk associated with its use. For this reason biological control need not be placed in the same category as, for example, proposed introductions of GMOs or novel garden plants. This is not because biological control releases are theoretically less hazardous, but because there is greater historical evidence of the level of risk associated with biological control releases. Agricultural agencies, which have a long association with biological control, accept this more readily than the custodians of the natural environment and areas of high biodiversity. Historically all countries assessed the risks of biological control separately from other types of introductions even if there was no legislative need for this. This puts biological control releases in a separate category to either the registration of new chemicals, which attract a higher perception of risk, or the release of GMOs, which attract a higher or lower perception of risk than biological control depending on the country.

Only South Africa and New Zealand fail to accept this. The Environmental Conservation Act (1989) in South Africa specifically lists biological control agents as a threat to biodiversity and the environment requiring the same level of assessment as any other environmental impact activity. Under the HSNO Act (1996) in New Zealand biological control agents, GMOs and new chemicals must pass through the same RBC assessment. Only in Australia does biological control operate within a formal legislative acceptance of the benefits it can offer society under the Biological Control Act (1984). This followed a detailed test-case benefit-cost analysis of high public profile (Cullen & Delfosse, 1985).

Risk-Benefit-Cost Assessment

RBC assessment consists of two separate stages: identification, where all potential hazards and benefits are listed, and exposure analysis, which quantitatively (where possible) defines the likelihood of a particular hazard or benefit occurring and the significance of the impact, should it occur. All countries carry out some form of ecological risk assessment beyond simple host specificity testing of agents; however, there is significant variation in how comprehensively this is done. Nearly all countries fail to apply an RBC assessment for biological control releases across *all* potential categories of risk (Table 2).

Identification of Hazards and Benefits

In Australia there is no formal hazard identification procedure. Only recognition of obvious conflicts of interests is made in the release application and hazards relating to direct non-target impacts are identified through host specificity testing. Similarly the US/ Canadian system generally has no explicit separation of hazard/ benefit identification from exposure analysis. Identification of likely project benefits generates most attention. In South Africa some collective hazard identification involving affected industries takes place when potential risks to plants of economic importance are identified early in programme development. In New Zealand the ERMA methodology for hazard identification recommends the use of common sense, analogies to known cases, 'what if' and scenario analysis, brainstorming, checklists, decision trees, experiments and tests of performance elsewhere, and is the most complete process of hazard identification of any country (Table 2).

Exposure Analysis

Exposure analysis quantitatively assesses the likelihood that each identified hazard or benefit will occur and the consequences should it occur. Such analyses can generate a field of risk for each hazard or benefit, based on the probability of the hazard or benefit occurring (i.e. the base rate) at different levels of importance or consequence (Smith *et al*., 1999). Exposure analysis includes associated uncertainty bounds to such predictions while recognizing that the capacity to predict an occurrence decreases with the probability of it occurring. This provides the basis for quantifying the uncertainty and significance associated with each biological control release.

In Australia, little exposure analysis is formally required beyond analysing direct non-target exposure in the results of host specificity tests. Benefits are poorly analysed, because the target status of the weed has already been justified or recognized. Scientists in South Africa do include some quantitative exposure analyses of potential benefits to industry and the environment together with negative impacts of the weeds (e.g. Higgins *et al.*, 1997), although there is no legal requirement for this unless DEAT makes this a specific demand.

Exposure analysis of threats to native species and benefits from control is included in the 'Potential Environmental Impacts' section of the release petitions in Canada and the USA. The petitioner alone, however, is responsible for the completion of this section and quantitative analyses are only required "if available". TAG members are advised and petitioners encouraged to identify conflicts of interest and to also consider other hazards and benefits to agriculture (such as reduced pesticide use and associated control costs), or of releasing the wrong species, and to speculate on long-term ecological consequences of releases. TAG agency perspectives will play a role along with those of specialists, industry, members of the National Plant Board, the Weed Science Society of America and other recognized societies, and representatives from Canada and Mexico called on for input. The Environmental Assessment, for public consumption, covers direct and indirect impacts on native

Table 2. Examples of some comprehensive hazards and benefits, their causes and consequences identified in recent applications to ERMA (New Zealand) to release classical biological control agents.

Hazard/Benefit	Cause	Element of risk
No impact on target	Failed establishment or low abundance and/or insufficient damage	i) Pest persistence/expansion and associated hazards
Target removal	Successful control	i) Adverse effects on ecosystem structure ii) Native species displacement due to changes in food and cover availability iii) Changes in nutrient cycling iv) Changes in water flow and water quality v) Erosion vi) Adverse effects on elements of public which may benefit from target for economic, social, aesthetic reasons
High agent abundance	Agent population growth	i) Ecosystem deterioration through increased predator pool ii) Direct nuisance to public iii) Indirect nuisance to public via increase in predator abundance
Direct adverse effects on non-target populations	Insufficient specificity	i) Losses to agriculture, forestry, horticulture and ornamentals ii) Native species displacement and ecosystem deterioration iii) Interference with other biocontrol agents
Indirect adverse impacts on non-target populations	Insufficient specificity and high abundance	i) Native species displacement and ecosystem deterioration
Target replacement (by something worse)	Target removal	i) Losses to agriculture, forestry, horticulture and ornamentals ii) Native species displacement and ecosystem deterioration
Agents toxic or venomous	High abundance	i) Public health
Agents are disease vectors	Agent type is known vector	i) Losses to agriculture, forestry, horticulture and ornamentals ii) Public health
Accidental introduction of associated organisms	Ineffective screening/cleaning methods	i) Predators, parasitoids, hyperparasitoids, pathogens, phoretic organisms released
Target removal	Successful control	i) Reduced competition with the native community ii) Increased biodiversity in affected habitats iii) Protection and aesthetic improvement of culturally important sites iv) Reduced risk of current and future invasion of other suitable native habitats v) Increased agricultural productivity vi) Improvements to ecosystem services such as nutrient and water cycling vii) Reduced use of agrochemicals viii) Reduced levels of environmental disturbance ix) Protecting values of indigenous people x) Reduced associated health, recreational, aesthetic, nuisance, toxin or allergy issues associated with target

species and sensitive habitats, the consequences of doing nothing or release failure (continued herbicide usage), the risks of host shifts of the agent and the irreversible nature of biological control, and any consequences on low income, minority populations or children. The Biological Assessment is the detailed quantitative scientific document required by FWS, analysing direct and indirect impacts on endangered species (plants and animals); however, it is sometimes used to assess larger issues such as habitats and ecosystem services using individual endangered species as the authorizing vehicle.

In New Zealand a formal quantitative exposure analysis is required within the limits of available data or expert judgment. For each risk and benefit identified, exposure analysis must take into account the nature of the adverse effect, the probability of occurrence and the magnitude of each adverse effect independently and in combination, and the options for managing any identified risk, with associated uncertainty bounds and base rates.

Host Specificity Testing – a Key Tool in Weed Biocontrol RBC Assessment

Assessment of the chance that the proposed weed biological control agent will lead to direct non-target impacts is traditionally carried out using host specificity testing. The process of selecting the test plant list follows the internationally recognized phylogenetic centrifugal approach (Wapshere, 1974). This approach is built on the premise that species closely related to the target are at greater risk of attack than more distantly related species, such that the number of test species required (the degree of testing) decreases in plant groups increasingly distantly related to the target. Testing screens the agent's capacity to feed, develop and/or reproduce on non-target species under as natural conditions as possible, either with or without the presence of the target. Despite the general acceptance of this approach, there is wide variation in its interpretation and application. Such testing is an explicit requirement in agent release applications in all countries except New Zealand. As interpretation and the way test lists are selected is an explicit way in which biological control

practitioners assess risks to non-targets, we briefly compare and review procedures used in the different countries.

Hazard Identification in Host Specificity Testing

Hazard identification in host specificity testing begins with the process of selecting which non-target test plants should be included in the testing. Most countries require formal approval of test lists preferably prior to submitting a release application if delays are to be avoided. Most also adhere to the argument of preferentially including native and economic test plants that occur within the current and potential distribution of the target. While further criteria for test species selection have been suggested to improve the focus of risk assessment (Briese & Walker, 2002) such as similarity in life history or phenology to the target, these have yet to be added to formal procedures.

Host specificity testing is used to define the host range of potential agents, but it is also used directly to assess risks of feeding, development and reproduction on specific sensitive non-targets. In a strictly scientific sense, the former should also affirm the latter, and there should be no need for testing on any basis other than purely host plant phylogeny (Briese *et al*., 2002a). Few countries fully accept this; however, most do not require related test species to be added to test lists just because they are rare and endangered.

The USA is the exception and insists on strict specific screening of risks to all rare and endangered species, such that all in the same genus and many in the same family as the target (or acceptable surrogate species) are included on the list. Plants on the test list must be selected based on seven categories (Table 3); which include all the "and other" categories in Wapshere (1974) that do not all strictly follow a phylogenetic logic (e.g. category 7). The test list is vetted by FWS (for category 4) and TAG (for the other categories). An overall list is submitted and approved; however, leaving test species off or adding them to this list can be justified for a particular agent species (e.g. in relation to category 7, Table 3).

In Canada a simplified US system for defining test lists is vetted through BCRC. TAG categories 5–7 (Table 3) are not mandatory and Canada does not have a list of threatened and endangered species in the strict sense of the one that FWS in the USA uses to define species to be tested in category 4.

Australian proposed test lists are strictly vetted, but there is no rigid system for designing the list and categories 4–7 (Table 3) are not always consistently required and may or may not be included depending on the applicant. Applicants can also counter reviewer requests for additional species on the lists if these species are hard to obtain or if they are outside categories 1–3. Test lists are also approved to be used for designated agent species or guilds, leading to specific arguments for test plant suitability based on agent biology.

An internal collegiate peer review process is used for test plant list definition in South Africa. The Biocontrol Group made up of all biological control researchers in the country meets regularly to complete this. Lists generally include plants selected in TAG categories 1–3 (Table 3), but a standard list of economic plants is also included and additional cultivars are added if such plants are closely related to the target. An example of this was the extensive testing of potato and aubergine cultivars for insects released against weeds in the same genus, e.g. *Solanum elaeagnifolium* Cavanilles (silverleaf nightshade) (Olckers *et al*., 1995). NDA or DEAT may also request additions of closely related threatened species.

Table 3. Categories of test plants under the USDA-APHIS-PPQ system for selecting test plants for host specificity testing of potential biological control agents for weeds*

Category	Test plants
1	Genetic types of the target species
2	Native and economic species in the same genus (divided by subgeneric division) as the target
3	Native and economic species in the same family (divided by subfamily, tribe, etc.) as the target
4	All threatened and endangered species in the same genus and some in the same family (divided by subfamily, tribe, etc.) as the target
5	Native or economic species in the same order that have some phylogenetic, morphological or biochemical similarities to the target
6	Native or economic species in other orders that have some phylogenetic, morphological or biochemical similarities to the target
7	Any plant on which the biological control agent or congeneric species have been previously found or recorded to feed and/or reproduce

* Adapted from TAG reviewers manual, www.aphis.usda.gov/ppq/permits/tag/tag.pdf.

In New Zealand, where there is no formal requirement for host specificity testing, there is, however, an informal consultation-based process of test list acceptance and, as such, rare and endangered species may or may not be specifically included depending on demand.

Selecting the type and design of tests is an equally important part of the process. This requires a good understanding of agent biology and genetic variation with respect to host use. Test choice and design to minimize false negative results has been reviewed elsewhere (Withers *et al.*, 1999), but this is a critical component of assessment of non-target impacts, with increasing demands for agents with highly restricted host ranges. Deductive reasoning might suggest that conservative tests should be carried out first (the no-choice starvation test) followed by tests for other behavioural responses such as oviposition or natural field tests, but this ordering of test type is rarely followed (Sheppard, 1999). The arguments for release are rarely based solely on the results of the most conservative tests where these might lead to the rejection of effective agents. In the USA, TAG critically reviews the test design and specialist advice may be sought. Of all countries the US system adheres most to a requirement for starvation tests. In New Zealand ERMA staff usually seek expert advice (peer review) to interpret test results in order to put the most informed interpretation before the authority. In South Africa, peer review is first carried out by the WGBICW and then by the NDA review panel, while in Australia test design criticism is more at the whim or expertise of each cooperator.

Exposure Analysis in Host Specificity Testing

Analysing and interpreting the results of the host specificity testing equates to exposure analysis for the purposes of direct threats to non-targets. In the USA this includes justification of (a) how inferences about risk to untested species will be drawn from the test results and (b) the level of polyphagy of agents that is acceptable within the phylogeny of the target weed. While the results of host specificity tests are usually quantitative, for highly specific agents, where only plants in category 1 (Table 3) experience agent feeding or support

agent development and reproduction, there is generally no need for any quantitative analysis of the data. Where agents prove to be less specific and/or test designs can evaluate more complex behavioural responses of agents, the results may show some degree of agent acceptance of closely related native species. Such results are amenable to quantitative exposure analysis. This analysis might assess the chance that feeding, development or reproduction on the non-target might lead to significant impacts on non-target populations, and the consequences if it did. Usually such cases are simply argued with deductive reasoning, but when correctly applied, quantitative statistical analysis of host specificity test results can assess the chance of a certain level of damage to non-targets relative to the level of damage observed on the target. Such an approach was used by Wan & Harris (1997), but was not accepted in this case by Canadian or US reviewers. This approach has been used in several projects in South Africa where it has helped prevent agent rejection (Olckers, 2000, 2003). Such analyses can also assess the effectiveness of the test design, particularly the value of testing all categories of test plants (Briese & Walker, 2002; Briese *et al.*, 2002a). The methodology adopted for exposure analysis in host specificity testing remains at the discretion of the scientist in all countries.

Risk-Benefit Management

Risk management or mitigation provides a mechanism to reduce hazard occurrence and define what could be done should it occur. While this is a recognized step in formal RBC analysis it is rarely considered in the regulation of biological control releases. One way self-mitigation of risk is creeping into projects in the USA is through the increasing selection of targets that do not have closely related native species. This avoids non-target concerns. Most countries carry out research to enhance biological control safety and manage environments to prevent weed replacement, but such activities are not standard practice. Preventing weed replacement is one way of managing the benefits of biological control releases as are recent research interests in biocontrol-based integrated weed management. While these may be laudable aims to enhance the success rate of biological control releases it is hard to see such activities becoming a formal requirement.

Risk management includes consideration of release conditions such as ‘semi-quarantine’, caged or restricted releases. Acceptance of such options has its origins in the concepts of hazard and exposure. The chance of a hazard occurring can be reduced through limiting exposure, at least while the significance of the hazard can be understood. As already discussed, however, biological control has many high risk characteristics; therefore to consider that it can be contained outside an appropriate and properly managed high security quarantine facility is in itself hazardous.

That possible hazards from a biological control agent can be contained and assessed by changing the conditions of release does not have broad acceptance. The US system is perhaps the most optimistic and accepts the potential value of all types of containment. The recent conflicts of interest around *Tamarix* spp. (saltcedar) (DeLoach *et al*., 2000) recommended solutions to mitigate possible non-target effects by initially caging releases to study the likely impacts of the agents in the field. Also, recommendations for only carrying out releases in certain areas were allowed by APHIS-PPQ. The escape of the rust fungus *Puccinia carduorum* Jacky from experimental field plots after permission was given for localized field trials to prove effectiveness and verify glasshouse high specificity (Baudoin *et al.*, 1993) is an example of the perils of semi-quarantine.

In Australia, semi-quarantine procedures have also been accepted by AFFA-AQIS to contain releases while they are evaluated, although there are few examples from the biological control of weeds. The best known case was the limited release of rabbit haemorrhagic disease virus on Wardang Island several kilometres off the coast of South Australia, which quickly escaped to the mainland and increased doubts about the value of such procedures.

In South Africa, if NDA can be convinced of the safety of the process it may allow modification of quarantine conditions for conducting host specificity testing of agents in cases where secure quarantine prevents adequate testing. Such conditions may allow sleeve cage testing in semi-quarantine areas or even open-air experiments in very remote areas. This has been allowed for experimental releases of beetles on *S. elaeagnifolium* (Olckers *et al.*, 1995) and the cecidomyiid *Dasineura dielsi* Rübsaamen on *Acacia cyclops* A. Cunn. ex G. Don (rooikrans) at designated sites only. This was seen as a temporary modification of containment requirements rather than limited releases against the weed. However, such concessions are made by NDA in exceptional cases only.

New Zealand and Canada are the most conservative in their approach and do not authorize restricted releases, although in the former this may change with new legislation that would allow ERMA to put conditions on release.

Risk-Benefit Evaluation

Evaluation should test predictions made during exposure analysis in the field following release. Project evaluation even to determine the level of effectiveness of biological control releases is in itself a fairly recent undertaking. The apparent high number of unsuccessful biological control releases may in part be due to the dearth of information on the impacts of biological control agents on their targets. Even for some classic successes where complete control was observed (Dodd, 1940) the ecological impacts and economic benefits remain unquantified. A failure to evaluate usually results from shortages in project funds or precocious investment in the next project. In the face of this, it is not surprising that possible direct and indirect effects against non-targets have until recently received so little attention. Funding agencies for weed biological control, increasingly managed on a commercial model requiring evaluation of return on investment, have been a recent pressure for project evaluation in Australia, at least in terms of predicted economic benefits. Most projects now undergo some form of evaluation, although this rarely receives comprehensive ecological (Room & Thomas, 1986; Vogt *et al*., 1992; Hoffmann & Moran, 1999; Paynter & Hennecke, 2001; Sheppard *et al.*, 2002; Swirepik & Smyth, 2002) or economic (Doeleman, 1989; Le Maitre *et al*., 2001; Nordblom *et al*., 2002; De Groote *et al*., 2003; McConnachie *et al.*, 2003) treatment.

In a legislative sense, evaluation remains almost entirely optional. In Canada only the locations of releases need to be reported. In South Africa DEAT “requires that a monitoring and auditing programme must be implemented and records of monitoring must be made available.” In Australia the permits issued for agents that exhibit some non-target threat require evaluation in the field following release, but this is not enforced due to associated costs. Consistent evaluation of non-target impacts has only recently started to happen (Pemberton, 2000; Willis *et al.,* 2003) following the high profile publication of results suggesting non-target population impacts of a biological control agent against native species (Louda *et al.*, 1997). In the USA, USDA Agricultural Research Service (USDA-ARS) representation on TAG is increasingly insisting that evaluation and the reporting of it be a standard component of release petitions to ensure the true benefits can be seen and any adverse impacts evaluated. Evaluation is not a requirement, however, in current USDA-APHIS procedure or incidentally for the support of federal agencies responsible for threatened species and habitats.

In New Zealand evaluation of exposure analysis predictions is only required for importations into quarantine where the possibility of escape has been identified, but not for the final release. New legislation not yet in force, however, could allow ERMA to impose the requirement for monitoring of biological control releases with respect to identified risks.

Communication of Risks and Benefits

Open communication is critical throughout the RBC analysis where there are consequences for a broad range of the community. This involves notifying and engaging groups likely to be affected by biological control releases in the process of RBC analysis. Such activities, however, should not significantly increase the cost of releases or prevent the decision to the point where (a) the negative impacts of target species outweigh the potential risks of the agent or (b) stakeholders resort to illegal importations.

Only in Australia are weed targets declared as suitable targets for biological control independently of biological control programmes. In Australia and the USA only government agencies are actively involved or informed about biological control projects during the risk assessment process. Risk assessment is largely conducted by the applicant behind closed doors. In the USA this has attracted criticism for a lack of transparency or external peer review (Strong & Pemberton, 2001). A clear separation of risk assessors from practitioners is not always apparent in this procedure, although TAG can call on inputs from all public or private representatives in identified cases of conflicts of interest. In contrast, Canada and South Africa have unaffiliated and university scientists reviewing release applications, while submissions to ERMA in New Zealand require that all interested groups be identified and engaged in dialogue and included in the RBC analysis, and conflicts of interest are cleanly resolved via a public hearing.

In Canada there is currently no public notification process, although this is likely to change. In Australia public notifications occur both before and after risks to the Australian environment are assessed, but the public may only comment in this context. The Biological Control Act (1984), which should assist in the resolution of conflicts of interest by allowing for public consultations and enquiries (Cullen & Delfosse, 1985), is rarely used in practice. In the USA, public notification of agent releases occurs after federal agencies have assessed and accepted the risks. It is not clear whether a valid public objection at this stage could prevent a release permit being issued, although presumably the process does not prevent further consultation or a public enquiry. In New Zealand public notification of submissions to ERMA are made through national newspapers, and an increasingly mandatory public hearing.

In South Africa, stakeholders are engaged directly when there are recognized threats to economic plants (e.g. programmes against Australian *Acacia* species that have commercial value). Public notification occurs through the national newspapers and all respondents are kept informed directly or indirectly through workshops or reports of research results prior to application for release. Also release only occurs when there is unanimous agreement in all nine provinces and when key stakeholders have given their consent.

The Decision

How the final release decision is made depends ultimately on the perception of risk adopted by the regulator and the degree to which the assessment includes both risks and benefits. This section compares this process across all five countries.

In Australia decisions are made to release biological control agents by AFFA-BA and the Commonwealth Minister for DEH. The AFFA-BA decision generally follows a unanimous acceptance by the 21 local and federal government cooperators. The ministerial decision has potential for being influenced by political factors, but both agencies are effectively sympathetic to biological control and so, for the present at least, adopt a risk accepting to risk neutral perception for such introductions. This may no longer be the case if increasing public concerns are expressed to the Minister.

In South Africa, NDA follows a similar perception of risk (risk neutral to risk accepting) to agricultural departments in other countries. In contrast the DEAT decision process appears full of inconsistencies, such as an apparent acceptance of the concept of balancing the risks of hazards with benefits, but then holding the applicant responsible should there be deleterious impacts. The inexperienced province representatives and even national DEAT staff have a tendency to adopt the precautionary principle when a risk to a native is identified or, in one case, when successful biological control was not a guaranteed outcome. DEAT can also reserve the right to withdraw its release permit should its conditions not be met. These inconsistencies reflect poor understanding and training in biological control and a high turnover of decision makers. Risk perception in DEAT can range from risk accepting to risk averse depending on the participants.

In the USA, the TAG recommendation is completely managed by the participating largely sympathetic federal agencies. The decision by APHIS-PPQ is therefore also one largely based on the scientific conclusions rather than a broad objective RBC analysis. The strict responsibility of FWS for endangered species, however, ensures that APHIS-PPQ is risk averse for such situations. On most other aspects of the application TAG is risk accepting and a history of biological control against the same weed adds weight and can be used to assess cases.

Canada differs from the USA in that unaffiliated and university scientists review release petitions as part of BCRC. The Chair of BCRC's recommendation is used by CFIA-PHPD. CFIA-PHPD tends to adopt a risk accepting to risk neutral approach based on the outcome of the basic cost-benefit analysis in the application, although risks of non-target impacts on native and particularly threatened species are treated seriously.

ERMA, in New Zealand, is the most independent decision agency, being totally uncoupled from the practitioners or organizations sympathetic to biological control. It is risk averse to risk neutral on *all* aspects coming out of the complete RBC analysis. Risk to native species is a critical area in which it must maintain its neutrality.

Dealing with Conflicts of Interest

Contrasting approaches are used between the five countries to deal with conflicts of interest in the analytical process. The US APHIS-PPQ and Canadian CFIA-PHPD consider these are adequately identified and analysed by TAG and BCRC respectively. It is currently unclear in the USA how conflict of interest would be dealt with should it appear after the public publication of the Environmental Assessment.

In Australia, South Africa and New Zealand there have been examples where public consultation was used to resolve conflicts of interest. In New Zealand, before the project against *Clematis vitalba* L. (old man's beard) started considerable effort was put into detecting potential conflicts of interest, and consultation with those groups resulted in a detailed assessment of possible hazards and

benefits and conciliation to prevent any future court action. This provided a basis for the preventative approach to conflicts of interest that is now used in this country (Greer, 1995). Under the current system, ERMA invariably convenes a public hearing, as has happened for two recent applications targeted against weeds; *Ageratina riparia* (Regel) R. M. King & H. Rob. (mist flower) (Frölich *et al*., 2000)[g] and *Hieracium* spp. (hawkweeds) (Grundy 1989)[h].

In South Africa affected parties can register themselves following nationwide advertisement and are kept directly or indirectly informed of project development through workshops and progress reports. When control was required for feral *Acacia mearnsii* De Wild. (black wattle), for example, which is also grown commercially, the industry accepted the principle of using seed feeders when biological control practitioners demonstrated how seed orchards could be protected (Zimmermann & Neser, 1999). DEAT can insist that consultation on all registered conflicts of interest take place even at local levels for national issues.

In Australia, public consultation has occurred in at least two projects, the most recent of which, against *Emex australis* Steinh. (double gee), occurred following submission of the release application. Significant possible indirect impacts on a food source of native black cockatoos were identified (Scott *et al.*, 2000) and resolved through consultation causing only a slight delay in releases. Should consultation not resolve such issues, a public enquiry is a more costly option. Public enquiries are more likely to occur when the total potential benefits of a project are large compared to the costs and risks. This has only happened once in Australia. The conflict of interest raised by graziers and beekeepers with regard to the biological control of *Echium plantagineum* L. (Paterson's curse) led to a public enquiry (Delfosse, 1985) and ultimately the Biological Control Act (1984). This Act protects the research organization if an inquiry suggests benefits outweigh the risks (Cullen & Delfosse, 1985). Only one other weed biological control target has been proposed and recognized under the Act (*Rubus fruticosus* agg., blackberry). All other applications have not been considered suitable by the Australian Weeds Committee because of the associated likely costs of public enquiries. In such cases, activities associated with weeds or prospective agents that pose potential conflicts of interest may simply grind to a halt. Reforming the Act to make it applicable to all biological control releases is being considered, as this now represents the preferred option of lawyers in some agencies conducting releases.

System Weaknesses and Consequences

The historical mutual understanding of classical biological control between plant protection agencies and research providers generated a smooth albeit simple assessment process for exotic biological control release, until the CBD decision in 1992 on alien species woke governments up to their responsibilities for such threats to global biodiversity. Classical biological control agents, as exotics, became by default part of this threat. The main development in the last 10 years to the assessment process therefore has been the involvement of environmental agencies responsible for protecting native species and communities. This advance offered benefits of broadening both consultation and the standpoints and criteria on which release decisions are made. Environmental agencies have also brought with them experience in advanced processes of risk analysis and are now rightly insisting on formal hazard identification and exposure analysis procedures and greater public involvement in the analytical process. Naturally such analyses cost more, and in a 'user pays' society, these costs tend to fall on the stakeholder. In New Zealand passage through the ERMA process usually costs US$90,000 per agent including the public hearing.

A broader, fairer and more in-depth assessment system was always going to lead to cost increases; however, a balanced decision process appears to have become somewhat compromised by a general broad adoption of the precautionary approach (as defined in the 1992 Rio Declaration on Environment and Development) for all introductions of alien species since the CBD came into effect. Some environmental agencies apply this rigorously even judicially without fully appreciating or even considering the ecological benefits classical biological control offers against the alien weeds already present. The risk averse atmosphere within which such agencies operate has also not been tempered by a series of high profile science articles since 1997 expressing grave concern that biological control has very occasionally caused damaging non-target effects on rare native species (e.g. Louda *et al.*, 1997; Pemberton, 2000; Louda *et al.*, 2003; see also Strong & Pemberton, 2001). These articles have raised further the level of precaution applied since the late 1990s, even though the possibility of such damage by the agents in question was presented to and accepted by the agricultural agencies during the decision making process, and although the initial releases were mostly made decades ago, at a time when few government activities required any kind of environmental risk assessment. Unfortunately these perceptions remain poorly counterbalanced by sufficient published quantitative analyses of the ecological and economic benefits classical biological control can provide.

The delays resulting from risk aversion in environmental agencies affect the stakeholders who have invested in developing a new agent. This contributes to stakeholders and funding agencies becoming sceptical of the ability of weed biological control to deliver. In some instances this has become critical. In the USA, key states that were involved in funding biological control work, such as Montana, are pulling out of funding projects, frustrated by the precautionary attitude the FWS and as such USDA-APHIS applies and the resulting extended assessment process and associated costs. In Montana, the delays were associated with the release of a weevil against *Cynoglossum officinale* L. (hound's tongue) and the very extended testing required, despite the weevil having already been released across the border in Canada (De Clerck-Floate & Schwarzländer, 2002a, b).

Delays and cost hikes result not just from a more complete RBC analysis and increased vigilance, but also from legislatively induced duplication of effort. In all countries except New Zealand and Canada (which may soon change) two risk assessments are required, evaluated separately by both the traditional plant protection agency and the environmental agency. Different agency agendas lead to significant duplication of effort as different issues have to be adopted, arguments presented and processes pursued for each independent application. In South Africa this has reached an extreme, as multiple untrained regional regulatory staff are required to verify applications in draft as well as the final evaluation, and these regional staff provide little constructive input and show high turnover. In this country, too, another layer of biodiversity legislation threatens to toughen measures further.

[g] www.ermanz.govt.nz/appfiles/execsumm/pdf/noc02002-003.pdf

[h] www.ermanz.govt.nz/appfiles/orgctrl/pdf/nor000007con.pdf

Staff turnover and loss of corporate understanding of biological control are recognized issues amongst environmental evaluators in New Zealand, South Africa and the USA. These are exacerbated when individuals with strict viewpoints can gain influence or when the decision is made on a judicial basis circumventing any requirement for consultation with the applicant. In Canada and Australia there has been a conscious effort by regulators to think constructively about reducing effort duplication, but their systems remain poor models using largely in-house assessment. From a risk management perspective, ERMA in New Zealand adopts the closest to a flawless democratic and complete process. The application requirements present a good model for others to follow. Their main deficiency lies in a failure to fully take into account the historical safety of biological control releases over other proposed exotic organisms, and a strict political requirement for often unnecessary public hearings and the additional costs and time delays this imposes on control efforts. A strictly ERMA type consultation process might therefore grind applications to a halt in larger countries with more divergent interested parties.

Protracted processes also increases the risk of illegal releases. While the regulators continue to debate, stakeholders see their livelihoods disappearing while the weeds continue to spread, Illegal releases have already happened in a number of cases (blackberry rust, *Phragmidium violaceum* (Schultz) in Australia, rabbit haemorrhagic disease virus in New Zealand), and should in themselves be considered a hazard associated with an over precautionary regulatory process.

The current situation in South Africa also sounds warning bells. As developing countries without regulatory processes for applying biological control, beyond the IPPC (1996a) Code of Conduct, copy their richer neighbours and develop parallel CBD linked precautionary environmental legislation, there is also a significant risk that classical biological control may become an unworkable tool in such countries before it can even be tried.

Practitioner Perceptions

Our practitioner perception is that risk aversion amongst environmental regulators continues to increase, leading to a crisis in the making for classical biological control, despite a history of benefits that far outweigh the realized hazards. A principle of fewer agent releases is becoming increasingly adopted by regulators. All countries except New Zealand show a major decline in releases over the last 5–10 yrs (Figure 1(a–e)). Regulators in some countries increasingly insist on releases of one agent at a time against each target, the next release only being considered when the first agent is known to have failed to complete the task. It may take years before this becomes clear and ignores the possibility that control may be best achieved through a complex of agents (e.g. Briese *et al.*, 2002b). Target selection is also undergoing restriction based on the number of closely related native species. All these precautionary developments can reduce the future viability of classical biological control, from its funding through its application to the realizable benefits. Meanwhile many times more exotic organisms enter countries than are deliberately introduced for biological control. To lose, in this way, the only tool that can permanently suppress weed populations would be a sad reflection on our capacity to protect our planet from global invasions.

Conclusions

To assure a viable future for classical biological control it is important to highlight where changes are necessary or further efforts are required to ensure that the regulatory procedures do not prevent the use of safe and effective agents. In order to address this we propose a series of recommendations, relevant for all participants in the process, which we consider as key elements to maintaining a fully functional decision-making process that ensures biological control release applications are given a fair go. Several of these recommendations have been made before (Lonsdale *et al*., 2001), but merit continued emphasis. From the practitioners perspective they relate to increasing public ownership in target selection, increasing public perception of the benefits classical biological control provide and the successes it has achieved, and accepting greater public involvement in their activities. From the regulators perspective they relate to formalizing an RBC analysis procedure across relevant regulatory agencies to avoid duplication, avoiding the temptation to use risk assessment through host specificity tests to evaluate the risks to each and every rare and endangered native, and working towards a transparent, objective and balanced decision making process without too much bureaucratic baggage. Practitioners and regulators need to work together to achieve many of these amendments, ensuring also that there are appropriate resources available to test the predictions of all RBC analyses. Such collaboration can still avert a crisis in the management of alien weeds around the world.

Recommendations

Target Selection

Agencies conducting biological control should select targets and agents for which there is wide support that the benefits outweigh the risks (Lonsdale *et al*., 2001).

Public Perception

Organizations involved in releasing biological control organisms should recognize that there is little public confidence in their activities, and that this is because of limited public experience and understanding of the risks or the benefits. Such organizations need to engage with the public and their representative organizations to improve understanding and awareness of the benefits and risks (Lonsdale *et al*., 2001). Dialogue and understanding between practitioners and regulators, critics and stakeholders need to be ensured. An explicit, balanced and trust building best practice for RBC analysis of biological control releases, going beyond simple direct non-target impacts, needs to be developed (c.f. Balciunas, 2000). ERMA's process in New Zealand would seem to be a reasonable starting point.

Benefit Analysis

The analysis of benefits of biological control releases has a meagre history, perhaps because a traditional acceptance of benefit by plant protection regulators made more thorough analysis unnecessary. Successful biological control programmes need to conduct comprehensive benefit analyses, to support the 'before and after' photographs, based on economic gains and benefits to biodiversity. Past evaluations and future predictions should be broadly publicized so that stakeholders, critics, supporters and the wider public can see the benefits as clearly as the currently much more widely publicized threats.

Host Specificity Testing

This should be used within the context for which it was developed, i.e. to define the host range of the agent to a recognizable level (e.g. host subspecies, species, clade, genus, subtribe, etc.) using test plant species scientifically selected to provide sufficient representatives at each of these phylogenetic levels, fulfilling the internationally recognized phylogenetic centrifugal approach. Such selections from

the native or economic flora correspond to precise phylogenetic requirements of the test list including also, where possible, similarity of geographic distribution and life history to the target. Suitable test plants might include rare and endangered native species. Certain national systems and associated agencies, however, see host specificity testing as a direct assessment of the threats of the proposed agent against many (or all) related sensitive, rare or endangered species. Such agencies can require the inclusion of such species on the test list, whether or not they correspond best to the phylogenetic selection criteria or whether or not the relevant phylogenetic level is already adequately represented on the test list. This practice should be discouraged. The scientific and risk analysis justification for it is poor and it represents a key reason why costs are escalating to the point where some biological control programmes are no longer viable.

Public Comment

Clear objectivity in the assessment of biological control agent release applications, with opportunities for public comment, and defendable conflict resolution should be encouraged in all countries. This must, however, be married with a process that prevents needless and hazardous delays and ensures public confidence in the outcomes. This is vital, but will nevertheless be hard to achieve given very diverse public and scientific opinion.

Evaluation

The predictions of the RCB analyses of biological control programmes need to be evaluated, post-release, and publicized to minimize public uncertainty and enhance confidence. Evaluation of the ecological and economic outcomes of biological control programmes is vital.

The Decision

It is in the interest of all that the decision process can be accepted as being fair and balanced. Risks to non-targets need to be assessed in a balanced context against the risks of doing nothing. A model is required that ensures objective academic appraisal of the RBC analysis with explicit criteria for making the decision following public consultation. ERMA has shown that a quasi judicial approach to this has some merits, as long as previous decisions can be used as evidence in new cases to ensure experience and historical aspects are considered in the evaluation.

Regulatory Changes

Research agencies should engage and work with regulators to ensure future regulatory changes are built into an internationally recognized best practice for RBC analysis specifically for classical biological control agents that is neither dominated by the believers nor derailed by related precautionary decisions from international conventions. Regulatory complexity also needs to be minimized to prevent resource wastage and to discourage illegal importations by stakeholders.

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