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INVASIVE ALIEN SPECIES: THE APPLICATION OF CLASSICAL BIOLOGICAL CONTROL FOR THE MANAGEMENT OF ESTABLISHED INVASIVE ALIEN SPECIES CAUSING ENVIRONMENTAL IMPACTS

Note by the Executive Secretary

BACKGROUND

1. The Executive Secretary is circulating herewith, for the information of participants in the fourteenth meeting of the Conference of the Parties, a document on the application of classical biological control for the management of established invasive alien species causing environmental impacts.

2. The document is relevant to the work of the Convention on Biological Diversity, in particular with regard to addressing (a) tools for conducting analysis for the management of invasive alien species, (b) the risks associated with trade in live alien organisms, and (c) achieving Aichi Biodiversity Target 9.

3. The document is being circulated in the form and language in which it was received by the Secretariat.

* CBD/COP/14/1.

The application of classical biological control for the management of established invasive alien species causing environmental impacts

Summary for Policy Makers

Prepared by: International Union for Conservation of Nature (IUCN), Species Survival Commission Invasive Species Specialist Group (ISSG)

***Note that the full report follows on from this Summary for Policy Makers document.**

Summary for policy makers

Convention on Biological Diversity (CBD) COP13 Decision XIII on Invasive Alien Species (IAS) recognized '**that classical biological control can be an effective measure to manage already established invasive alien species**', and encouraged 'Parties, other Governments and relevant organizations, when using classical biological control to manage already established invasive alien species, … [to take] into account the summary of technical considerations[1]' that was annexed to the decision.

Following this decision, SBSTTA22 adopted a recommendation on IAS that requested the 'Executive Secretary to continue collaboration with the International Union for Conservation of Nature (IUCN), its Invasive Species Specialist Group (ISSG) and relevant international organizations **to report on the use of biological control agents against invasive alien species**,… and to report to the Conference of the Parties at its fourteenth meeting'.

IUCN ISSG has collaborated through the Global Invasive Alien Species Information Partnership and compiled information from Parties, scientific institutions, and other relevant organizations, to produce an evidence-based **assessment of best practice use of classical biological control** (CBC) for the management of established invasive alien species that threaten biodiversity and ecosystem services. This assessment report '*The application of classical biological control for the management of established invasive alien species causing environmental impacts'* is being provided to CBD Parties at COP14 as an information document.

This **summary for policy makers** presents the report's key findings and recommendations.

<u>Please note: The full report can be found following this summary for policy makers document.</u>

What is biological control?

Biological control, often referred to as "biocontrol", is a method of reducing or eliminating the impact or damage caused by a target pest or weed using a biocontrol agent, traditionally a predator, herbivore or pathogen.

There are a number of forms of biological control; classical biological control, which the assessment is principally focused on, is where host-specific natural enemies, generally from the native range of the target invasive alien species (IAS), are selected (based on clear evidence of host specificity and capacity to control the target), and released into the environment. Following release, it is expected that the biocontrol agent will establish permanently from the small founder populations. Classical biological control rarely results in the eradication of the target IAS, but rather aims to reduce its level of abundance so that the environmental impacts are alleviated, ideally below measurable damage thresholds. This approach offers sustained control of the target IAS for many years at low ongoing cost and with minimal environmental impact. Classical biological control, is not amenable to

[1] The summary Annexed to COP13 Decision XIII derives from an expert workshop convened by the Secretariat of the CBD from 28 to 30 October 2015 in Montreal, Canada.

commercialization and so is generally funded by public or not-for-profit agencies and applied as a public good.

Other forms of biological control include augmentative biological control, whereby biocontrol agents are released to achieve a rapid but short-term control of the target at critical times; conservation biological control, focuses on managing the environment for enhancing populations of naturally-occurring enemies of pests; and sterile insect technique involving the inundative release of especially bred sterile males of the same pest species.

What can classical biological control be used for?

Classical biological control can potentially be used to manage a variety of IAS, including unwanted invasive plants (e.g. aquatic weeds, smothering vines, shrubs and trees), invertebrates (e.g. mites, insects, snails, crabs), plant pathogens (e.g. fungi and microbes) and some vertebrates negatively impacting biodiversity and ecosystem services. This cost-effective and sustainable management technique has the potential to mitigate the costs and biodiversity impacts of biological invasions and should be explored by all governments.

What can be used as classical biological control agents?

Successful classical biocontrol agents include:

a) Micro-organisms, including (i) fungi, particularly rusts, for weed targets; and (ii) viruses for vertebrate pest targets (e.g. myxomatosis virus and rabbit hemorrhagic disease virus against European rabbits in Australia).

b) Invertebrates as (i) predators or parasites (e.g. parasitoid wasps against insects, parasitic flies against insects and snails or entomopathogenic nematodes against insect pests); and (ii) herbivorous arthropods from a broad range of groups against weed targets (e.g. Cactoblastis moths to control prickly pear).

What are the potential negative non-target impacts?

Historically there have been a small number high profile early cases of negative direct impacts upon non-target native species from released generalist predatory 'biocontrol agents' (e.g. the release of cats and mongoose on islands and cane toads against agricultural pests). These were all at a time when the concept of biological control was applied in an unregulated way e.g. there was no required risk assessment. In-direct non-target impacts, e.g. through resource competition between the biocontrol agent and native species, have received much less attention than direct impacts, most probably because they are less obvious and more difficult to measure.

The application of rigorous risk assessment procedures from the 1950s reduced incidents of unpredicted non-target impacts to a very low and largely predictable level, a trend that is predicted to continue with the systematic inclusion of molecular tools, behavioral studies, chemical ecology, and future scientific and analytical advancements. In addition, potential negative indirect impacts of biocontrol agents that have undergone rigorous risk assessment are ephemeral if control is achieved and confined to areas in close proximity to the target organism and are likely to be minor, compared to the direct negative impacts of the target IAS upon native ecosystems and/or agricultural production.

Initiating a biocontrol programme - gaining consensus with stakeholders

Before initiating a classical biological control programme against a specific target, it is very important to gain broad consensus that the target is undesirable in most circumstances including across land use types and stakeholders. Consensus is also important because biological control programmes are in general long–term investments with significant upfront costs, not always successful and involve the release of self-perpetuating 'beneficial' alien species requiring a precautionary approach.

To assess the suitability of a target IAS for classical biological control and to avoid potential conflicts of interest, the economic, environmental and social impacts of the target IAS need to be considered. These assessments should inform a final decision on any proposal to initiate a biological control programme. This should involve a diversity of stakeholders such as conservation groups, farmers, public health representatives, forest and wildland managers, policymakers, biological control practitioners, and the general public. The use of structured decision making processes, supported by rigorous cost-benefit and risk analyses, not only provide a sound broadly accepted rational for investment but also contribute to the credibility and success of this approach.

Public engagement is essential: there needs to be open and objective communication between experienced practitioners and the general public and between countries that have benefited from effective biological control programmes and those that have not yet considered biological control approaches. To effectively guide decisions about introducing classical biological control, public engagement must: (1) consider objective assessment of the threat invasive species pose to conservation, (2) create community consensus on the need to control invasive species and the conditions under which biological control is an appropriate strategy to consider and (3) enhance the public's trust that government agencies are upholding the public's interest through appropriate regulatory review.

Initiating a biocontrol programme – risk assessment

Once the decision to conduct a biological control programme against a specific target has been taken, a rigorous science-based risk assessment[2] for all types of biocontrol agents should be conducted, including their host range and potential impacts in the recipient environment. This should determine:

a) direct impact of the biocontrol agent on non-target species;

b) potential for indirect impacts of the biocontrol agent, including effects on organisms that depend on the target pest and non-target species and competition with resident biocontrol agents and other natural enemies;

[2] Risk assessment for a candidate biocontrol agent is an internationally recognized requirement under the International Plant Protection Convention (IPPC) for regulatory approval for release in all jurisdictions. This precautionary approach is embodied in IPPC International Standards for Phytosanitary Measures (ISPM) relating to Pest Risk Analysis (PRA) (ISPM 2 and 11; IPPC, 2016a; 2017b) and IPPC Guidelines for biocontrol agents (ISPM 3; IPPC, 2017a). Signatory governments have an obligation to respect these requirements.

c) possible direct or indirect impact on threatened and endangered species, ecosystems, agriculture, and forestry, in the country of introduction;

d) impact of the biocontrol agent on humans (health, social and cultural), and

e) impact of the biocontrol agent on the physical environment (e.g. water, soil and air).

Initiating a biological control programme – approval for agent release

Decisions to approve the release of a classical biocontrol agent are generally made but suitable independent regulators based on the risk assessment, release permit application, and other relevant required material submitted to the regulatory agency in the country of introduction. These submissions generally require public comment and scientific peer review, as a part of regulatory evaluation. It is also common practice to consult with neighboring countries before making a decision.

The release of biocontrol agents on or near culturally significant or sacred sites and waterways traditionally occupied or used by indigenous peoples and local communities requires active engagement. Appropriate risk communication on both negative impacts posed by invasive alien species and the environmental and economic benefits of the use of biocontrol agents is essential to all stakeholders and the public at large.

Initiating a biological control programme – post-release monitoring

Once a biocontrol agent has been released, post-release monitoring and evaluation is necessary to confirm establishment of the agent (completion of multiple generations in the field that lead to increasing local population levels), measure negative impacts on the target species and positive biodiversity benefits, and to validate the risk assessment expectations of non-target impacts.

While biological control programmes can be costly, cost effectiveness is generally very high when successful. Capturing the costs of developing the application of biological control and comparing this with the benefits (immediate and long term) for environment, agriculture and cultural integrity continues to help justify the necessary investment. The public interest needs to be understood amongst public stakeholders including where possible an ecologically-based risk/cost/benefit analysis justifying classic biological control.

Climate change

Climate change is increasingly postulated as a potential disruptor of some successful biological control outcomes as conditions may disrupt the equilibrium between agent and target populations. However, there is little evidence to date that this is happening. Policymakers should focus on the IAS-related problem at hand but also support research into the ongoing impacts of climate change.

Need for international collaboration and standards

International collaboration in exploring natural enemies, risk assessment, management and communication, as well as internationally accepted processes for the collection and use of biocontrol agents from native range countries (such as those outlined under the Nagoya Protocol[3]) are vital for the continued successful use of classical biological control agents against IAS.

Countries in North America have also worked together under the North American Plant Protection Organisation (NAPPO) to take a regional (continental) approach to collectively manage biological control release activities that affect multiple jurisdictions. Governments should encourage the international adoption of best practices.

The International Plant Protection Convention (IPPC) is aimed at protecting cultivated and native plants by preventing the introduction and spread of pests, and the Commission on Phytosanitary Measures (CPM) develops and adopts International Standards for Phytosanitary Measures (ISPMs)[4]. International standards, guidelines or recommendations developed by the IPPC are recognized by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) as the basis for phytosanitary measures to apply in trade. Other ISPMs may be relevant and should be taken into consideration as they relate to biocontrol agents and other beneficial organisms.

However, there are significant gaps in existing ISPM guidelines in the use of biocontrol agents in the context of managing IAS in natural terrestrial and aquatic ecosystems. Relevant guidelines for a broader needs case should be developed by both scientists and policymakers. For example, Australia has developed a national process for the consideration of viruses for the control of invasive vertebrate pests that could be more widely considered.

To overcome uncertainties in the process of assessment and assist decision making, a platform for risk communication, such as Deliberative Multi-Criteria Evaluation (DMCE), may be useful, in which scientists, stakeholders and decision-makers can interact and discuss the uncertainties associated with biological invasions.

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[3] https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/other%20organizations/IOBC/iasem-org-iobc-bio-01-en.doc

[4] IPPC ISPMs https://www.ippc.int/en/core-activities/standards-setting/ispms/

The application of classical biological control for the management of established invasive alien species causing environmental impacts

Full report

Prepared by: International Union for Conservation of Nature (IUCN), Species Survival Commission Invasive Species Specialist Group (ISSG)

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Contents

I. EXECUTIVE SUMMARY

This technical report aims to support the understanding and use of classical biological control for the management of invasive alien species that threaten biodiversity and ecosystem services, or already degrade or transform native ecosystems and natural environments. This report also supplements the “Summary of technical considerations for the use of biological control agents to manage invasive alien species” annexed to decision XIII/13. The report provides a detailed review of the history of the success, failure and cost effectiveness of classical biological control programs against the different taxonomic groups of invasive alien species across the agricultural and environmental sectors showing that the likelihood of success is quite target specific, but that the benefits are not always sector specific. There may be Joint benefits for both natural and agricultural ecosystems.

The need to address ethical and societal acceptance of the introduction of another ‘beneficial” alien species to control an existing impactful invasive alien species is also explored to show how classical biological control has obtained public acceptance in some contexts and regions, but processes need to put in place to address such issues more broadly around the world. An ethical framework is proposed. Two sections cover existing national and international regulatory mechanisms and agreements supporting the application of biological control both at a national and regional level, while also identifying regulatory gaps. The report also provides a comprehensive review of direct and indirect non-target impacts from historical extant biological control programs and the risk factors (both perceived and real) that contribute to this. After a brief discussion of the future prospects of classical biological control for invasive alien species threatening or harmfully transforming environmental assets, the report concludes with an overview of what countries and jurisdictions, which do not currently or actively undertake classical biological control, need to consider in order to start to adopt such an approach and use classical biological control in the future, should they wish to consider it. This report also contains in an unbiased manner the information and inference based on the submissions from Parties and other Governments in response to the Convention on Biological Diversity notification 2015-052[5].

[5] https://www.cbd.int/doc/notifications/2015/ntf-2015-052-ias-en.doc

II. INTRODUCTION

In paragraph 9(g) of decision XII/17 on invasive alien species the Conference of the Parties to the Convention on Biological Diversity (CBD) requested the Executive Secretary compile, in collaboration with the International Union for Conservation of Nature and through the Global Invasive Alien Species Information Partnership, information from Parties, scientific institutions, and other relevant organizations, on experiences in the use of biocontrol agents against invasive alien species. In response to this decision the Secretariat of the CBD convened an expert workshop from 28 to 30 October 2015 in Montreal, Canada[6]. The outcomes of the expert meeting were presented at a side event on the margins of Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) at its nineteenth meeting[7,8,9,10,11].

The outcome on the expert workshop was considered by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) and the Conference of the Parties at its thirteenth meeting. The conclusion of the above consisted of the "*Summary of Technical Considerations for the Use of Biological Control Agents to Manage Invasive Alien Species*"[12] annexed to decision XIII/13.

In the same decision the Conference of the Parties encouraged Parties, other Governments and relevant organizations, when using classical biological control to manage already established invasive alien species, to apply the precautionary approach and appropriate risk analysis, including the elaboration of contingency plans, taking into account the summary of technical considerations in the annex, as appropriate.

To support Parties, other Governments and relevant organizations to consider applying biological control against invasive alien species in wide range of taxa and environments, this technical report was prepared by the International Union for Conservation of Nature (IUCN) Species Survival Commission Invasive Species Specialist Group (ISSG). The authors collaborated through the Global Invasive Alien Species Information Partnership and compiled information from Parties, scientific institutions, and other relevant organizations, an evidence-based assessment of the use of classical biological control (CBC) for the management of established invasive alien species, in particular the release into the environment of alien species for this purpose. The report aims to provide detailed information to support Parties to use biocontrol agents in the management of already established and spreading invasive alien species. Relevant technical background information on classical biological control is also provided through an

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[6] https://www.cbd.int/doc/meetings/ais/iasem-2015-01/official/iasem-2015-01-06-en.doc

[7] https://www.cbd.int/doc/meetings/ais/iasem-2015-01/official/iasem-2015-01-06-en.doc

[8] https://www.cbd.int/doc/meetings/sbstta/sbstta-20/official/sbstta-20-07-en.pdf

[9] https://www.cbd.int/abs/side-events/abs-9/id1899-iobc.pdf

[10] https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-13-en.pdf

[11] https://www.cbd.int/invasive/done.shtml

[12] https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-13-en.pdf

evidence and risk-based narrative that is also built around reviews of the science, realised benefits and risks (target and non-target impacts), and the ethical and regulatory frameworks underpinning the approach.

This compilation of information and the assessment aims to be as objective as possible by including cases where not only classical biological control delivered both beneficial suppression of the target invasive species, but also all significant cases in which target invasive species were not significantly suppressed or where non-target impacts had also been identified and relate these to the application of an appropriate risk analysis.

This report explains the risk assessment process for classical biocontrol agents, based on information from peer-reviewed scientific publications and reviews, country submissions to this decision and outcomes of the expert meeting mentioned above[13].

The intended audience of this report is policy makers and staff of agencies responsible for invasive species management in the context of biodiversity conservation and for import and release of new species and genotypes into the relevant jurisdictions. It is also aimed at proponent agencies of invasive alien species management, communities, non-government or government agencies and the general public.

This report covers the definition and scope of classical biological control in the context of the CBD and the IUCN (Section III), key steps in a classical biological control programme (Section IV), the history successes, failures and cost effectiveness of classical biological control (Section V), a framework for the approach based on ethical and social values (Section VI), national and international legislative policy and regulatory frameworks for the application of (CBC) (Sections VII & VIII), a review of impacts from biological control programs (IX), and future prospects. A glossary of terms is attached to this document as an annex.

[13] https://www.cbd.int/meetings/IASEM-2015-01

III. DEFINITION AND SCOPE OF INVASIVE ALIEN SPECIES AND CLASSICAL BIOLOGICAL CONTROL

The Convention on Biological Diversity defines Invasive alien species (IAS) as “species whose introduction and/or spread outside their natural past or present distribution threatens biological diversity”.

Biological control, often referred to as “biocontrol” is a method of reducing or eliminating the impact or damage caused by an invasive alien species (generally a targeted arthropod pest or weed species) by means of a biological agent, traditionally a predator, herbivore or pathogen (FAO, 1992).

Traditionally there are four major strategies of biological control depending on the way of introduction or origin or type of biological control agent (hereafter termed biocontrol agent) (Better Border Biosecurity, 2007):

Classical biological control: host-specific natural enemies, generally from the country of origin of the target alien pest or weed, are identified, and one or more are risk assessed, imported and released to control the target, based on clear evidence of specificity and expected capacity to control the target. Following release, it is expected that the biocontrol agent (micro or macro-organism) will establish permanently from relatively small released founder populations, and that these populations will independently and rapidly reproduce and spread (Caltagirone, 1981; Bellows and Fisher, 1999). Redistribution of such biocontrol agents across the target range in the recipient environment or modifying that environment to improve agent fitness are also regularly used to assist in augmenting time to target population suppression.

Augmentative biological control: biocontrol agents, which are resident native or introduced natural enemies of the target pest or weed are released to achieve a rapid but short-term control of the target at critical times. This type of biological control provides the basis of the globally significant biocontrol industry. Where the agents are expected to rapidly reproduce, relatively few may be released (inoculative release e.g. bacteria such as *Bacillus thuringiensis* used against insect pests of plants or fungi such as *Beauveria spp. or Metarhizium* spp. against arthropod pests) or many may be released for rapid knockdown of the pest (inundative release e.g. commercially produced ladybirds against sedentary arthropod pests). Micro-organism agents can also be developed into biopesticides for commercial use either against pests or weeds. The condition of the recipient environment (e.g. field or green house) may be modified to enhance the impacts of the biocontrol agents.

Conservation biological control: this strategy is focused on managing the environment for enhancing populations of naturally-occurring enemies of the pests. For example, crops can be sown with diverse borders of flowering plants, or plant diversity of cropping systems may be increased by intercropping or by interspersed patches of native communities, that support and augment higher natural enemy populations, which then move out into the crops when pests are present and provide pest management services (Barbosa, 1998; van Emden, 2003).

Sterile insect technique: Specific agricultural insect pests are also being very successfully controlled through the inundative release of sterile males of the same species. These sterile males are produced in specifically built rearing facilities where males are irradiated to render them sterile and then released in very large numbers into natural pest populations, where through copulation with wild type females, they reduce pest populations in density or distribution. This approach is widely used to control fruit flies and other dipteran and lepidopteran agricultural pests. More recently this type of control is being achieved through the insertion of symbiotic microorganisms or genetic constructs into the genomes of pests as another means of reducing pest fitness.

In the context of this report we are principally focused on the classical biological control approach, largely because this is the principle type of biocontrol applied to effectively control invasive alien species. Classical biological control by its very nature is not amenable to commercialization and so is generally funded by public or not-for-profit agencies and applied as a public good activity.

Classical biocontrol agents

Classical biocontrol agents of pests and weeds are primarily micro-organisms or invertebrate animals that are highly specific to their target host organisms and are likely to establish in the recipient environment. The use of generalist vertebrate predators as "biocontrol agents" was practiced in the 1700's to early 1900's prior to restrictions on alien species introductions or the need for risk assessments prior to introduction (e.g. releases of cats to control rodents or mongooses to control snakes on islands, or cane toads to control sugar cane pests), however these introduced animals generally became pests themselves and the non-target impacts of these early introductions are so clear now that such practices are no-longer sanctioned by environmental or agricultural agencies.

Classical biocontrol agents that have been successfully relevant for this report include:

(a) Micro-organisms, including (i) fungi, particularly rusts, for weed targets; and (ii) viruses for vertebrate pest targets (e.g. myxoma virus and rabbit hemorrhagic disease virus against European rabbits in Australia).

(b) Invertebrates as (i) predators or parasites of invertebrate pests (e.g. parasitoid wasps against insects, parasitic flies against insects and snails or entomopathogenic nematodes against insect pests); and (ii) herbivorous arthropods from a broad range of groups against weed targets (e.g. *Cactoblastis* moths to control prickly pear);

These types of agent were chosen because of very high levels of specificity to the target invasive alien species, a prerequisite of any candidate classical biocontrol agents. Other types of highly specific candidate biocontrol agent might also be relevant in the future and so this report does not just restrict consideration to these taxa, however after more than 100 years of practice, the discovery of other taxa as effective biocontrol agent seems of low likelihood.

IV. KEY STEPS IN A CLASSICAL BIOLOGICAL CONTROL PROGRAMME

For classical biological control, the use of highly specific invertebrate natural enemies (predators or parasitoids) as biocontrol agents to control invertebrate pests (Lynch and Thomas, 2000; van Lenteren et al., 2006a, b; Parry, 2008; Kenis et al., 2009; Hajek et al., 2016) and the use of highly specific invertebrate herbivores or plant pathogens as biocontrol agents to control invasive alien plants is internationally accepted as a practical, low risk (Barton, 2004; Paynter et al., 2004; Pemberton, 2000), and environmentally benign management approach applicable across both natural and agricultural ecosystems (van Lenteren et al., 2006a; Charudattan, 2001).

Application of classical biological control against vertebrate invasive alien species is relatively rare compared to invertebrate pest and weed management. In Australia, classical biological control of invasive vertebrates has only been used against the European rabbit, a major agricultural and environmental pest, involving two highly specific viruses. The myxomatosis virus was released in the 1950s and rabbit hemorrhagic disease virus was first released in the 1990's.

The myxoma virus was a "new association". European rabbits exposed to this virus, endemic in other lagomorphs in South America, were highly susceptible to infection, with lethal effects. It was released in Australia in the 1950s after extensive risk assessment against Australian native animal families and caused massive decline in rabbit populations until natural resistance started to develop in rabbits. No direct non-target impacts have been recorded to native species. Rabbit hemorrhagic disease virus (RHDV) is endemic to European rabbits, but mutations of the virus created a highly pathogenic form and this new strain (RHDV1) was similarly risk assessed and released in Australia in the 1990s. It further suppressed Australian feral rabbit populations, again with minimal non-target impacts. Rabbit biological control in Australia has not led to sustained benefits for native vegetation, because of the very low threshold of rabbit density required to increase native plant community regeneration. However, the decline in rabbit density has led to the reduction of feral populations of alien invasive predators, mainly foxes and cats as rabbit prey availability declined (Cox et al., 2013) (see BOX 1). This case has clearly demonstrates that highly specific and pathogenic animal viruses, while generally rare in nature, can provide low risk classical biological control for certain vertebrate pests, provided the risk of the virus spreading to parts of the world where potential hosts are valued can be mitigated.

In all situations, classical biological control rarely results in the eradication of the target organism but aims to reduce its populations to levels of abundance where agriculture productivity is improved or environment impacts alleviated, ideally below measurable damage thresholds. After the release of effective agents classical biological control generally offers sustained control of the target for many years at low ongoing cost and minimal environmental impact.

For targets, such as invasive arthropod and plants, adherence to the international guidelines (FAO, 1995; IPPC, 2017a) for the selection and testing of all potential agents for classical biological control before release ensures insect and pathogen potential agents are highly host specific and will not damage valued non-target native or agriculturally important species.

A classical biocontrol programme typically involves the following steps, usually in a sequential manner, but some activities may occur concurrently.

A. Target approval and goal definition

Before initiating a classical biological control programme against a specific target, it is very important to gain broad consensus that the target is causes harmful impacts and is undesirable in most circumstances including across land use types and stakeholders. This is because biological control programmes, in general, run for more than 10 years and are therefore costly. Also, their releases are likely to be uncontrollable and positive or negative impacts are likely to occur at the landscape to continental scale. Control of population of invasive alien species that have clearly measurable impacts on native species and communities may be valued in certain agricultural systems or by society as pets or garden plants. Without broad consensus, programmes are likely to generate resistance in certain stakeholder groups which could lead to a wasted effort. Where there isn't consensus, there needs to be clear mechanisms to demonstrate that the potential benefits of biological control outweigh any potential negative impacts to certain stakeholder groups and that any potential negative impacts can be negated or compensated for by some means (legislative mechanisms to address this exist e.g. the Biological Control Act in Australia – see Section VII).

Assessment using biological and socio-economic factors of the feasibility (e.g. areas of the world where potential agents occur are readily accessible and agents exportable) and likelihood of success (e.g. there is a strong likelihood that potentially successful biocontrol agents can be found and released) of a biological control programme against a particular target should also be undertaken, as far as possible prior to initiation to be realistic about potential benefits. Frequently used biological information for the selection of candidate invasive alien species include the nature of the invasive alien species (e.g. origin, distribution, mode of action), the availability and effectiveness of existing biocontrol agents, and the outcome of previous biological control projects, if any, in other parts of the world.

The assessment of socio-economic factors should consider the frequency and severity of economic losses, health problems and environmental degradations; the cost of controlling the pest using biological control vs. other approaches; the capacity of existing institutions and administration to undertake a biological control programme; the political constraints and pressures urging action. Efforts have been made to identify criteria and develop quantitative indexes for selecting best candidates for classical biological control (e.g. Barbosa and Segarra-Carmona (1993) and Harris (1991) for arthropod pests and weeds, respectively).

These assessments should inform a final decision to initiate a programme that should involve a diversity of stakeholders such as conservation groups, affected farmers, public health representatives, forest and wildland managers, policymakers, biological control practitioners, and the general public. Structured decision making processes, supported by rigorous cost-benefit and risk analyses, not only provide a sound broadly accepted rational for investment but also contribute to the credibility and success of this approach.

Countries that regularly undertake biological control programs often have some formal or informal approval and regulatory processes to support decision making.

In Australia there is a formal target nomination process through an across jurisdictional government committee, where the nomination must present evidence of both the impacts of the target, the feasibility and likelihood of success of a programme and that broad consultation has taken place without identifying significant conflicts of opinion. Australia has also enacted biological control legislation, under which biological control programs against targets where dissenting stakeholder exist can be assessed and a decision made. Where a formal decision to initiate a programme is taken following wide consultation based on demonstrable higher benefits of control over losses due to control, the legislation offers government decision makers, protagonists and biological control practitioners some legal protection.

In New Zealand there is no formal endorsement of a weed species as an approved target for biological control, and target weeds are selected by stakeholders, including regional councils, the Department of Conservation and industry collectives. However, Landcare Research, the relevant government research agency, always conducts a feasibility study, prior to commencing a biocontrol program, to ensure that biological control of a proposed target weed is justified. Where opposition to the use of biological control against certain target weeds has been identified, additional consultation and benefit-cost analyses are performed to determine whether or not a programme should proceed (e.g. Jarvis et al., 2006).

New biological control programs should also define a target goal against which success can be evaluated. In an agricultural context, this may be to simply suppress spread or the density of a target below some economic threshold. In an environmental context this is likely to be harder to define. Simply aiming to suppress the target organism might just allow other invasive alien species to invade and cause similar or even greater environmental impacts. For projects against invasive alien species (environmental pests), therefore, the goal should reflect the desired impact e.g. increase in relevant native species diversity or higher recruitment in some key native species that is being suppressed by the target. It might also be an improvement in some other form of ecosystem service, e.g. return to more a natural fire regime. The goal may also require more than the effectiveness of biological control alone, and therefore may need to be built also around habitat restoration or other integrated or adaptive management approaches. Goals should be SMART[14] for ease of future evaluation in and be based on broad consensus.

These processes generally require good ecological understanding of the impacts of the target

[14] Specific, Measurable, Achievable, Relevant and Time-bound.

invasive alien species, which means significant ecological and genetic research of the target in the invaded range may be necessary.

B. Target ecology

Classical biological control can be used to manage a variety of invasive alien species including invertebrates (e.g. mites, insects, snails, crabs), plant pathogens, weeds and some vertebrates. All these organisms possess their own biological and ecological characteristics, genotypes and phenotypes in the invaded range. Once an invasive organism has been targeted, a substantial understanding of its ecology in the invaded range is generally required to maximize the likelihood of success of a biological control programme.

The first step is to gather information, through a literature review and target surveys in the invaded range. It should include information about the target in the invaded range; ideally it taxonomy and genotypic diversity, biology and ecology of the invasive organism, its current distribution and capacity for spread, preferred biophysical niche, population dynamics and seasonal ecology and its origin and history of introduction and ecological impacts.

It should also include other information, such as the relatedness of the target to non-target native species, and what types of natural enemy and their impacts are already found on the target in the invaded range to avoid the cost of investing in developing an agent that is already present. The types and abundances of native natural enemies already present on the target, or on related species, in the same habitats can predict the risk of cross over predation or parasitism on to candidate biocontrol agents (Paynter et al., 2010). For example, the presence of ant tended insects on target weeds could mean that the target will be quite well protected from biocontrol agents vulnerable to ant predation (e.g. Paynter et al., 2012; Thum et al., 1997).

Ecological research has helped determine the ecological “Achilles heel” of some target species (i.e. stages in the life-history of the target weed that are most vulnerable to biological control) to help select potentially effective biocontrol agents (McEvoy and Coombs, 1999; Davis et al. 2006).

There are a range of ecological techniques and tools available to assist this and therefore assist target and future agent prioritization based on predictions of likely biotic resistance. For example, mode of reproduction (sexually or asexual), habitat (terrestrial or aquatic) and relative abundance of the target in the native and exotic ranges help predict the potential impact of biocontrol agents (Paynter et al., 2012b). Generalizations on what makes an effective agent for particular type of target, have also emerged that can assist decision making on target and agent selection (e.g. McFadyen, 1998; McClay and Balciunas, 2005; Stiling and Cornelissen, 2005). All this information will help to, first, characterize the current and expected status of the invasive organism and, second, identify which types of natural enemies are most likely to be good agents.

In some countries, detailed information on the ecology of the target invasive organism is mandatory when a dossier is submitted to a regulatory agency for the release of a biocontrol agent. The relevant knowledge on ecology of the target invasive organism is important for evaluating not only the feasibility and likelihood of success and the goals of the program, but also where to help know where and what types of biocontrol agents to look for.

C. Prospections in the native range

Surveys of natural enemies to identify potential biocontrol agents are generally conducted in regions that are considered to be the center of evolutionary origin of the target invasive alien species and/or regions in the native range that have a good climatic match with the region where biocontrol agents are required. Matching abiotic factors such as climate and biotic factors such as number of generations with those in the country of introduction can be key. The purposes of these surveys can include one or all of the following:

1. Find and identify species of natural enemy (arthropods or pathogens) found on the target species in its native range
2. Obtain information about the likely specificity (host-range) of these natural enemies based on their capacity to feed and develop on related species co-occurring with the target in the native range.
3. Collect data on the likelihood that the individual natural enemy species found may have the potential to suppress target populations, based on a number of biological and ecological characteristics

Native range surveys of the natural enemies of a target invasive alien species should generally include collaboration with one or more local research institutes in the native range. This is not only for logistic support, but it assists in knowledge sharing and collective understanding of the purpose of the surveys. It can alleviate concerns and issues about benefit sharing under the Nagoya Protocol and where necessary may facilitate the approval by exporting countries' issuance of export permits. Close collaboration with local research institutes in the countries of the native range of the candidate of the biocontrol agent can also cut costs of lengthy multi-year ecological surveys and observations

Surveys and sampling of natural enemies are generally conducted across multiple sites based on a range of criteria (e.g. altitude, latitude, target density, related species diversity, matched climate, and habitat) and, where possible, throughout the year to take into account the potential seasonality in natural enemy damage. Ideally surveys should be conducted over several years to account for variation in abundance of a candidate agent and its distribution, needed to understand the potential for impacts of natural enemies on target populations. Sampling techniques vary according to the type of agent being sampled and may include quantitative data on abundance and life stage. For arthropods, immature stages are often collected and reared through to adulthood to enable formal identification.

In some regions of the world, the fauna or fungal flora is very well known, and the likely host-range of candidate biocontrol agents may be determined from the published literature. Surveys of related species that are growing in proximity to the target, in the native range can also provide useful evidence of the likely host-specificity of a candidate biocontrol agent.

Expert identification to species ideally using up-to-date taxonomic keys of the natural enemies of interest as potential biocontrol agents is generally required for export and import permits to be obtained. Misidentifications or a failure to recognize the presence of additional cryptic species led wrong interpretations of effectiveness and host range and the importation and release of agents without a formalized risk assessment. Potentially effective agents may be missed, if misidentification leads to the perceived host range being too broad, particularly where specificity may vary with species and across the target distribution. For example, many published host-parasitoid lists are unreliable, because of misidentifications (Noyes, 1994). The use of DNA barcoding or genetic sequence data-based phylogenetic analyses of related species across the range of the target is another very valuable tool to determine species boundaries and define taxon relatedness as closely related species often share similar levels of specificity.

Generally, surveys and sampling are aimed at developing a short list of potentially specific and, where possible, likely effective agents, which with increasing amounts of this type of evidence can be prioritized before a decision is made of which one(s) to import into quarantine in the invaded range countries further study.

The search for viral and other diseases as candidate biocontrol agents for invasive vertebrate has been a more serendipitous process. While native range surveys may be carried out where sick individuals have been detected to understand the cause, generally potential agents are identified when mass deaths occur either in the field or in breeding colonies of the target, without apparent impacts on exposed related species. The causal agent is then isolated and identified and risk assessment for non-target impacts started. Generally, such disease outbreaks result from either a new association (e.g. between a virus and a novel host, such as myxoma virus in rabbits) or an endemic strain that mutated into a highly virulent form (e.g. RHDV1 virus in rabbits or Koi-Herpes virus (KHV) in carp). However, prospective activities for finding vertebrate biocontrol agents or biocontrol agents for marine invasive alien species (pests) remain relatively unexplored but are being increasingly undertaken based on new methods of genetic analysis, including genome sequencing of pest species and molecular detection of pathogen infection.

D. Host range assessment and efficacy assessment in native range

Once a number of natural enemy species considered potential biocontrol agents have been identified, experiments are initiated, and data can be collected in the native range to further understand agent host range (necessary part of risk assessment) and likely efficacy.

Standardized host-specificity (or host-range) tests exist for use in the field in the native range of the target or in laboratory or field cages to understand natural enemy host range, and the risk of feeding and development on non-target species. In some parts of the world (e.g., North and South America) the biology of many species is unknown. In such cases the biology of the candidate biocontrol agents must be understood before risk or efficacy assessment of them can be interpreted.

a. Host range assessment

Test organisms are the non-target species used to help define natural enemy host range, and are normally selected according to their phylogenetic relatedness to the target. Often referred to as the 'phylogenetic centrifugal approach', the tests involve exposing the tests organisms to a sequence of test species starting with species most closely related to the target and progressing to successively more distantly related test organisms until the host range has been adequately circumscribed using the target species as a control test (Wapshere, 1974). Additional "safeguard" test organisms may also be included (i.e. non-target species that are either economically important species or iconic/listed threatened native species, not necessarily closely-related to the target. It has been argued that test organism selection should be based strictly on phylogeny and testing safeguard economic species that have no phylogenetic justification is unnecessary and should be abandoned (Briese and Walker, 2002). A purely phylogenetic approach is standard practice in countries like New Zealand and Australia where host-range definition rather than risk to specific non-targets is seen as an adequate basis of the risk assessment. Collecting threatened species for testing is highly controlled in such countries. Precise test organisms should also be selected based on their likelihood of exposure to the potential biocontrol agent in the invaded range, i.e. they occur in the same climate and habitats and have feeding stages or sites appropriate for the agent being tested.

The simplest tests to interpret are 'no-choice' tests where, for pathogens, for example, test organisms are inoculated/infected with e.g. fungal spores, and monitored to determine if infection occurs. For arthropods agents, candidates are confined on a particular test organism and either feed and develop, or starve and die. Results are extremely robust and can be used to reliably define the 'fundamental' or 'physiological' host range of a particular species, - i.e., all the organisms tested on which a candidate agent can survive and complete development (Cullen, 1988).

Reliance on no-choice or starvation tests, however, carries a risk of needlessly rejecting specific agents because, given no choice, candidate biocontrol agents often feed on test organisms that they would not attack under natural field conditions, so a range of other tests are used, including choice oviposition tests and field choice tests to predict the 'realised' or 'field' host range of a potential biocontrol agent. Quantitative host-range testing data that compares the relative performance (e.g. oviposition rate, larval survival) on the test organism and the target organism can also be used to determine whether a test organism is likely to be a host in the field (Paynter et al., 2015).

For arthropod candidate biocontrol agents, the artificial environment of laboratory or field cages can result in both false positive (test organism that are within the fundamental host range but would not be used in a true field setting) and less frequently false negatives (test organisms that are not used in tests but fall within the field host range of the potential agent), because of a range of impacts non-field test conditions can have on arthropod behavior (Sheppard et al., 1996). Current standard types of host-range testing used with an understanding of their strengths and weaknesses have a good record of reliably predicting the host-range of potential biocontrol agents (Suckling and Sforza, 2014).

b. Predicting the efficacy of a candidate agent

Understanding the potential efficacy of a candidate biocontrol agent has been a recent additional focus of pre-importation and pre-release studies. Agents are generally effective because:

(a) they are resource limited in the native range where the target may be quite rare and rapidly increase in abundance and impact when introduced onto dense and widespread in the invaded range,
(b) they are suppressed by their own natural enemies in the native range, but can escape these when introduced as clean populations in the invaded range and following release therefore generate higher levels of impact than seen in the native range.
(c) the agents are 'pre-adapted' to novel biotic (target organism) or abiotic (environment) conditions of the invaded range and perform better there than in the native environment e.g. are able to complete a greater number of lifecycles or have a higher reproductive rate in each time step.

One method of predicting the potential impact of biocontrol is to investigate evidence of higher target performance in the introduced range. For example, greater relative abundance, growth rate or reproduction of the target organism in its introduced range may be a result of enemy-release that could potentially be reversed following the release of an impactful agent (Müller-Schärer and Schaffner, 2008). It can be difficult to determine the impact of individual species as candidate agent in the native range because, typically, multiple natural enemies attack the target there, making it hard to determine the impact of any one species. Life table studies, used particularly for invasive arthropods and built from quantitative ecological data collected in the native range, can help determine which natural enemy is most likely to have a regulate host population change, as such natural enemies could be more effective agents (Gassmann, 1996). Laboratory experiments that test the impact of individual agents can give an indication of potential impacts, assuming the density of agents used in the experiment is a realistic approximation of the likely density in field conditions. History can also be used to predict effective agents.

Particular agent types have proved effective in historical biological control programs (e.g. root feeding insects on herbaceous perennial weeds or egg parasitoids for insect pests that lay their eggs in batches have been consistently effective agents) and can be used to decide which agent to select. That the effectiveness of an introduced agent may be compromised by parasitism in the invaded environment can be predicted to some extent if ecological analogue species (closely related species of very similar biology likely to co-occur with the biocontrol agent following its release) are present on the target weed, or on closely-related plant species. The potential for indirect agent suppression mediated by predators is considered much harder to predict.

Similarly, agent selection is influenced by the goal of the biological control program, for example, if the goal is to reduce target spread rather than impact, then agents affecting reproductive output will be favoured over agents reducing growth and longevity of target individuals. Full prediction of potential agent efficacy is rarely possible, however, as only following release can the effect of the novel environmental conditions in the invaded range on the biocontrol agent be fully understood.

E. Import risk assessment in the country of introduction

Risk assessment for a candidate biocontrol agent is an internationally recognized requirement under the International Plant Protection Convention (IPPC) for regulatory approval for release in all jurisdictions. This is covered in IPPC International Standards for Phytosanitary Measures (ISPM) relating to Pest Risk Analysis (PRA) (ISPM 2 and 11; IPPC, 2016a; 2017b) and IPPC Guidelines for biocontrol agents (ISPM 3; IPPC, 2017a) (see Section VIII A).

Broadly risk assessment for all types of biocontrol agent should determine:
(a) direct impact of the biocontrol agent on non-target species;
(b) potential indirect impacts of the biocontrol agent, including effects on organisms that depend on the target pest and non-target species and competition with resident biocontrol agents and other natural enemies;
(c) possible direct or indirect impact on threatened and endangered (T & E) species in the country of introduction;
(d) impact of the biocontrol agent on humans and other vertebrates; and
(e) impact of the biocontrol agent on the physical environment (e.g. water, soil and air).

As a baseline, procedures generally follow a phytosanitary measure as an Import Risk Assessment process or operate under specific legislation within jurisdictions (i.e. political boundaries such as countries). This is based on an IPPC defined “precautionary approach” referring to evaluating risks of direct non-target impacts with jurisdictional specific consideration of indirect non-target impacts. For classical biological control the testing elements of risk assessment consist of understanding the host range of potential agents through increasingly standardized testing procedures either in the native range (see section

IV.D) or in certified containment/quarantine facilities. Test design is less standardized for biocontrol agents for insect pests or vertebrate pests.

Indirect impacts of the biocontrol agents on native species and ecosystems, humans, other vertebrates (e.g. wildlife, livestock) and the physical environment are generally determined through review of the literature, consultation and expert opinion, although analytical approaches have been developed from field data have been developed in some cases (Paynter et al., 2010). It is generally assumed that such potential negative indirect impacts of biocontrol agents will be confined to areas in close proximity to the target organism and are likely to be minor, compared to the direct negative impacts of the target on native ecosystems and/or agricultural production. Furthermore, if biocontrol succeeds in reducing the abundance of the target, the potential for negative indirect impacts will decline as the agent abundance follows that of its target, provided it is host-specific. Reports of potential health impacts in humans or vertebrates generally require further study to characterize the risks.

F. Release decision making

Decision to approve the release of a classical biocontrol agent is based on the risk assessment report, release permit application and other relevant required material submitted to the regulatory agency in the country of introduction. These submissions generally require public comment and scientific peer review, as a part of regulatory evaluation. A peer review process generally makes a recommendation to the regulatory authority who will then make a final decision based on not only the science, but also on a broader public acceptance of the benefits over the risks of release and, where appropriate, approve conditional or unconditional release through a permission process. The regulatory authority, may choose to consider only risks (from the risk assessment) or also the benefits of releasing the biocontrol agent (e.g. risk of not releasing, probability of success) in making the decision and include a whole suite of other criteria in the decision, which may include impacts on cultural values, human wellbeing and/or threatened and endangered species and local communities. In countries with land borders with their neighbors or in close enough proximity that the agents could easily cross such borders it is also common practice to consult with neighboring countries before making a decision. It is important that a transparent and documented process for the decision making is recorded to avoid undue influence of advocates. Where conflicting evidence or opinions arise and a decision needs to be made “on balance”, then delays can ensue unless there is a legislative framework to underwrite such a decision basis (e.g. the Biological Control Act in Australia – see Section VII). Approval is generally contingent upon providing evidence. The agent species should have been correctly identified and characterised with reference specimens placed in national repositories and that the culture is clean e.g. free from contaminants, disease or parasitism, generally achieved by passage through a quarantine process.

G. Mass rearing and release

The successful establishment of a candidate biocontrol agent in a new location generally requires the capacity to multiply and release adequate numbers of high quality agent material. The probability of establishment is most often correlated with the amount or number of agent material released. In classical biological control, techniques are generally developed to multiply or mass rear colonies of agents in ways that preserve their intrinsic genotypic qualities either in quarantine facilities, prior to release permission, or outside in the introduced range. Many agents are relatively easy to rear, but this is not always the case, and mass rearing is labor intensive and therefore costly. The quality of produced biocontrol agents is contingent on their genetic diversity being maintained in the rearing environment. Continuous rearing of biocontrol agents during extended periods under artificial conditions can greatly reduce genetic diversity and fitness related life-history traits. Procedures for quality assessment have been developed in mass production of different types of agent (van Lenteren, 2003). Many of these issues can be avoided if field releases can happen rapidly after agent material is imported from the native range.

Several principles should guide field releases. The probability of establishment following release may depend on identifying the life stages, field conditions and timing of release to optimize chance of survival and establishment. Adults of arthropods are most often selected because they are robust, ready to reproduce and mobile, but other life stages (egg, pupa, parasitized larva) may be better if cheaper to mass-produce, tend to be more sedentary after release, or are easier to move around. Three main reasons for release failure in arthropod agents are: a) low abundance of healthy target organisms or suboptimal environmental conditions at the release site; b) target poor synchrony between the life stage and the seasonal phenology of the target, and c) failure of successful reproduction following release as male and female agents are at densities too low to meet (the Allee effect; Hopper and Roush, 1993). Consideration to site selection and timing of release, therefore, greatly maximize the likelihood of establishment. Favorable release sites should also have good conditions for infection (e.g. appropriate dew periods for fungal pathogens) or provide alternative foods (e.g. nectar and pollen for insect parasitoids) and protection from adverse environmental conditions or risk from pesticide applications. It is not unusual for classical biological control programs to necessitate repeated releases before the successful establishment of a non-native biocontrol agent in its new environment and for challenging agents optimal release strategies may need to be learnt (Shea and Possingham, 2000).

Continuing to mass-rear arthropod agents may also be optimal in parallel to field releases until populations build up there from which agents can be easily collected for redistribution at a fraction of the cost of mass-rearing. Once established in the field, agent populations should increase, spread, and hopefully have a sustaining effect on the target pest.

H. Redistribution

To accelerate the rate of colonization of new effective biocontrol agents, it is generally, but not always (e.g. for highly fecund and mobile agents) optimal to undertake a redistribution programme and increase the chance and extent of its effectiveness. To facilitate agent establishment and spread it is, therefore often sensible to organize open days at release sites where agents are established in large enough amounts for redistribution, where stakeholders can collect candidate agents and be given advice on how and where to take and release the agents. These activities have an important public engagement role for

(a) communicating with the stakeholders and general public about the biological control programme and associated potential
(b) passing on the ownership of the research outputs to the community and, following training, empowering them to have control over generating the local benefits from the released agents.

I. Monitoring and evaluation

Once a biocontrol agent has been released, post-release monitoring and evaluation is necessary to confirm establishment of the agent (completion of multiple generations in the field that lead to increasing local population levels), measure impact on the target species, and to validate the risk assessment expectations of non-target impacts.

A post-release monitoring and evaluation plan should include:

(a) measures of the biocontrol agent's establishment, increase and spread;
(b) incidence and level of direct attack on target pest and on potential non-target organisms (i.e. those species identified as potential hosts during review of host records or during host-specificity testing);
(c) changes in target population and attacked non-target species growth, reproduction, survival and various population parameters (follow up research should be conducted where non-target use is found but not expected from the risk assessment);
(d) agent-induced changes in community-level processes and structure (e.g. shift in species composition or diversity) (De Clerck-Floate et al., 2006).
(e) Performance against the goal of the biological control programme (see Section IV A)

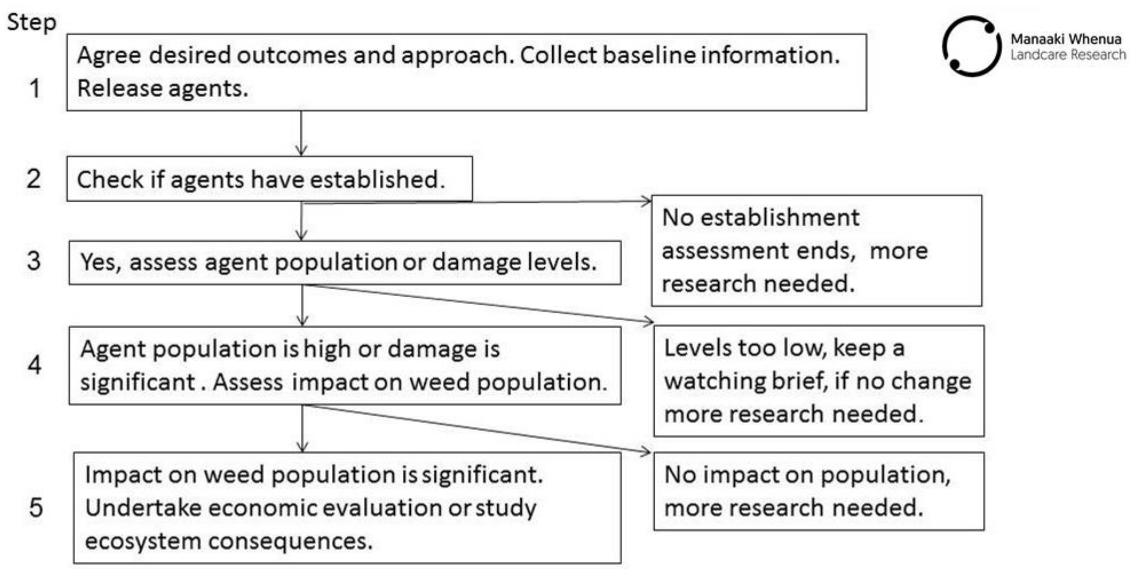

Fig. IV.1 Hierarchical approach to weed biocontrol agent monitoring in New Zealand.

Monitoring of agent impact can be based on a hierarchical approach (Figure IV.1.). It may take several years to detect an impact of an agent, however the post-release monitoring data generated is important to further decision-making for the current and improving future programs.

V. HISTORY AND SUCCESS, FAILURE AND COST EFFECTIVENESS OF BIOLOGICAL CONTROL AGAINST THE TARGETTED INVASIVE SPECIES

A. Invertebrate targets

Interest in the use of natural enemies to control pests dates back many centuries in China, where farmers manipulated Pharaoh's ant to control stored product insects in barns. Further efforts to use natural predators to control insect pests of agriculture or introducing cats to control rodents on islands were made mainly during the 18th and 19th centuries around the world. Ecological understanding of the risks and side effects associated with these releases was very rudimentary and the only consideration was a hope the pest could be controlled. There were therefore many uncontrolled attempts at unregulated biocontrol using generalist predators moved from one country to another. Examples of unscientific and uncontrolled biocontrol include the introduction of Indian mynah birds from India to Mauritius to control red locusts in 1762 and the introduction of the cane giant toad from South America into Martinique and other Caribbean countries in 1859 and into Australia in the 1930's to control sugarcane pests (Simmonds *et al.,* 1976; Van Driesche & Bellows, 1996). In the case of the toads, the released predators themselves have become major pests in their own right.

The science of natural history developed in the late 19th and early 20th centuries and a realization of the errors of the past resulted in the emergence of a more science-based classical biological control approach. The greater understanding provided a platform to make better selection of natural enemies and improved methods of implementation of the agents, but approaches were still very empirical and attention primarily focused on the improving control, not on other ecological considerations.

Nonetheless, many current practitioners of biological control consider that 'modern' classical biological control 'started' with the United States Department of Agriculture (USDA) initiative in 1888 to use insect natural enemies from Australia for the outbreaks of the cottony cushion scale, *Icerya purchasi* Maskell (Margarodidae), in California which was devastating the citrus industry there. Searches were made in Australia, the region of origin of the scale insect, and the most important natural enemy introduced from there into the Californian citrus groves was the predacious ladybeetle, *Rodolia cardinalis* (Mulsant) (Coccinelidae), which brought the scale under control within two years of release. The project was hailed as a complete success. This was not the only successful project that time because an effort in 1883 to control cabbage white butterfly, *Pieris rapae* (L.) (Pieridae), in the USA using the parasitoid wasp *Cotesia glomerata* L. (Braconidae), imported from England, was also successful. However, it was the spectacular impact of *R. cardinalis* and the immense economic benefits to the citrus industry that galvanized an expansion of classical biological control in agriculture, first in the USA and then in other countries ((Simmonds *et al.,* 1976; Van Driesche & Bellows, 1996). Ten countries led the early activities including also Australia, Canada, the UK, New Zealand, Mauritius, Fiji, France, Israel and South Africa. In the first few decades of the 20th century, several more successes were achieved in agriculture which provided further impetus for the growth in biological control (Cock *et al.,* 2016).

Classical biological control against invertebrate invasive organisms developed into a more exact technology during 20th and the first part of the 21st centuries, but most of the development has been for the management of agricultural pests. The major stages in this development has been reviewed by Greathead & Greathead (1992) and more recently updated by Cock *et al.* (2016). The focus of these reviews is the classical biological control of insect pests using insect parasitoids and predators, but these targets and biocontrol agents have been the bulk of the activity since the late 1800s. Overall, since the early 1900s, there were decadal increases of releases of biocontrol agents up until the 1980s (to about 60 per decade), before falling back to 1960s levels (to about 50 per decade). Although there were many failed attempts, there was a significant and steady increase in the percentage of releases that became established and contributed to substantial biological control. A much greater research effort from the 1970s to understand the ecology and agent-target interactions of biocontrol agents helped drive improvements in subsequent decades. A notable example is the research that was conducted to improve the biological control of cereal stem borers in tropical regions (Greathead & Greathead, 1992). Another important trend has been the increase per decade in number of countries making biological control releases, which reached 80 in the 1990s; but the number of introductions made by the original ten countries decreased in the 1980-90s.

A major development was international guidelines in 1995 (IPPC, 1995) under the International Plant Protection Convention (IPPC) for the safe introduction of biocontrol agents which are now the International Standards for Phytosanitary Measures (ISPM) No. 3 (IPPC, 2017a). These guidelines were largely for the use of arthropod predators, parasitoids, arthropod herbivores and pathogens for use as biocontrol agents and the guidelines provided a stimulus for more countries to use biological control (Kairo *et al.* 2003).

One of the earliest projects targeting an invasive alien species (environmental arthropod pest) was in the 1940s against Bermuda cedar scales, *Carulaspis minima* (Signoret) and *Lepidosaphes newsteadi* (Sulc) (Diaspididae) causing extensive damage to the endemic cedar, *Juniperus bermudiana* L. (Cupressaceae), A classical biological control programme was initiated and several insect agents were introduced in the late 1940s/early 1950s. Even though these caused heavy mortality of the scale, outbreaks of the pest have continued (Van Drieche, 1994). It was not until the 1990s that classical biological control targeted insect pests affecting the environment as a direct goal in itself (Van Driesche, 1994).

Overall and up to 2010, 6158 independent introductions of insect parasitoids and predators had been made globally; 32.6% of these became established and this led to 620 satisfactory controls against 172 different pests (Cock *et al.* 2016). There have also been an increasing number of arthropod biological control programs using fungal pathogens (e.g. *Metarizium* and *Beauvaria* spp.) and parasitic nematodes of agricultural insect pests based on a more inundative release approach. In the case of the use of classical biological control for the protection of nature, 21 separate insect pests had been targeted by 2010, some in more than one geographical location. Taking all the protection of nature projects together the results include: 62% controlled, 19% partially controlled and 43% were still in progress (Van Driesche *et al.*, 2010). Examples of successful control include white wax scale, *Ceroplastes destructor* Newstead (Coccidae), affecting a range of native plants in Australia (Sands *et al.,* 1986) and the European spruce sawfly, *Gilpinia hercyniae* (Hartig) (Diprionidae), affecting natural spruce stands in North America (Magasi & Syme, 1984).

Several reasons have been suggested for the decline in the total number of introductions since the 1980s, but probably the most significant is a growing risk-averse culture in many countries resulting from a greater environmental awareness, since the 1992 Rio Conference on the Environment and the subsequent growing concerns about invasive alien species. Increasing concern about the potential for non-target effects of biocontrol agents led to more cautious approaches being taken in biological control release programmes (Cock *et al.*, 2016). Much research in the early 2000s led to greater guidance on methods for host specificity testing of agents for arthropod biological control and in particular, the assessment of risks to the environment (Bigler *et al.*, 2006).

Despite this greater caution, the percentage of establishment and success rates of total global introductions continues to rise, and classical biological control remains a core component of many countries pest management strategies. Assessments of the benefit: cost ratio of some earlier projects in agriculture showed the overwhelming benefits that accrue once an agent(s) is established, spreads and begins to have a controlling impact on the target. For example, the parasitoid wasp agent, *Anagyrus lopezi* De Santis (Encyrtidae), released in Africa in the early 1980s for the control of the cassava mealybug, *Phenacoccus manihoti* Matile-Ferrero (Psuedococcidae), devastating cassava crops, provided a benefit: cost ratio of 199:1 based on world market price (Zeddies *et al.,*2001). Other examples of analyses of classical biological control programmes showing the positive benefits of the technology are given by Cock *et al.,* (2015).

B. Terrestrial vertebrate targets

Globally, a wide range of introduced invasive alien vertebrate species are causing significant environmental, economic, and social impacts (Vitousek et al., 1996; Mack et al., 2000; Pimentel et al., 2005; Williams et al., 2010). Many of these were deliberately introduced as biocontrol agents but have had significant unintended consequences (Simberloff and Stiling 1996; Simberloff et al., 2000; Courchamp et al., 2003; Pipalova, 2006; Van Driesche and Hoddle, 2009); e.g., the release of peacock bass into Florida to control other introduced cichlid fish (Shafland, 1995), mongooses to control reptiles into the West Indies, Japan and Hawai'i (Simberloff et al., 200), stoats and weasels into New Zealand to control rabbits (Parkes and Murphy, 2003) and many historical releases of cats into new land masses to control rodents (Howard, 1967; Hoddle, 2004). Beyond these early unregulated releases of vertebrate predators to control vertebrate pests, cases of regulated classical biological control attempts of vertebrates using specific pathogens or parasites are rare, as are associated cost-benefit analyses (Van Driesche et al., 2010; Saunders et al., 2010). This is despite the high economic and environmental cost of current control methods, such as poisoning, trapping, shooting and exclusion (Howard 1967; Van Driesche et al 2010; Saunders et al., 2010). The following sections cover biological control history for the different vertebrate groups.

a. Invasive alien fish

Invasive alien fish have multiple negative impacts on native species through predation, competition, hybridisation and introduction of new diseases (Allendorf, 1991). Globally, more than 200 species have established non-native populations (Lever 2002). Classical biological control has only been attempted occasionally, mainly because of the difficulties in finding suitable agents (Thresher et al., 2014).

Common or European carp, *Cyprinus carpio* L. (Cyprinidae), are a major invasive alien species of freshwater ecosystems in Australia. In the 1990s a virus*, Rhabdovirus carpio*, was evaluated as a biocontrol agent but discounted because of its uncertain efficacy and low species-specificity (Crane and Eaton, 1997). In 1998, a viral disease (termed Koi herpes virus disease KHVD or cyprinid herpesvirus-3 (CHv-3)), first noticed through outbreaks in cultured common carp in Israel and the USA, and now regularly reported from Europe, South Africa, USA and Asia (Rathore et al., 2012; Thresher et al., 2017) is now completing evaluation. Many of the questions and issues about efficacy, safety and acceptability have been addressed and remaining information gaps have been identified, and this virus strain is specific and aggressive enough to be an effective agent (McColl et al., 2014; 2017). Significant progress has also been made in determining the process and information needs required before an application to release the virus can be prepared. The Australian government in partnership with the fisheries and aquaculture sectors has dedicated enough funds to support this proposal through to potential release approval (See BOX 2). At the same time, various genetic options for control of invasive fish, particularly "daughterless" approaches, have been under investigation but have not gone beyond proof of concept (Teem et al., 2014; Thresher et al., 2014).

b. Invasive alien amphibians

Globally, at least 347 species of anurans have successfully established populations outside their native range (Kraus, 2008). A few species, such as cane toads, *Rhinella marina* (L.) (Bufonidae), bullfrogs, *Rana catesbeiana* Shaw (Ranidae), and coqui frogs, *Eleutherdactylus coqui* Thomas (Leptodactylidae), are well known because of their ecological and other impacts (Beard and Pitt, 2005), but most species are poorly studied (Kraus, 2008) and there are no classical biological control releases. Economic costs of invasive alien anurans are high for some species. On Hawaii, property loss values resulting from noise pollution by coqui frogs alone were estimated at US$8 million p.a.; additional costs accrue from direct and indirect impact on agriculture and the nursery industry (Kraus, 2009).

Biological control was considered initially for coqui frogs because Hawaii has no native frogs (Pitt, 2012). Unfortunately, no diseases or organisms have been identified that would effectively reduce coqui frog populations. One parasite was identified from Puerto Rico that could have an effect, but testing showed it did not affect coqui growth or survivorship (Marr et al., 2010).

Biological control for cane toads has been actively pursued in Australia, principally to mitigate their impacts on native fauna. The current status of control options are reviewed by Reid et al. (2017). In the early 1990s, pathogens in the toad's native range in Venezuela were investigated, and a number of viruses belonging to the family Iridoviridae, genus *Ranavirus*, were identified. Although these viruses killed 100% of cane toad tadpoles, they were not species specific. Bacteria (Shanmuganathan et al., 2010) from the native range and a lungworm (Dubey and Shine, 2008) found to have come into Australia with the toads were also assessed as potential biocontrol agents, but all of those assessed proved unsuitable. After a research shift to try and obtain toad specific self-disseminating genetically modified organism failed to deliver, further research on biological control was discontinued (Pallister et al., 2007; Shanmuganathan et al., 2010). Recently, however, a draft genome of the cane toad has been successfully assembled (Edwards et al., 2018) and using a combination of DNA and RNA sequencing sampling of cane toads from different Australian locations, researchers have found three new viruses that may have potential as biocontrol agents (www.sciencedaily.com/releases/2018/09/180919111525.htm).

c. Invasive alien reptiles

Globally, at least 711 species of reptiles have successfully established populations outside their native range but few have been extensively studied (Kraus, 2008). As with amphibians, a few species are well known because of their ecological and other impacts (Kraus, 2015), such as the Burmese python, *Python molurus* (L.) (Pythonidae), in the Florida Everglades National Park (Pitt et al., 2005), the brown tree snake, *Boiga irregularis* (Merrem) (Colubridae), on Guam (Pitt et al., 2005), and the green anole, *Anolis carolinensis* Voigt (Dactyloidae), on Pacific islands (Abe et al., 2010). Costs of brown tree snakes to the Guam's economy have exceeded $4.5 M per year. US Department of Interior spent US$3.7 million on brown tree snake management in Hawaii and the Western Pacific from 2015[15]. An economic study by the United States Department of Agriculture National Wildlife Research Center estimated the cost of the brown tree snake's impacts at $1.7 billion per year if it were ever introduced to Hawaii[16].

Parasites as biocontrol agents for brown tree snakes were the subject of several investigations, but none of the potential agents identified were specific enough, nor had available vectors (Howarth, 1999; Rodda and Savidge, 2007; Kraus, 2009).

d. Invasive alien birds

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[15] https://www.doi.gov/sites/doi.opengov.ibmcloud.com/files/uploads/08122015-Brown-Tree-Snake-Press-Release-FINAL.pdf

[16] http://dlnr.hawaii.gov/hisc/info/invasive-species-profiles/brown-tree-snake/

Globally, at least 416 avian species have successfully established populations outside their native range (Cassey et al., 2004), and many of those have had significant impacts on the environment and agricultural production (Kark et al., 2009; Brochier et al., 2010). A wide variety of techniques are used to control invasive alien birds but no classical biological control approaches are being trialled or used (Tracy and Mary, 2006).

e. *Invasive alien mammals*

Globally, at least 124 species of terrestrial mammals have successfully established populations outside their native range (Clout and Russell, 2008). Sixty eight of these are listed in the Global Invasive Species Database because of their impacts on native biodiversity[17]. Introducing alien predators as biocontrol agents for invasive alien mammals has been wrought with perverse outcomes.

The use of parasites and pathogens as biocontrol agents for invasive alien mammals has been widely suggested, but rarely used successfully (Howard, 1967; Tompkins and Begon, 1999). Many agents have been investigated, such as bacteria and protozoans for rodent control (Howard, 1967; Singleton, 1994), trypanosomes for rabbits (Hamilton et al., 2005) and classical swine fever and hog cholera for feral pigs, *Sus scrofa* L. (Suidae) (Howard, 1967; Nettles et al., 1989), but very few have demonstrated efficacy in reducing pest populations (Saunders et al., 2010). Modelling and laboratory and field studies suggested potential efficacy for the nematode *Capillaria hepatica* Bancroft (Capillariidae), for biological control of house mice, *Mus musculus* L. (Muridae), in cereal-growing areas of Australia (Singleton and McCallum, 1990). However there was no significant reduction in wild mouse numbers after field releases (Singleton and Chambers, 1996). More success in rodent biological control appears to have been achieved using *Sarcocystis singaporensis* (Sarcocystidae), a cyst-forming coccidian with rodents of the genera *Rattus* and *Bandicota* as intermediate hosts and snakes as the definitive host (Jäkel et al .,1996), particularly where it is used as part of an integrated management programme (Jäkel et al., 2016). Rodents are infected by feeding on bait pellets containing sporocysts, with the subsequent development of these in the rats causing death (Jäkel et al., 1996). There is no transmission of the parasite between rats so the effect is solely biocidal but with the advantage of genera specificity. In a recent novel suggestion for biological control, the potential of behaviour-manipulating parasites to improve the efficacy of control of rodents has been assessed by modelling (Tompkins and Veltman, 2015). *Toxoplasma gondii* Nicolle & Manceaux (Sarcocystidae) is an intracellular parasite with felid [cat, *Felis catus* L. (Felidae)] definitive hosts and most other warm-blooded animals as intermediate hosts. Infection in rats as well as increasing probability of predation by cats is known to increase activity and reduce neophobia. These latter behavioural changes are likely to increase probability of rats being trapped, with the modelling suggesting control targets could be achieved with a reduction of up to 33% in trapping effort across a range of trap densities.

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[17] http://193.206.192.138/gisd/

The most effective biocontrol agents against invasive alien mammals have been two viral pathogens to control European rabbits, namely myxomatosis and rabbit haemorrhagic disease (Saunders et al., 2010) [See BOX 1]. In addition, the release of feline parvo virus and the consequent epidemic of feline panleucopaenia was a significant contributor to the successful eradication of feral cats from Marion Island (Van Rensburg et al., 1987). After its introduction in 1977, cat numbers decreased by about 80% by 1982 but subsequently evidence suggested that the disease was becoming less effective as the rate of decline was slowing, and trapping and shooting were also implemented (Bloomer and Bester, 1992). During the eradication of feral cats from Jarvis island, a few cats were infected with the virus and released; some cat-to cat transmission may have occurred but the impact on the cat population was minor (Rauzon, 1985). Feline parvo virus has not been used for any further feral cat eradications mainly because of immunity problems and welfare issues. It -can also infect all members of the cat family where present. A review of alternatives for biological control against cats concluded that no other feline diseases would cause rapid death of a large enough proportion of a cat population in a relatively humane manner to be useful for biological control (Moodie, 1995).

BOX 1: RABBITS CASE HISTORY

Myxomatosis is caused by a poxvirus (family Poxviridae, genus Leporipoxvirus) and is vectored by insects. In rabbits of the genus *Sylvilagus* in the Americas, infection causes only localized skin tumours, but infection caused high mortality in European rabbits. After much investigation, the virus was released in Australia in the late 1940s and illegally in France in 1952 and spread to Britain in 1953. In Australia rabbit numbers were reduced initially by 90-99% and by about 90% in Britain. But rabbits that survived infection developed immunity, attenuated strains of the virus emerged and there was strong selection for resistance to infection, all of which reduced the impact of myxomatosis. Australia subsequently released the European rabbit flea, *Spilopsyllus cunciuli* (Dale) (Pulicidae), in 1968 to enhance general myxomatosis transmission and the Spanish rabbit flea, *Xenopsylla cunicularis* Smit (Pulicidae), in 1993 to enhance transmission in hot dry regions (Cooke, 2014).

In the mid-1980s a novel disease of rabbits emerged, rabbit haemorrhagic disease, caused by a single-stranded positive-sense RNA virus (RHDV1; family Caliciviridae, genus Lagovirus). RHDV1 initially killed millions of rabbits in China, where it probably originated, and then spread rapidly to Europe, where rabbit mortality was again very high. The potential of RHDV1 as a biocontrol agent was quickly recognised. In 1991, RHDV1 was imported into containment in Australia for assessment and testing. A contained field trial with rabbit in outdoor enclosures began in March 1995 on Wardang Island off the coast of South Australia. Despite strict biosecurity and quarantine, within months the virus had escaped to the mainland and spread rapidly. Both the escape and the subsequent rapid spread were most likely vectored by flying insects (carrion flies). In September 1996, RHDV1 was officially registered in Australia as a pest control agent

(Saunders et al., 2010; Cooke, 2014). A vaccine for the released strain was subsequently developed and made available to the domestic and pet rabbit trade[18].

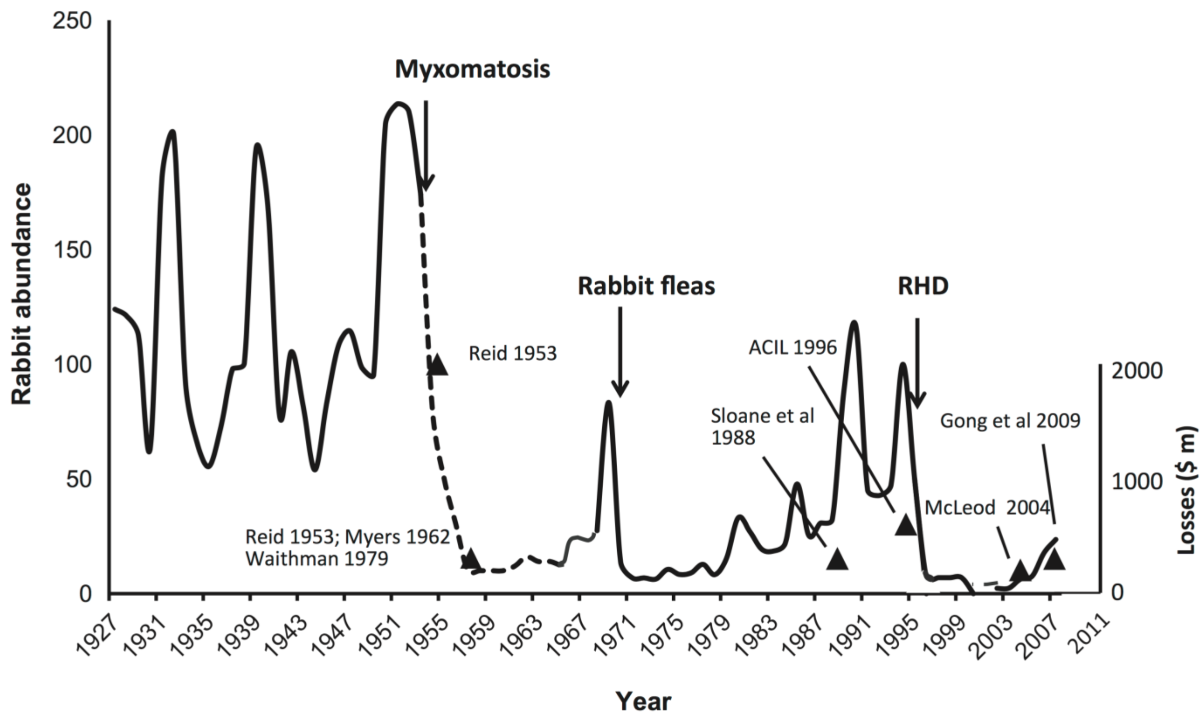

Figure V.1. Diagram showing how rabbit abundance in semi-arid South Australia has varied through time in response to the release of biocontrol agents. The estimated Australia-wide economic losses to rabbits (black triangles) are also shown. Scale for losses shown on right-hand side of figure. Figure adapted from Saunders et al. (2010)

In New Zealand, an application to the Director General of Agriculture in 1997 to import the virus for release was rejected, principally because of concerns about suggested effects on some native animals. Soon afterwards RHDV1 was illegally imported into New Zealand and released. The Ministry of Agriculture and Forestry (MAF) attempted to contain the outbreak and advised that possession of virus material would incur harsh penalties. Regardless, some landholders promoted the spread of the virus by a variety of means. Given the extent of spread MAF subsequently announced that it was no longer illegal to be in possession of the virus, and many other landholders actively engaged in spreading the virus onto their properties. As in Australia the disease spread rapidly, both through the efforts of farmers and natural vectors (Lough, 2009) and in accordance with the risk assessment, has infected no other hosts.

In both Australia and New Zealand more than 90% of rabbits were killed in the initial disease outbreak in many places. However, kills in the wetter and more temperate regions of both

[18] http://www.ava.com.au/rabbit-calicivirus

countries were more variable and lower (Lough, 2009; Cooke, 2014). Some of this variation in both countries was associated with prior infection with a non-pathogenic rabbit calicivirus (Cooke, 2014). Subsequently, there was a progressive reduction in efficacy in both countries attributable to the development of resistance to infection (Parkes et al., 2009) and some novel strains of the virus (Lough, 2009; Cooke, 2014; Eden et al., 2015). This has prompted research into ways to improve the efficacy of RHDV1. The novel strains, of which there are at least 22 in New Zealand, vary in lethality and time to death and so suitable existing strains could be released in areas where they are currently absent. A joint programme between Australia and New Zealand (RHD Boost) identified an RHDV strain from Korea (K5) that is better suited to more temperate regions and has some lethality for immune rabbits (www.pestsmart.org.au/pestsmart-rhd-boost/). RHDV1 K5 strain has now been released in both Australia (2017) and New Zealand (2018). A second programme in Australia (RHD Accelerator) aims to use experimental systems that will allow accelerated evolution and targeted selection to produce strains of RHDV that are able to overcome immunity and potentially resistance to existing RHDV1 strains. This non-GMO approach will provide a platform technology for the continuous supply of suitable calicivirus strains for subsequent releases that will help to address Australia's rabbit problem[19]. Since 2014 two novel strains of RHDV have been found in Australia, both apparently border biosecurity breaches. In December 2013 an RHDV1-type Chinese strain was found in NSW and later in the ACT, but this virus has not been widely reported since. The second, RHDV2 is also of unknown origin. It was first detected in France in 2010 and subsequently caused epidemics in wild and domestic lagomorph populations throughout Europe, including RHDV2 was first found in a dead rabbit in Canberra in 2015. Within 18 months of its initial detection, it had spread to all Australian states and territories and rapidly became the dominant circulating strain, replacing RHDV1 in mainland Australia (Hall et al., 2015; Mahar et al., 2018)

The original release of RHDV1 in Australia was estimated to have cost about A$12 million over seven years for the research, including safety aspects. The return on that investment has been estimated at A$350 million annually (Saunders et al., 2010). Considering myxomatosis and RHD together, the overall value to the wool and meat industry in Australia is estimated to have produced cumulative economic benefits of about A$70 billion in 2011 dollar terms (Cooke et al., 2013). Regardless, post-RHD rabbit populations still cost the Australian wool and beef industry an estimated A$200 million annually (Gong et al., 2009). In addition to the economic benefits there have been significant benefits for Australian native biodiversity, particularly through growth and regeneration of native plants browsed by rabbits (Cooke, 2014), although maintaining these gains will require rabbit numbers to be kept at very low numbers (Denham and Auld, 2004). Other complex changes may have also occurred. For example, the reduction in rabbit burrows may have impacted on native snakes, lizards and geckos, increased kangaroo numbers, expanded the ranges of native predators, and altered native predator-prey

[19] www.invasiveanimals.com/research/phase2/land-pests/landscape-control-rabbits/rhd-accelerator/

interactions (Cooke, 2014). In New Zealand, while there were similar positive benefits for some native plants, fast growing weeds also benefitted. In the absence of their main prey, rabbit predators such as feral cats, ferrets and stoats increased predation on native species, particularly native birds and lizards, though this effect may have been relatively short-term (Norbury et al., 2002; Haselmayer and Jamieson, 2001). Conversely, lizards in some habitats may have benefitted because the increased grass and shrub cover reduced the risk of predation (Norbury et al., 2002).

f. Conclusion

Generally, the same principles apply to classical biological control of vertebrates as to other organisms (Van Driesche et al., 2010). The apparent shortage of successful biocontrol agents for vertebrates highlights the difficulty of finding target-specific highly aggressive pathogens. Even when such agents have been initially highly successful at reducing target numbers, success usually wanes relatively quickly due to development of resistance in the target or further mutation in the biocontrol agent, as has happened with both myxomatosis and RHD for rabbit control (Kerr and Donnelly, 2013). Thus, as with other pest groups, classical biological control of vertebrates is likely to be most sustainable when used as one tool in a larger integrated pest management programme (Stokes et al., 2009). Future assessments of potential classical biocontrol agents for vertebrates need to deepen understanding and evaluation not just of the agent and the target and their interactions, but also of the potential wider ecosystem effects resulting from both the introduction of a new organism and the consequences of its impact. As noted by Simberloff and Stiling (1996) such effect may be ‘tortuous’. For example, the arrival of myxomatosis to Great Britain compounded the effects of agricultural intensification and ultimately led to the extinction of the large blue butterfly, *Phengaris arion* (L.) (Lycaenidae). The lack of grazing by rabbits changed habitat suitability for the ant, *Myrmica sabuleti* Meinert (Formicidae), its populations declined greatly and, with that, the availability of underground nests in which the butterfly caterpillars developed by feeding on the ant larvae.

C. Weed Targets

Biological control of invasive alien plants (weeds) has been undertaken for over a century: the first programme began in 1902 when A. Koebele carried out exploration in Mexico for the Hawaiian Department of Agriculture to find agents for the weed *Lantana camara* L. (Verbenaceae) (Greathead, 1994). By December 2012, 551 weed biocontrol agents had been released against 224 weed species worldwide (Winston et al., 2014). Reviews (e.g. McFadyen, 1998, Schwarzländer et al., 2018) indicate that complete successes, where biological control is so dramatic that no other control methods are required, account for approximately one-third of all completed programs and programs that deliver ‘substantial’ or ‘partial’ control, where biological control contributes to management, but other control methods are still required, are more typical. Failures are considered to be rare, although are potentially underestimated, because programs that have been shelved or are in a state of hiatus without agents having been released are often only reported in inaccessible grey literature. Data for Australia, South Africa and NZ is available and indicates that *c.* 11-18% of weed biocontrol programs in these countries have been halted without any agents being released (Paynter et al., 2015). Some failures are due to insufficient funding or a lack of political will (Fowler, 2000) indicating that agents probably could be released for some of these species, given more resources. Approximately two-thirds of abandoned programs were associated with the presence of valued plant species that are closely-related to the target weed, which can make it difficult and costly to identify sufficiently host-specific biocontrol agents and hard to attract ongoing support (Paynter et al., 2015).

A major advantage of weed biocontrol over other management options is that, after an initial investment, a successful programme can provide long-term control at no extra cost. The economic benefits of successful programs can therefore greatly outweigh the costs: for example benefit-cost ratios of six programmes in South Africa ranged from 34:1 to 4333:1 (van Wilgen et al., 2004). The benefits of successful projects can more than pay for projects that were not successful: For example, an analysis of all weed biocontrol programs in Australia, including those that did not succeed, indicated that the overall economic benefits of weed biocontrol outweighed programme costs by 23:1 (Page and Lacey, 2006).

The potential for success is to some extent predictable: Paynter et al. (2012) found that biocontrol impact (measure in terms of proportional reduction in the target weed) varied according to whether a weed was reported to be a major weed in its native range, mode of reproduction (sexual or asexual) and ecosystem (aquatic or wetland versus terrestrial) (Fig. V.2).

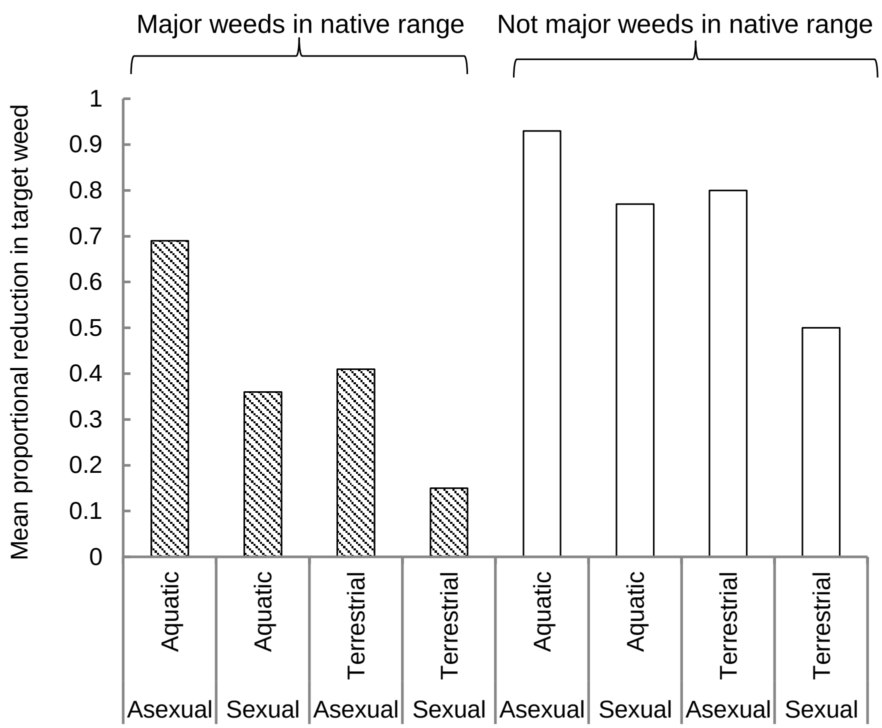

Fig. V.2 Predictions of the proportional reduction achieved by biological control of weeds for each of the eight combinations of the predictor variables (Paynter et al., 2012).

It is important not to read too much into predictions of success, as weed biological control has also been successful against some challenging targets (e.g. sexually reproducing weeds that are considered to be a major weed in their native range such as *Jacobaea vulgaris* Gaertner (Asteraceae)). Moreover, even when impacts of biological control have no direct impact on target weed density their other effects (e.g. reduced seed production) may nevertheless facilitate control using other management approaches. It is recognised that some invasive alien plant species are best managed by integrating biological control with other management practices (Moran et al., 2005). This suggests that weeds predicted to be difficult targets for biological control should still be targeted provided they are sufficiently high priority to ensure that the higher risk of failure is offset, by the greater benefits of success.

The success of a weed biological control programme is generally measured in terms of economic benefit from weed suppression to agricultural industries. Control of invasive alien plants (environmental weeds) should be measured in terms of recovery of local biodiversity following successful weed biological control, but this is rarely the case (Morin et al., 2009; Reid et al. 2009). A few studies have demonstrated a return of the native flora following weed biological control (e.g. Barton et al., 2007), but detailed evaluation is rare generally due to lack of resources (Morin et al., 2009).

a. New Zealand

As of May 2016, 58 weed biocontrol agents (52 insects, 2 mites and 4 fungal pathogens) have been released to control 22 weed species in New Zealand, where the number of naturalised seed plant species already exceeds the number of native plants and biological control is often the only cost-effective method of managing widespread weeds. (Fig V.3). Of the 58 agent species released, 43 are confirmed to have established and five it is considered too early to confirm establishment.

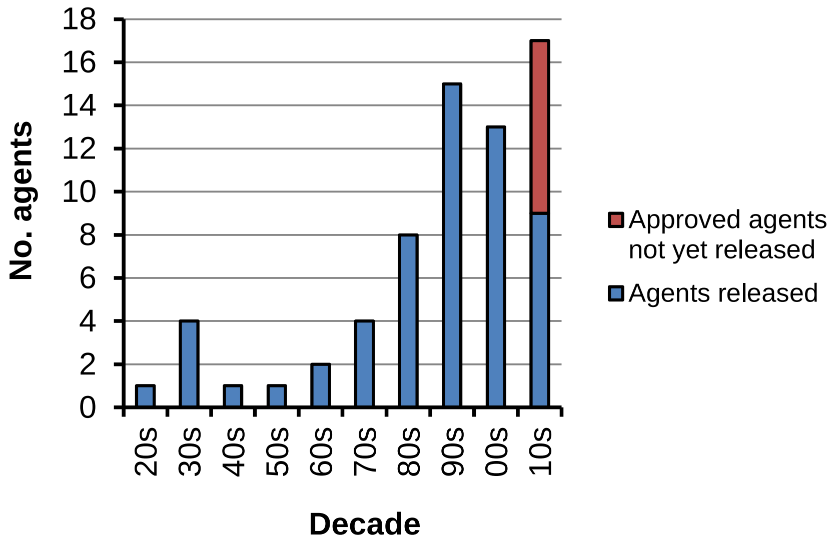

Figure V.3. Number of weed biocontrol agents released in New Zealand by decade.

Active programs are targeting a diverse range of pastoral and environmental weeds. The economic benefits of individual weed biological control programmes in New Zealand range from negligible to massive (Suckling, 2013). For example, the benefits from a programme against St John's wort, *Hypericum perforatum* L. (Hypericaceae), using *Chrysolina* leaf beetles seventy years since release is estimated to be between NZ$140 - $1,490 million (depending on different estimates of rate of spread) with a benefit cost ratio of 10-100:1 which in dollar terms at least pays for all weed biocontrol programmes undertaken in New Zealand to date (Hayes et al., 2013). Biocontrol of environmental weeds has also resulted in major benefits, notably complete control of mist flower *Ageratina riparia* (Regel) R.M.King & H.Rob. (Asteraceae), which declined by 98% and was replaced largely by native plants and resulted in the status of *Hebe acutiflora*, a rare native plant that was threatened by smothering mist flower stands, being changed from 'endangered' to 'range restricted' (Barton et al., 2007). The economic benefits of this programme were calculated to exceed the costs by 2.5:1 (Hayes et al., 2013). Extensive programs against a few weeds, notably Old Man's beard *Clematis vitalba* L. (Ranunculaceae), Gorse *Ulex europaeus* L. (Fabaceae) and Canada thistle *Cirsium arvense* (L.) Scopoli (Asteraceae), have not been hugely effective to date. Ongoing surveys, however, indicate that a recently introduced beetle *Cassida rubiginosa* Müller (Chrysomelidae) is beginning to have an impact on *C. arvense*, which could potentially result in major economic benefits, and additional agents are being developed for *C. vitalba*. Moreover, to date there are few sites where the full suite of agents released against gorse are present, so the potential combined impact of these agents is as yet unknown. Overseas studies indicate that reduction in gorse seed set due to *Exapion ulicis* Förster (Brentidae) reduced the invasion rate of this weed (Norambuena and Piper, 2000), which should help make gorse infestations easier to contain by conventional means.

Future challenges for weed biocontrol in NZ include addressing the increasing importance of grass weeds, submerged aquatic plants, and the potential application of biocontrol to reduce the invasiveness of commercially important species, such as using seed-feeders to contain wilding conifers.

b. Canada

Biological control of weeds has a long history in Canada. The use of phytophagous species for biological control began in the mid-20th century with the introduction of chrysomelid beetles against Klamath weed or St. John's wort , *Hypericum perforatum* L. (Hyperiaceae), in 1952 (Harris and Peschken, 1971; Mason and Huber, 2002). Since then, 89 agents have been released against 27 weed species (Winston et al., 2014). Among the 75 agents where impact is known, six (all beetles) are considered to be highly successful: *Neogallerucella calmariensis* (L.) and *N. pusilla* (Duftschmidt) (Chrysomelidae) against purple loosestrife, *Lythrum salicaria* L. (Lythraceae), *Mogulones crucifer* (Pallas) (Curculionidae) against houndstongue, *Cynoglossum officinale* L. (Boraginaceae), *Aphthona lacterosa* (Rosenhauer) (Chrysomelidae) against leafy spurge, *Euphorbia esula* L. (Euphorbiaceae), *Chrysolina quadrigemina* (Suffrian) (Chrysomelidae) against *H. perforatum*, and *Mecinus janthinus* Germar (Curculionidae) against common toadflax, *Linaria vulgaris* Mill. (Scrophulariaceae). Another eight agents have been highly successful in some but not all habitats, while 30 agents have had some impact on the target. A total of 29 introduced agents did not establish and two had no impact. Evaluation of new agents is ongoing, seven agents having been released from 2008-2016.

c. Australia

Weed biological control started in Australia in 1903 against *Opuntia* cacti with the failed introduction of the cochineal *D. ceylonicus* to control Barbary fig. The better success of the 1913-14 introductions led to the successful control of prickly pear over approximately 25 million hectares from 1921-1935 largely due to the introduction of the *Cactoblastis cactorum* (Berg) (Pyralidae) moth and associated soft rot fungi and more recently by *Dactylopius* spp. (Julien et al., 2012). This spectacular success ensured biological control continued to be strongly supported by the community and elected representatives over the decades to come, with parallel and subsequent programmes against Lantana (*Lantana camara*) , Noogoora burr (*Xanthium occidentale*), St John's wort, *Hypericum perforatum* L. (Hyperiaceae), ragwort, *Jacobaea vulgaris* Gaertn. (Asteraceae), crofton weed, *Ageratina adenophora* (Spreng.) King & H.Rob. (Asteraceae), and gorse, *Ulex europaeus* L. (Fabaceae). These programs resulted in reasonable success against crofton weed and some success against St John's wort, but no significant reductions in the other weeds (Wilson 1960).

Weed biological control was kick-started again in Australia during the 1970s following the success of the programme against skeleton weed, *Chondrilla juncea* L. (Asteraceae) where a plant pathogen was used for the first time globally. By 2014, Australia had or was undertaking 73 programs on weed species or species groups with 271 spp. of agents released (Winston et al. 2014).

The rate of release of new agents peaked in the 1990s and declined significantly after 2000. Reviews in 2005 and 2012 conservatively estimated that of the 58 programmes that are sufficiently complete, 69% have been successful or partially successful against as much environmental as agricultural weeds and for the 36 latter targets economic benefit to Australia been close to $100M a year since 1903 at a benefit-cost ratio of 23:1 (including all unsuccessful programmes) (Page and Lacey 2006; Julien et al. 2012). Very low level of non-target impact have been reported in Australia (Hinz et al., in press). Since 2015, new funding from the Australian government and industry has led to multiple new weed biological control programmes.

d. South Africa

Since 1913, South Africa has established 93 biocontrol agents on 59 species of invasive alien plants. Six of the early South African projects, against four species of cacti, lantana and St. John's wort, were projects based on research and precedents from other countries. Since the late 1960s, South Africa has targeted many weed species that have not been tackled anywhere else in the world, being able to share this knowledge with other countries undertaking weed biological control.

Of the weed species in South Africa on which agents have become successfully established, 23% have been completely controlled (i.e. no other control measures have been needed) and 38% are under substantial biological control (i.e. other control measures may be intermittently or routinely needed, but less effort or expenditure is required than would have been the case in the absence of biocontrol agents). In most cases these benefits have been sustained for decades and will continue to accrue into the future.

There has been a surge in activity (i.e. number of species targeted and biocontrol agents released in recent years with 15 new weed targets in South Africa currently the subject of active research (Moran et al., 2013; Zachariades et al 2017).

D. Plant Pathogens

Plant pathogens have been the target of augmentative biological control in a number of systems (Harman et al., 2004; Haas and Défago, 2005; Pal and Gardener, 2006; Sharma et al., 2009; Bach et al., 2016; Bae et al., 2016; Stirling, 2017). Classical biological control opportunities have been more elusive (Pal and Gardener, 2006).

E. Marine Invaders

Biological control of marine invasive alien species has not been effectively applied although it has been considered. Secord (2003) and Lafferty et al. (1996) have undertaken reviews of the opportunities and the risks.

VI. AN ETHICAL AND SOCIETAL VALUES BASED FRAMEWORK FOR INTEGRATING BIOLOGICAL CONTROL OF IAS INTO BIODIVERSITY CONSERVATION

The introduction of a non-native classical biocontrol agent into a new region, if it establishes, is the introduction of an alien species that is expected to increase in abundance and spread over large areas. This is both an ecologically and ethically significant act. The potential for associated undesirable consequences on the environment, agriculture and society, is in large part the basis of national and international concerns about the practice of classical biological control. The release of a novel biocontrol agent is a special category of alien species introduction that, to be ethically supportable, should be justified by benefits to social values and conservation goals. Human mediated species movements and introductions of invasive alien species to new global regions are perceived by society at large as having significant negative impacts on ecosystem services, societal values and biodiversity. Biological control is a deliberate attempt, in this context, to negate such invasive alien species impacts through the further deliberate introduction of alien species. A perception that classical biological control is potentially pouring fuel on the biological invasions fire creates the ethical dilemma for society. Such actions therefore need to be justified and accepted by society in terms of both: (a) the scale and type of existing invasive species impacts against which classical biological control is being proposed; and (b) the likelihood and consequence of any classical biocontrol agent release of either reversing the impact of the targeted invasive species, or going on to cause any other socially undesirable and unintended impacts. In short, as the concept of invasive alien species and their consequences are accepted and quantified by current societal values and ethics, so the introduction of more alien species, that are also expected to ecologically invade following introduction have to be governed under the same societal values and ethics. Introducing alien species with the expectation that they will spread beyond any capacity for containment is inherently a high-risk action.

Over the past thirty years as environmental awareness and protection have intensified, the practice of classical biological control has, therefore, been the subject of some criticism by conservation scientists and some sectors of society, partly on scientific and partly on ethical grounds. As a consequence, relative to thirty years ago, classical biological control programmes require many more years of careful research and scientific evaluation before an application to release a novel agent is submitted to a regulatory body. Similarly, the regulatory mechanisms and decision-making governance used by countries that undertake classical biological control have become much more complex, risk averse, and evidence-based. Much more so, for example, than the absence of any such processes when the cane toad was released into Australia for the control of sugarcane grubs in the 1935, the less stringent processes that existed before the enactments of environmental protection legislation in most countries from the 1970’s. This section will explain why classical biological control has an ethical dimension and offer an idealized framework to guide the integration of classical biological control with conservation activities.

A. The ethical dimension of classical biological control

Conservation biology and biological control practice are both value-laden sciences. All scientific practice that seeks a social or environmental goal is necessarily ethically laden, meaning that it is oriented toward a social idea (Shrader-Frechette and McCoy, 1993). Both fields claim to act in the public interest, to undertake their work on behalf of the public, and thus to be public interest science. Public interest science is evaluated based on good science but also by its practical accomplishments for society. To a considerable degree, disagreements about the release of classical biocontrol agents are rooted in divergent assumptions about what constitutes the public interest.

The critics of biological control practice, generally from conservation science, have argued against the release of biocontrol agents on the grounds that they pose unwarranted risks, and have expressed their view that needs exist for greater restraint on management actions (Howarth, 1991), and more effective regulatory oversight (Strong and Pemberton, 2000). Biological control scientists have responded that the spread of invasive species and the resultant economic harm and ecological disruption they cause is so great that humans are obligated to take action, including through biological control when appropriate (e.g. Hoddle, 2004). However, most research scientists, practitioners, land managers, and regulatory scientists, of course, hold a pragmatic approach to biological control introductions, especially those who have landscape management responsibilities, since, if effective, classical biological control is both sustainable and cost effective.

Governments (regulatory ministries or agencies) are effectively custodians of the public interest, guided by legislation and legal precedent. Government officials frequently must navigate decision criteria that may be in conflict: societies want the environmental and economic benefits of invasive alien species control but wish to avoid any risk to native biodiversity and beneficial species from introduced agents. Classical biological control projects and permitting of agents for release are caught up in this broader social ambivalence. Better data can address this, but cannot fully resolve it, because different countries and social groups bring different values and assumptions to their understanding of the environment, and to the nature of the public's interest. There is no global norm to public perceptions and values of the harm caused by invasive alien species or the risks associated with biological control, despite the harmonizing processes under international conventions.

A democratic ethic suggests that increasing public participation in decisions that affect the public will result in better outcomes and more support for the substance of the decision itself. Without some expression of public support, a community of scientists cannot legitimately claim to be acting in the public interest, just as an environmental advocacy group needs some expression of public support to claim legitimacy.

Scholars of science policy have articulated a new decision-making framework for relating scientists and their institutions to society at large. Participatory public engagement with science and technology (hereafter shortened to "public engagement") facilitates mutual learning among the public, scientists, and regulatory officials with respect to the development and application of science and technology in modern society (Mooney, 2010). Public engagement is a semi-structured transparent deliberative process that establishes consensus views on evidence, method, interpretation, and social values frameworks as the basis for making a scientifically-informed decision (Rowe & Frewer, 2005). Public engagement processes allow scientists to speak directly about the situation in the environment but requires scientists to communicate environmental conditions and a rationale for any conservation action (involving biological control or not) in terms that can be understood by non-scientists. To effectively guide deliberations about introducing classical biological control as a conservation strategy, public engagement must: (1) foster greater, objective social understanding of the threat invasive species pose to conservation, (2) create greater social consensus on the need to control invasive species and the conditions under which biological control is an appropriate strategy to consider and (3) enhance the public's trust that government agencies are upholding the public's interest through appropriate regulatory review.

Tools from ethics can inform the dialogue of public engagement. Like the natural sciences, the field and status of ethics is neither static nor geographically uniform. As societal values change, so too ethical perspectives evolve. For example, as human caused environmental problems became increasingly evident, concerned individuals formalized a new subfield, environmental ethics. Originally focused on conservation and chemical pollution, environmental ethics now also wrestles with the problems of biodiversity loss, invasive species control, and climate disruption. Concepts from ethics can help analyze the composition and structure of human values, and content of moral arguments, and how these shape human behavior.

Criticism and defense of biological control practice have been made on the grounds of practical ethics. Practical ethics focuses on specific examples of how humans apply – or could apply – ethical values in their decision making. Practical ethics include professional ethics (e.g., how doctors, lawyers, and scientists make decisions). Society has conferred significant decision-making authority to the professions because their members develop specialized, expert knowledge (which makes evaluations by nonmembers difficult). In exchange for significant decision-making autonomy, society expects professionals to internalize a code of ethics of service to society, above and beyond financial compensation. When a professional has to weigh his or her professional responsibilities to society against personal gain, this situation is known as a "conflict of interest." This does not mean that a professional has acted improperly or unethically; it merely means that a professional is faced with a decision in which he or she might have to choose between personal gain and professional duties. Some criticism of biological control practice has been made on the basis of (professional, scientific) ethical conflict of interest. Biological control researchers and practitioners should, therefore, not be put in or find themselves in a public position of biological control advocacy.

B. An idealized ethical framework

The effective integration of classical biological control into conservation practice could be advanced by enhancing pubic engagement and informing this with ethical reasoning. When a government agency creates structured and transparent decision-making framework that supports appropriate democratic participation, conflicts can be avoided and better decisions can result. The following are key elements of a practical ethical framework to improve decision making, informed by principles of public engagement and ethics.

Separation of public advocacy for invasive species control from selection of specific control strategies

Organizations, individuals, communities, or stakeholders should speak to the broader public about the need for controlling an invasive species (see BOX 2). The problem of invasive alien species, first defined as a problem by scientists, needs to be explained to the public, and the public should express some form of consent to tackle this problem before any specific management action is proposed. Without some description of harms caused by invasive species, there is no reason for the public to support the introduction of a novel biocontrol agent.

Transparency of decision-making criteria and processes

Public agencies, stakeholder organizations, and scientists should devise public engagement processes that enhance the capacity of stakeholders to understand science and agency decision making processes. For public engagement to succeed, it must convene a structured co-learning process in which everyone, from critics to supporters, participates in establishing the same scientific information about the invasive species and possible control methods. Public engagement fails if parties have divergent information about the problem and possible remedies. Some public concerns about biological control are founded, at least loosely, on popular conservation concerns such as: (1) is the invasive alien species really a problem, (2) why is it necessary to introduce another organism, (3) what other organisms will the agent attack, and (4) what will the agent do when it consumes all its hosts. These questions touch on scientific, democratic, and ethical concerns. Few non-scientists stakeholders are able to contribute to decision making with the knowledge that they initially bring to such a process, therefore, education of stakeholders is essential to any kind of engagement.

Stakeholders (not researchers) should explain why control (using any means) of the invasive species is in the public's interest

When invasive species cause direct economic harm, those who wish to alleviate that economic harm are potential beneficiaries, such as community groups or conservation groups, or other stakeholders. When invasive alien species cause harm to ecosystem service function or endangered species, organizations must be able to speak on behalf of their conservation. Conservation groups should, ideally, speak on behalf of the public or society at large. Creating greater consensus on the need to take such conservation actions is a critical first step that is fundamental to success. When stakeholders are the advocates, research scientists are not put into a position where they have a conflict of interest, and are thus not vulnerable to criticism.

Stakeholders (not researchers) should present an ecologically-based risk/cost/benefit analysis justifying biological control on conservation rounds

Chemical and mechanical control strategies are easier and cheaper and more immediate than classical biological control in the short run, but when effective, classical biological control is more affordable and sustainable over time. Research projects to determine an appropriate biocontrol agent take many years and funding from public sources, and pose at least some potential risk, even though that risk is usually trivial. Thus, it is the responsibility of stakeholders to advocate for the release of a classical biocontrol agent, and to do this by providing robust research, in advance of any decision, to the public and to governmental bodies. Stakeholders have to, in essence, prosecute the case for the introduction using evidence. For example, in New Zealand, permit applicants articulate an economic justification that makes clear the advantages of biological control over other forms of control to tax payers. Although this appears costly, in practice it appears that this is more than offset by decreased costs and conflicts associated with the actual regulatory decision. Other countries could benefit from this approach, although in most cases, it would mean going beyond what is minimally required by law.

Public agencies should gather stakeholder input on how their criteria apply to a specific permit application

Regulatory agencies are required to develop and maintain expert knowledge to evaluate proposed species introductions, and they are legally authorized to make decisions on behalf of the public. However, they also have the responsibility to share their decision-making criteria with the public, and to explain how they apply that criteria. Regulatory agencies need not consult the public on every regulatory decision. However, the public legitimacy of these ministries (agencies) can be enhanced by inviting members of the public, appropriately vetted and with expertise, to review how a public agency applies its criteria to specific cases.

C. Summary

To determine when it is appropriate to introduce a biocontrol agent requires negotiating conflicting social values. This depends upon excellent scientific data, prudence and good judgment when data are lacking or limiting, but also upon clear eyed ethical analysis, including a shared understanding of the public’s interest in conservation.

Some form of public consent is necessary for the application of public-interest science. To foster sustained public engagement over time, the problem definition of invasive species should be separated from specific management actions, including the solution of a biological control introduction. Fostering social consensus on the need to control the invasive alien species is a pre-requisite for action. Public engagement requires careful attention to devising appropriate roles for stakeholders, and opportunities for public input in decision-making processes. An integrated risk/cost/benefit analysis does a better job of modeling the implications of these management decisions on real world landscapes, and this approach should inform policy and regulatory reform.

BOX 2: EUROPEAN CARP – STORY SO FAR

Introduced into Australian water bodies in the 1800's, European carp were not seen as causing environmental harm until numbers exploded following flooding events in the 1980's, particularly in the Murray Darling Basin in South Eastern Australia. It is now estimated that 80-90% of fish biomass in this river system is carp. While early impacts of this carp invasion were hard to measure beyond reduced aquatic macrophytes and increased water turbidity, evidence has increased significantly that carp cause multiple impacts to the ecosystem services provided by the river system from recreational fishing benefits to impacts on water birds and native fish abundance. A 1998 outbreak of an apparently carp-specific virus in an Israeli aquaculture facility created the opportunity for Australia to consider a virus-based biological control programme to manage carp in a manner similar to that used to control European rabbits from the 1950's (see BOX 1). Cyprinid herpesvirus-3 (CHV-3) was brought into high containment in Australia in the 2000's and host specificity testing undertaken that clearly demonstrates only the immune system of carp recognizes CHV-3 as an infective viral agent (McColl et al., 2017). In 2016 as part of an election promise, the Australian Government made A$15M available to develop the case for whether the virus should be deliberately released into Australian water bodies to control carp. A national carp control plan (NCCP) has been developed (www.carp.gov.au), which involves partnership between government and the fisheries and aquaculture sectors. Any release of CHV-3 will not occur before the end of 2018. The ethics of the biocontrol approach have been widely questioned both nationally and internationally through both the scientific literature (Lighten and van Oosterhout 2017; Marshall et al., 2018) and social media. This case is a good example of the impact of ethics and public values in the perception of a particular biological control programme and the need for a transparent and ethically comprehensive process for the development of the programme. Firstly, Australia has led the way in deliberately released a non-native virus to control an invasive vertebrate species; the highly successful rabbit biological control programme. Australia was also the first country to use pathogens in biological control - the release of a rust fungus which successfully controlled skeleton weed in the 1970's. Most other countries do not practice classical biological control so national experience provides little to support decision-making. Even amongst countries that do practice biological control, the use of pathogens is blocked in some by regulatory processes largely based on a perception (not supported by the scientific evidence) that pathogens are by their very nature higher risk than say arthropods This illustrates that risk perceptions, values and ethics vary widely across jurisdictions in the context of biological control introductions. Varying societal perceptions of risks and potential benefits in countries and individuals, based largely on understanding the scientific knowledge and experience, lead to different positions of acceptability in its use. In the case of the potential use of CHV-3 to control carp, there has been significant international concern about the rigor of the Australian risk assessment, and the likely global impact should Australia proceed. This is in part because CHV is a notifiable aquaculture disease under the World Organisation for Animal Health (OIE). These concerns have been addressed through a highly detailed and evolving Frequently Asked Questions section on the NCCP website and two recent scientific publications directly addressing the scientific concerns (McColl, Sheppard and Barwick, 2017; McColl, Sunarto and Neave, 2018). It was also clear that internationally there is poor understanding of the rigorous regulatory processes involving 4 pieces of legislation that govern any viral release in Australia). Despite this within the Australian community, where the regulatory processes are understood and respected, the safety of the virus is of a much lower concern than the logistics of any cleanup and the risk that the virus will provide only short-term localized carp population suppression. Under the National Carp Control Plan Australia is setting a benchmark for the most publicly explicit and rigorously governed (from science, implementation and communication perspectives) classical biological programme anywhere in the world, starting several years before any application for release has any likelihood of being submitted into the regulatory process and considering issues as diverse as disease humaneness and potential uses of tonnes of dead carp. Clearly some sectors of society and some countries are much more risk averse than others, so proposals such as this provide opportunities to learn from other's experiences rather taking a risk averse stance based on lack of experience in the application of biological control.

VII. EFFECTIVE NATIONAL LEGISLATIVE, POLICY OR REGULATORY FRAMEWORKS

This section describes a range of legislative, policy and regulatory frameworks required for reliably managing the release of biocontrol agents across a range of jurisdictions. These are important to obtain public acceptance and confidence of the management of risks from introduced biocontrol agents (Sheppard et al., 2003).

A. Australia

Australia is the only country to have specific biological control legislation: the Biological Control Act (1984)[20]. The Biological Control Act was the direct consequence of a legal challenge to a particular biological control programme and is aimed to provide some legal protection for government agencies involved in high profile biocontrol agent releases. When it is applied (generally only to cases where the potential for conflicts are evident), targets and agents are declared under the Biological Control Act, leading to a requirement of a public enquiry to consider risks, costs, and benefits. This Act is used for all viral agents for vertebrate control.

Guidelines for the introduction of exotic biocontrol agents for the control of weeds and plant pests[21] define a process for these agent types managed through the National Biosecurity

[20] https://www.legislation.gov.au/Details/C2017C00008

[21] http://www.agriculture.gov.au/biosecurity/risk-analysis/biological-control-agents/protocol_for_biological_control_agents/guidelines-introduction-exotic-bcas-weed-and-plants

Committee (NBC), which includes nominating the weed or feral animal species of interest as a target of biological control, before permission to release a biocontrol agent is sought. As part of the regulatory process for the application to release a biocontrol agent, a risk assessment must be completed showing risks of release are very low or negligible. This is consistent with Australia's appropriate level of protection (ALOP)[22].

Risk assessments are required under the Biosecurity Act 2015[23] regulated by the Department of Agriculture and Water Resources (DAWR) and carried out by research providers, in consultation with scientific specialists and other stakeholders. The core of this assessment is direct non-target risk, based on host-range or host-specificity testing under controlled experimental conditions, which demonstrate beyond reasonable doubt that the proposed biocontrol agent is specific enough to not lead to direct non-target impacts on species on economic importance and/or native to Australia. Such experiments may be undertaken in the native range of the pest/weed or within a suitable Australian quarantine containment facility.

Animal biocontrol agents and agents likely to impact listed threatened and endangered species and communities also considered under the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act)[24], administered by the Department of the Environment and Energy (DEE) as part of the DAWR led process. DEE allows a 'testing permit' to be issued for potential agent importation into appropriate quarantine-approved facilities for risk assessment against Australian native species. The process is managed such that only one release application is prepared for regulatory requirements under both Acts managed by DAWR. From the release application the DAWR consults and prepares a standard import risk analysis used for the approval process through the NBC. This is based on the internationally agreed Pest Risk Assessment process outlined in the process generally aligns with internationally agreed import risk assessment procedures under the International Plant Protection Convention[25]. If approved by NBC a release permit is granted by DAWR while the Minister for the Environment gazettes approval to include the biocontrol agent as a new species on the List of Specimens Taken to be Suitable for Live Import (the live import list).

The regulatory process for the release of a viral agent for vertebrate biological control generally has additional regulatory requirements. This includes (where deemed necessary) a full Environmental Impact Assessment (EIA) under the EPBC Act. This is a much more comprehensive where possible quantitative risk assessment including potential indirect non-target impacts on listed threatened and endangered species and communities. Approval for use is also required through the Australian Pesticides and Veterinary Medicines Authority (APVMA)

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[22] http://www.agriculture.gov.au/market-access-trade/sps

[23] http://www.agriculture.gov.au/biosecurity/legislation/new-biosecurity-legislation

[24] http://www.environment.gov.au/epbc

[25] http://www.agriculture.gov.au/plant/health/international-plant-protection

under the Agricultural and Veterinary Chemicals Code Act 1994 where considered to be a biopesticide. Release permits require broad agreement on the manner to which the biocontrol agents will be released to ensure maximum impact.

B. New Zealand

All biological introductions into New Zealand are regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO)[26]. The legislation is focused on the health and safety of people and the environment. HSNO is implemented by the Environmental Protection Authority (EPA), a quasi-judicial body of 6–8 people appointed by the Minister for the Environment. Under these standards, the Authority must decline the application if the new organism is likely to:

(a) Cause any significant displacement of any native species within its natural habitat; or

(b) Cause any significant deterioration of natural habitats; or

(c) Cause any significant adverse effects on human health and safety; or

(d) Cause any significant adverse effect to New Zealand's inherent genetic diversity; or

(e) Cause disease, be parasitic, or become a vector for human, animal or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.

Approvals to import candidate biocontrol agents into containment are required from both the EPA and the Ministry of Primary Industries (MPI), but can be generic at the institutional level where approved quarantine facilities exist. Obtaining MPI approvals to import organisms into containment facilities is usually straight forward, provided the candidate agent is not on a list of unwanted organisms.

The EPA reviews biocontrol agent release applications, which include a risk assessment along EPA guidelines. These are made available for public comment and EPA also reviews the associated public submissions before making a decision by evaluating risks, costs, and benefits of introducing the agent. For biocontrol agents, the emphasis is mainly upon (a), (b), and (d). The process has a set time frame and decisions must be made within 100 working days of the formal receipt of an application to release a weed biocontrol agent. Once approval to release a candidate agent has been obtained from the EPA, additional approval is required from the MPI, prior to an agent being released from containment. This approval is contingent upon providing evidence that the agent species has been correctly identified and that the culture is free from disease.

[26] http://www.legislation.govt.nz/act/public/1996/0030/96.0/DLM381222.html

C. South Africa

The introduction and release of biocontrol agents in South Africa is subject to the Agricultural Pests Act, No. 36 (1983)[27], which is administered by the Department of Agriculture, Forestry and Fisheries (DAFF) and the National Environmental Management Biodiversity Act (NEMBA), No. 24 (2004)[28], administered by the Department of Environmental Affairs (DEA). The Agricultural Pests Act, which is aimed primarily at preventing and combating agricultural pests, stipulates that controlled goods, including all plants, pathogens and insects, may be imported into the country only on the authority of a permit. The Act also provides a mandate for biological control by making provision for the importation of non-indigenous pathogens or insects for the purpose of combating undesirable plants, pathogens, insects or exotic animals. The regulatory process for the import and release of biocontrol agents by DAFF is in accordance with the IPPC and the relevant International Standards for Phytosanitary Measures developed by the Food and Agriculture Organisation (FAO) of the United Nations.

The process of issuing a release permit requires the applicant to provide specific information on the target weed; the candidate biocontrol agent and the envisaged research; as well as a prediction on the potential impact of the biocontrol agent on the environment. Import permits for candidate biocontrol agents are issued by DAFF subject to the requirement that the candidate agents be confined to an approved quarantine facility. During that period, the biology, behaviour and host range of the candidate agents are examined, together with any other aspects (e.g. impact on the target weed in the laboratory) necessary to convince the decision makers of their safety for release into the environment. A comprehensive report is then submitted to DAFF, which incorporates the results of quarantine trials, and sometimes field surveys in the native range of the agents, as well as information obtained from the literature. Based on this report, the Bio-control Release Application Review committee takes the decision whether or not to authorize the release of the biocontrol agent into the environment. Since 1993, each application submitted in terms of the Agricultural Pest Act, was submitted to three independent reviewers, who provide recommendations to the committee.

The NEMBA provides for the management and conservation of South Africa's biodiversity within the NEMBA framework. Chapter 5 of NEMBA addresses issues that deals with alien species and organisms that pose a potential threat to biodiversity. This chapter is also supported by the Alien Invasive Species (AIS) Regulations, 2014[29]. The AIS Regulations are

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[27] www.nda.agric.za/docs/NPPOZA/Agricultural%20Pests%20Act.pdf

[28] https://www.environment.gov.za/sites/default/files/legislations/nema_amendment_act10.pdf

[29]

https://www.environment.gov.za/sites/default/files/legislations/nemba10of2004_alienandinvasive_speciesregulations.pdf.

aimed at preventing the introduction of more species that may be potentially invasive in the country, as a first priority. The *Bio-control Release Application Review Committee*, has representatives from DAFF (both agriculture and forestry), DEA, private consultants (experts in Invasive Alien Plants (IAP) and insect biological control), and the Forestry and Agricultural Biotechnology Institute. Protocols were drawn up, including a standard application format and guidelines (which request the applicant to consider, inter alia, the need for biological control for the IAP; the identity, safety and potential efficacy of the candidate agent; a proposed release strategy: possible ecological effects its release would have; and plans for post-release mitigation, if needed) as well as a standard review format and guidelines. A list of potential expert external reviewers, at both national and international levels, was compiled (including IAP and insect biological control experts, entomologists, pathologists, botanists and others). For each application, the committee solicits voluntary reviews from three experts (usually two national and one international reviewer for each application), with a timeline of four weeks. The reports from these experts are then read and discussed by the committee members, either over e-mail or more commonly at a meeting, and a recommendation is passed from the committee to DAFF. DAFF then either issues a release permit or passes on the committee's recommendation for further information, which may require either a desktop study/response, or further host range testing or other work. This process has enabled the release of a number of new agents in the past three years.

D. Canada

Organisms used as biocontrol agents are regulated under the Plant Protection Act (1990)[30] and the Pest Control Products Act (2002)[31] (Mason et al., 2013). Under these Acts biocontrol agents introduced for classical biological control, inundative biological control, including commercial products, and formulated microbial-based biopesticides are regulated to ensure safety or quality. Introduction of classical biocontrol agents may also be regulated under one or more Provincial Acts.

Submissions made to the Canadian Food Inspection Agency (CFIA) for invertebrate biocontrol agents are reviewed by an arms-length committee, the Biological Control Review Committee (BCRC) (Mason et al., 2017[32]). The information contained in the submission includes a statement of the proposed action and rationale, target pest information, biocontrol agent information, host-specificity test methods and results, environmental and economic impacts of the proposed release, pre-release compliance and a plan for post-release monitoring. A submission is sent to the CFIA who forward it to the BCRC with a request to conduct a review.

[30] http://laws-lois.justice.gc.ca/eng/acts/P-14.8/

[31] http://laws-lois.justice.gc.ca/eng/acts/P-9.01/

[32] http://www.publications.gc.ca/site/eng/9.843006/publication.html

Individual reviews are done by scientists with expertise in taxonomy, ecology and biological control, and specialists at the Pest Management Regulatory Agency and CFIA. The comments are summarized and a recommendation is provided to the CFIA Plant Health Directorate where a final decision is made. The Director of the Plant Health Directorate informs the applicant in writing of the CFIA's decision. The process and requirements for importing and handling of biocontrol agents are included in the CFIA's Plant Protection Directive D-12-02: Import Requirements for Potentially Injurious Organisms to Prevent the Importation of Plant Peats in Canada[33].

The petition process is not required for biocontrol agents from commercial sources that have already been approved by the CFIA as listed in Section 5 of Appendix 1 to D-12-02. While permits issued by the CFIA may include risk mitigating conditions (e.g., regarding source, identification and monitoring), movement within Canada of approved and released agents is not restricted. However, movement may be subject to restrictions under Provincial Acts..

E. United States of America

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine (PPQ) regulates biological control organisms based on the Plant Protection Act of 2000[34] (Mason et al., 2005; TAG, 2014). This legislation provides APHIS with the authority to regulate organisms that may directly or indirectly harm plants or plant products. The Plant Protection Act broadly defines biocontrol agents and recognizes their potential to control plant pests. APHIS is authorized to regulate the importation, interstate movement and environmental release of biocontrol agents, and this is done by issuing permits. APHIS may deregulate the interstate movement and environmental release of those agents that they have determined not to be plant pests. Any federal agency actions by APHIS, such as issuing permits, are subject to the Endangered Species Act (1973)[35] and the National Environmental Policy Act (1970) (NEPA)[36], which requires review of an intended action (i.e. to grant a permit to release a biocontrol agent) to determine if it will have an adverse effect on a listed Threatened or Endangered species, or significant impact in the environment, respectively.

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[33] http://inspection.gc.ca/plants/plant-pests-invasive-species/biological-control-agents/eng/1514956211166/1514956212112

[34] https://webcache.googleusercontent.com/search?q=cache:JZb8i5kTONcJ:https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/PPAText.pdf+&cd=4&hl=en&ct=clnk&gl=au&client=firefox-b

[35] https://www.epa.gov/laws-regulations/summary-endangered-species-act

[36] https://www.epa.gov/nepa

Once APHIS issues a permit individual States may require their own permits under State laws and regulations.

In the United States, submissions are made to the USDA-APHIS-PPQ. In the case of phytophagous invertebrate biocontrol agents the petition is sent to the Executive Secretary of the *Technical Advisory Group* (TAG) who then forwards it to TAG members for comment. The TAG Chair reviews the comments and makes a recommendation that is sent to USDA-APHIS-PPQ for a decision and communication with authors of the petition of the recommendation and next steps. These include an impact assessment required by the NEPA and, depending on that outcome, possible further assessment under the Endangered Species Act. Once these steps are completed USDA-APHIS-PPQ communicates a final decision to the petitioners. In the case of entomophagous invertebrate biocontrol agents the petition is sent to an independent body for comment. The recommendation from that group is sent to USDA-APHIS-PPQ for further action and communication of a final decision, as for phytophagous invertebrate biocontrol agents.

F. Mexico

In Mexico, biocontrol agents are regulated by Sanidad Vegetal (Ministry of Agriculture) under the authority of the Plant and Animal Health Act (1980) of the Mexican States. Sanidad Vegetal authorizes the introduction of exotic arthropod species or the mass production of arthropods in insectaries, for use in the biological control of pests, according to requirements in Articles 101 and 102. As part of the importation requirements, the organisms must be accompanied by a certificate of biological purity and a certificate of origin provided by the phytosanitary authorities of country exporting the biocontrol agent. The permit is granted for one year and is renewable.

In Mexico, submissions are made to the General Director of Sanidad Vegetal. Submissions are sent by the General Director's office to the National Committee for Biological Control Review (NCBCR) which is responsible to conduct review of the submissions. The NCBCR may consult with the National Consultative Phytosanitary Advisory Group (NCPAG) which is composed of professionals from academia, government and research organizations. The General Director of Sanidad Vegetal informs the applicant in writing of the NCBCR decision.

G. Kenya

The Kenya Standing Technical Committee for Imports and Exports (KSTCIE) operates under the Plant Protection Act 2012 (1937)[37], and is responsible for regulation of the importation of all crop protection agents including exotic biocontrol agents and biopesticides (Songa, 2004). The

[37] http://extwprlegs1.fao.org/docs/pdf/ken18403.pdf.

Committee covers crop protection agents for scientific research needs, education or commercial production within the framework of the law. The regulations for biocontrol agents and biopesticides are based on, and in compliance with, the ISPM 3 (IPPC, 2017a) (see Section VIII A). However, a process of guiding the introduction of biocontrol agents was already in place and ratified before ISPM 3, but the development of ISPM 3 provided Kenya the means to validate the national process and add detail to procedures (Kairo et al., 2003). Applications for the introduction of any agent or product are made to the KSTCIE upon which the Committee then advises on the needs for dossier on the agent/product and the containment facilities planned. These documents are then reviewed by the Kenya Plant Inspectorate Service (KEPHIS) in line with the national regulations. If approved, an import permit is issued. Some of the criteria used in the review are: evidence of the successful use of the biocontrol agent in other countries; the specificity of the agent; a thorough risk assessment; and a risk management plan with control options.

An additional application has to be made by the importer for field releases.

VIII. EXISTING INTERNATIONAL REGULATORY FRAMEWORKS FOR CLASSICAL BIOLOGICAL CONTROL

This section outlines the internationally agreed regulatory frameworks that exist and their relevance and application in the context of classical biological control programmes. Under the CBD, voluntary guidance on introduction of alien species has been adopted by the Conference of the Parties[38], referring to existing international standards.

This section identifies relevant gaps in such frameworks where they exist. Countries in North America have also worked together under the North American Plant Protection Organisation (NAPPO) to take a regional (continental) approach to collectively manage biological control programme release activities that affect multiple jurisdictions. The way the NAPPO operates in this context is also described. Finally, this section covers international cost-benefit sharing agreements around the use of biodiversity and the implications of these for the practice on classical biological control.

[38] The Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Alien Species that Threaten Ecosystems, Habitats or Species. https://www.cbd.int/decision/cop/?id=7197 ; The Guidance on Devising and Implementing Measures to Address the Risks Associated with the Introduction of Alien Species as Pets, Aquarium and Terrarium Species, and as Live Bait and Live Food https://www.cbd.int/decision/cop/default.shtml?id=13379 ; and Summary of Technical Considerations for the Use of Biological Control Agents to Manage Invasive Alien Species https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-13-en.pdf .

A. International Standards for Phytosanitary Measures

The International Plant Protection Convention (IPPC) is aimed at protecting cultivated and native plants by preventing the introduction and spread of pests, the Commission on Phytosanitary Measures (CPM) develops and adopts International Standards for Phytosanitary Measures (ISPMs). International standards, guidelines or recommendations developed by the IPPC are recognized by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) as the basis for phytosanitary measures to apply in trade. The relevant standards for the application of a classical biological control programme are described below. Other ISPMs may be relevant and should be taken into consideration as they relate to biocontrol agents and other beneficial organisms. Adopted ISPMs are publicly available[39].

ISPM 2 "*Framework for Pest Risk Analysis*" adopted 2007 (IPPC, 2016a)

IPSM 2 provides countries with a framework describing the Pest Risk Analysis (PRA) process within the scope of the IPPC. It introduces the three stages of the PRA process (initiation, pest risk assessment and pest risk management) with an emphasis on the initiation stage. The PRA process is a technical tool used for identifying appropriate phytosanitary measures and it may be used for organisms not previously recognized as pests, including biocontrol agents and other beneficial organisms, but also for recognized pests, pathways and review of phytosanitary policy. This ISPM provides detailed guidance on the first stage of the PRA process, the initiation, and it summarizes the other stages and issues relevant to the entire PRA process. Once the initiation stage has been completed, the provisions included in ISPM 11.

ISPM 11 "*Pest Risk Analysis for Quarantine Pests*" adopted 2013 (IPPC, 2017b)

ISPM 11 should be used as a basis of risk assessment, as this standard provides detailed information on the integrated processes of Pest Risk Analysis (PRA) to be used for risk assessment and the selection of risk management options. This standard also includes provisions for pest risk assessment in relation to environmental risks and concerns related to the use of biocontrol agents. Australia uses PRA as the basis of its import risk assessment for biocontrol agents.

ISPM 3 "*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*" adopted 2005 (IPPC, 2017a)

ISPM 3 provides phytosanitary measures applicable for safe use of biocontrol agents and other beneficial organisms these organisms. It outlines the related responsibilities of contracting parties to the IPPC, National Plant Protection Organizations (NPPOs – specific to each jurisdiction) or other responsible authorities, importers and exporters. The standard covers biocontrol agents for pests of plants but also agents for the control of major weeds. The

[39] https://www.ippc.int/en/core-activities/standards-setting/ispms/

biocontrol agents covered are capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects used under SIT (sterile insect technique) for insect pest management (fruit flies, codling moth etc.) and other beneficial organisms (such as mycorrhizae and pollinators), and includes those packaged or formulated as commercial products. Some Regional Plant Protection Organizations (RPPO) have used ISPM 3 as a basis for specific guidelines for biological control introductions relating to the region concerned e.g. NAPPO Regional Standards for Pest Management 7,12 and 26 (NAPPO 2015a; 2015b; 2015c). Overall, ISPM 3 has provided a framework for formalizing good practice and given guidance on international standards to countries with little or no experience of biological control (Kairo et al., 2003).

Some guidelines included in the standard extend beyond the scope and provisions of the IPPC. For example, although the primary context of this standard relates to phytosanitary concerns, "safe" usage as mentioned in the standard is intended to be interpreted in a broader sense, i.e. minimizing other non-phytosanitary negative effects. Phytosanitary concerns may include the possibility that newly introduced biocontrol agents may primarily affect other non-target organisms, but thereby result in harmful effects on plant species, or plant health in habitats or ecosystems.

Under ISPM 3 each NPPO or other responsible authority) should:

(a) Carry out pest risk analysis prior to import or release of biocontrol agents and other beneficial organisms;
(b) Ensure, when certifying exports, that the regulations of importing countries are complied with;
(c) Provide and assess documentation as appropriate, relevant to the export, shipment, import or release of biocontrol agents and other beneficial organisms;
(d) Ensure that biocontrol agents and other beneficial organisms are taken either directly to designated quarantine facilities or, if appropriate, passed to mass rearing facilities or directly for release into the environment;
(e) Ensure that importers and, where appropriate, exporters meet their responsibilities
(f) Consider possible impacts on the environment, such as impacts on non-target invertebrates.

Further to the above, the NPPO or other responsible authority should maintain communication and, where appropriate, coordinate with relevant parties including other NPPOs or relevant authorities on:

(a) Characteristics of biocontrol agent and other beneficial organisms
(b) Assessment of risks including environmental risks;
(c) Labelling, packaging and storage during shipment;
(d) Dispatch and handling procedures;
(e) Distribution and trade;

(f) Release;
(g) Evaluation of performance;
(h) Information exchange;
(i) Occurrence of unexpected and/or harmful incidents, including remedial action taken.

In addition to the above, ISPM 3 indicates that the NPPOs or other responsible authority should implement the following measures:

(a) Quarantine of the cultured or reared biocontrol agents, for as long as considered necessary.
(b) Preserving specimens of the biocontrol agents and their targeted species;
(c) Documentary that are necessary for importing of biocontrol agents;
(d) Documentary on potential hazards and contingency plan related to biocontrol agents;
(e) Documentary related to researches in quarantine;
(f) Communication with local users, suppliers and neighboring countries on the risk;
(g) Authorization of release and monitoring on the impacts and evaluation of efficacy, if needed conducting emergency actions;
(h) Reporting to the International Plant Protection Convention Secretariat.

It is important to note that the scope of ISPM 3 does not include living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control. The practical implementation of ISPM 3 is covered in the next section.

ISPM 6 "*Guidelines for surveillance*" adopted in 1997 (IPPC, 2016b)

ISPM 6 describes the components of survey and monitoring systems for the purpose of pest detection and the supply of information for use in pest risk analyses and preparation of pest lists.

ISPM 20 *"Guidelines for a phytosanitary import regulatory system"* (IPPC, 2017c)

ISPM 20 indicates that contracting parties may make special provision for the import of biocontrol agents and other beneficial organisms for scientific research, and that such imports may be authorized subject to the provision of adequate safeguards. When non-phytosanitary risks are identified, these may need to be referred to other appropriate authorities for possible action. This implies that addressing the risk that are not of phytosanitary concerns may need to be backed up by a different authority, such as environment protection authority.

B. Application ISPM 3 and associated ISPMs for the use of classical biological control against invasive alien species

Under ISPM 3, undertaking a pest risk assessment is required to evaluate a biocontrol agent or beneficial organism for its potential as a pest. This should be applied in accordance with stage 2 of the Pest Risk Analysis (PRA) process (ISPM 2, IPPC, 2016a; ISPM 11, IPPC, 2017b).

Consideration should be given to uncertainties and potential environmental consequences, as provided for in those standards. Phytosanitary concerns may include the possibility that newly introduced biocontrol agents may affect other non-target organisms, and thereby result in harmful effects on non-target plant and animal species, or plant health in habitats or ecosystems. With regard to the potential environmental risks, available expertise, instruments and work in international fora with competence in the area of risks to the environment should be taken into account, as appropriate.

In assessing the pest risk (the risk of a biocontrol agent becoming harmful for non-target organisms) of biocontrol agents against invasive alien species, importing countries may require broader risk assessment than the one for agricultural pest risk assessment in order to cover the risks:

(a) On non-target vertebrate species (fishes, amphibians, reptiles, birds and mammals) as phytosanitary measures intend to protect plants and ISPM 3 stipulates that non-target organisms in the environment are such as invertebrates;
(b) On habitats or ecosystems (Although ISPM 11 considers the risk posed to the environment, the assessment of ecological impact on the longer term still remains in the expertise of assessors);
(c) On ecological integrity that are not only with direct impact by the biocontrol agent but also with climate and landscape changes in some complexed manner;
(d) Related to the negative impact posed by biocontrol agents that are native to the country. Regarding the use of native species as biocontrol agents, ISPM 3 considers only the risks posed by contaminated organisms and risk assessment on the environment is exemplified.

Often a PRA cannot be undertaken prior to import (ISPM 2 and 11). In such cases it should be undertaken prior to release, generally with an appropriately accredited quarantine facility, taking into account uncertainties, as provided for in those standards. The Australian government undertakes a pre-release risk analysis of proposed biocontrol agents under its import risk assessment responsibilities, which is built on the IPPC PRA process.

As also described in ISPM 3 (IPPC, 2017a) the role and responsibility of the NPPO (or other responsible authority) are core part of the risk management of biocontrol agents at the national level and where there are risks of across jurisdictional movement of released biocontrol agents.

Prior to release of an organism, NPPOs or other responsible authorities are encouraged to communicate details of the intended release that may affect neighboring countries. To facilitate information sharing in this manner, details of intended releases may also be communicated to relevant Regional Plant Protection Organizations (RPPOs) prior to release.

C. *RSPMs of the North American Plant Protection Organization (NAPPO) and how they are being implemented*

Costs to conduct the research needed to provide the required information in support of approval/registration are high, thus harmonization with other jurisdictions is strongly encouraged, not only to offset costs, but to strengthen the assurance of biocontrol agent safety while hastening their entry into the market as alternatives to synthetic pesticides. Harmonization of information requirements for invertebrate biocontrol agents has been achieved through the North American Plant Protection Organization (NAPPO).

Information requirements for invertebrate biocontrol agents in North America (Canada, United States and Mexico) have been developed by the NAPPO Biological Control Expert Group which includes members from the regulatory and research arms of Canada, Mexico and the United States, and representatives of the commercial biological control industry. These regional requirements are based on standards of the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization of the United Nations, in particular ISPM 3 (IPPC, 2017a). The NAPPO requirements are outlined in two Regional Standards for Phytosanitary Measures (RSPMs), RSPM 7 "*Guidelines for Petition for "First Release of Non-indigenous Phytophagous or Phytopathogenic Biological Control Agents"* (NAPPO, 2015a), and RSPM 12 "*Guidelines for Petition for First Release of Nonindigenous Entomophagous Biological Control Agents"* (NAPPO, 2015b). As well, RSPM 26 "*Certification of commercial arthropod biological control agents or non-Apis pollinators moving into NAPPO member countries"* (NAPPO, 2015c) has been developed with industry participation. The NAPPO RSPMs outline the minimum information required for a submission to a regulatory agency. Each country may have additional requirements that must be included in a submission.

In the NAPPO region, although each member country has its own review panel, experts from all countries are consulted and recommendations are exchanged among the national regulatory authorities. For example, recommendations from the Canadian Biological Control Review Committee are considered by USDA-APHIS when making decisions on release of invertebrate biocontrol agents.

D. *Gaps in frameworks*

Several gaps exist in existing ISPM guidelines. The scope of ISPM 3 (IPPC, 2017a) does not include living genetically modified organisms or issues related to registration of biopesticides for the control of plant pests. These types of organisms are generally regulated under separate legislation to phytosanitary legislation in most jurisdictions. Certain types of biocontrol agents e.g. pathogens may require consideration under regulatory requirements for chemical pesticides and other hazardous substances. Some countries that regularly use pathogens to undertake biological control programmes (e.g. Australia), do not consider some pathogen

biocontrol agents (e.g. plant fungal pathogens) as requiring this type of regulation as it is generally ill adapted to the use of self-reproducing live biocontrol agents.
Existing guidelines have generally been developed for agents for the control of arthropod pests and weeds of crops and the protection of the natural environment against these in terrestrial systems from invasive alien species.

With any risk of trans-boundary movement of alien species between jurisdictions, World Trade Organization trade facilitation rules also apply. These apply in the context of the potential of commodity contamination by the released biocontrol agents and the degree to which this could disrupt biosecurity regulated free trade agreements and importing countries Appropriate Levels of Protection (ALoP). The application of ISPM 3 guidelines to one region does not mean that the outcomes will be mutually acceptable to a region occupied by a trading partner.

Where biological control has also been considered against vertebrate pests or has been proposed to include the protection of marine ecosystems against invasive invertebrates the ISPMs are less relevant. The use of biological control for vertebrate invasive alien species (pests) has focused on microbial agents – viruses (e.g. successful biological control of European rabbits and proposed biological control of European carp in Australia). In marine systems, biological control has been considered and /or researched for the management of several invasive invertebrate species; for example the use of bacteria for the control of the atlantic comb jelly, *Mnemiopsis leidyi* A. Agassiz (Bolinopsidae), in the Mediterranean region (Richardson et al., 2009).

There are currently no international guidelines that cover the use of microbial agents for the control of either of these groups of invasive alien species. Australia has developed a national process for the consideration of viruses for the control of invasive vertebrate pests that could be more widely considered.

A broader application of classical biological control to new groups of invasive alien species with particular biological characteristics and different potential biocontrol agent types with associated potential environmental benefits and risks (i.e. to vertebrates and marine invertebrates), highlight the need for current guidelines to be extended to factor in any additional risks and procedures to facilitate the safe use of microbial (and other potential) agents for these invasive alien species. Clearly however this is out of scope for the IPPC, but could come under the auspices of the Convention on Biological Diversity[40].

E. Access and benefit-sharing regulations

[40] Annex I to recommendation 22/8 of the Subsidiary Body on Scientific, Technical and Technological Advice to be considered by the Conference of the Parties at its 14th meeting

The Convention on Biological Diversity (CBD) was setup to address two globally important issues; the conservation of biodiversity and the access and benefit sharing (ABS) of biodiversity across jurisdictions. To achieve the latter, agreements under the article 15 of the Convention and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* [41] were put in place. The Nagoya Protocol is a supplementary agreement to the CBD that provides a framework for the effective implementation of the fair and equitable sharing of benefits arising out of the utilization of genetic resources (Secretariat of the Convention on Biological Diversity, 2011). Jurisdictions that are party to the agreement must develop a legal framework to ensure that benefits that arise from sharing of their native genetic resources are shared equally among their citizens. Legally this applies from the date of jurisdictional ratification of the CBD.

Classical biological control makes use of genetic resources from one jurisdiction (provider) where an invasive alien species originates to assist control of that species in the invaded jurisdiction (recipient). Sourcing invertebrate and microbial biocontrol agents from the provider jurisdiction by the recipient jurisdiction therefore falls under this Protocol. Mutually acceptable trans-boundary movement of alien organisms, such as biocontrol agents, require this legal framework and appropriate national legislation to regulate such movements. When sourcing the biocontrol agents even from non-signatory jurisdictions, provider jurisdiction export permits and recipient jurisdiction phytosanitary and import permits are the minimum basis of transboundary movement.

Since countries started to practice classical biological control over 100 years ago, at least 7,000 introductions of biocontrol agents involving almost 2,700 species have already been made worldwide to date. The most widely used biocontrol agents have been introduced into more than 50 countries. Biocontrol agents from 119 different countries of origin have been introduced into 146 different recipient countries. A national or international research institute usually carries out the research. Biological control practices have traditionally not applied intellectual property rights to regulate access to, or use of, classical biocontrol agents. It has usually made good practical sense to collaborate with a research organisation in a (potential) source country, and as the need for more detailed risk and environmental impact assessment studies has grown, the need for collaborative research in the source country has grown. In the past, biological control has relied on the free multilateral exchange of genetic resources among providers and recipients and this practice has resulted in major public benefits to the global community (Cock et al., 2010).

Under the Nagoya Protocol formal agreements must be negotiated between jurisdictions for the use of genetic resources, such as for biological control (Mason et al., 2018). Implications for the provider may include:

[41] https://www.cbd.int/abs/; https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf; https://www.cbd.int/abs/about/;

(a) an obligation to develop a legal framework that will ensure access to its native biodiversity will provide benefits to its people;
(b) designation of a competent authority to negotiate with recipients on what benefits are appropriate for a particular biocontrol agent(s);
(c) implementing a process in which Mutually Agreed Terms (MAT) can be negotiated between itself (provider) and the recipient;
(d) allowing access to the biocontrol agents, respecting what is in the MAT;
(e) ensuring that the benefits derived from providing the biocontrol agents are shared among its people.

Implications for the recipient may include:

(a) requesting access to the biocontrol agents through Prior Informed Consent (PIC);
(b) defining the benefits to the provider that access to BCAs that may be derived from it;
(c) negotiating the MAT with the designated ABS authority;
(d) providing the benefits agreed to in the MAT;
(e) respecting the conditions of use of the biocontrol agent(s) as outlined in the MAT.

The Nagoya Protocol provides a new access and benefit sharing global framework. However, its adoption also introduced a potential for difficulty for biodiversity research and the research required to undertake biological control programmes. Some recent jurisdictional interpretations of CBD principles under the Nagoya Protocol, have become increasingly restrictive under national legislation or the application of associated regulations including phytosanitary regulations[42]. Some evidence shows that it has become more difficult to export biodiversity for taxonomic research (Prathapan et al., 2018) and export natural enemies as potential biocontrol agents from some countries (Cock et al., 2010). In the latter context, this has delayed export permits, subsequent testing and release of biocontrol agent species and potential environmental benefits in countries affected by the target invasive alien species that are native to those countries. Given that there is now global consensus (including among CBD Parties) that biodiversity of all countries are now under significant threat from invasive alien species, it will be critically important that this issue is addressed within relevant national legal frameworks under the Nagoya Protocol, as classical biological control is increasingly recognised as a proven tool for managing some internationally important invasive alien species. Without this, some mutual country, regional and global benefits from biological control of environmentally significant invasive species cannot be delivered and sustained.

To provide guidance to biological control practitioners and support due diligence the International Organization for Biological Control's Global Commission on Access and Benefit Sharing developed guidelines for Best Practice to facilitate continued free exchange and use of

[42] https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/other%20organizations/IOBC/iasem-org-iobc-bio-01-en.doc

invertebrate biocontrol agents[43] (Mason et al., 2018). These guidelines include the following recommendations:

(a) cross-jurisdictional collaborations to facilitate information exchange including the biocontrol agents that are available and where they may be obtained;
(b) knowledge sharing through freely available databases documenting biocontrol agent successes (and failures);
(c) cooperative research to develop capacity in provider jurisdictions; and
(d) transfer of biocontrol agent production technology to provide opportunities for small-scale economic activity.

IX. EXPERT REVIEWS OF BIOLOGICAL CONTROLS REGARDING NON-TARGET IMPACTS

Several intentional historic deliberate introductions of polyphagous predators for classical biological control purposes, such as the cane toad into Australia, or the rosy wolf snail, *Euglandina rosea* (Spiraxidae), have suggested catastrophic direct effects on biodiversity (Cowie, 2001; Shine, 2010). While the impacts of predatory snails on Hawaiian native snails remains a classic case of biological control direct non-target impacts on native species, the ecological impacts of cane toads seem to have been over-estimated or at least have declined over time (Brown and Shine, 2016; Taylor et al., 2017). It is important therefore to consider that any observed non-target impacts may be strongest during the early phases post-introduction when populations can reach levels well above equilibrium densities, increasing the strength of species interactions (Holt and Hochberg, 2001), but such effects may be temporary. This section reviews the evidence for direct and indirect non-target impacts from released biocontrol agents (Hajek et al., 2016).

A. Direct non-target impacts

The risk of direct effects on organisms related to the target pest has received by far the most attention in the scientific literature (White et al., 2006; Hajek et al., 2016). Classic historical arthropod biological control examples include a) the tachinid fly *Bessa remota* (Aldrich) (Tachinidae), suggested to have caused the extinction in Fiji of not only the target coconut moth, *Levuana iridescens* Bethune-Baker (Zygaenidae), but also of a related non-target native moth *Heteropan dolens* Druce (Zygaenidae) (Kuris, 2003) and b) the parasitic fly, *Compsilura concinnata* (Meigen) (Tachinidae), introduced to USA to control the gypsy moth, *Lymantria dispar* (L.) (Erebidae) more than 100 years ago (Boettner et al., 2000), but also controlled another pest, the brown-tail moth, *Euproctis chrysorrhoea* (L.) (Erebidae). A recent assessment considers that, without a comprehensive survey, the tachinid fly case cannot be verified

(Hoddle 2006). *Compsilura concinnata* has since been found attacking a wide range o/f hosts and was clearly just not specific (Elkinton and Boettner, 2012).

The two best-known recent examples of non-target impacts from arthropod biocontrol agents are ladybirds, the multicolored Asian ladybird beetle, *Harmonia axyridis* (Pallas) (Coccinellidae) (Koch, 2003, See Figure IX.1) and the seven spotted ladybird, *Coccinella septempunctata* (L.) (Coccinellidae) introduced against aphids in various parts of the world. These species have caused declines not only of aphids but also of other aphidophagous species, in particular other coccinellids (Evans, 2004; Roy et al., 2012). Whether the declines are caused by competition or predation is less clear and in some areas, these species got in accidentally rather than as deliberately released biocontrol agents (Roy et al., 2012).

Over the last 30 years apparent non-target effects from arthropod pest biocontrol agents have contributed to a declining use of classical biological control to control pest arthropods. However in an early review, Lynch and Thomas, (2000) found non-target effects in the classical biological control of insect pests only made up 1.7% (87) of all documented cases of introductions where there was some effect. Most of the reported effects were minor: 17 led

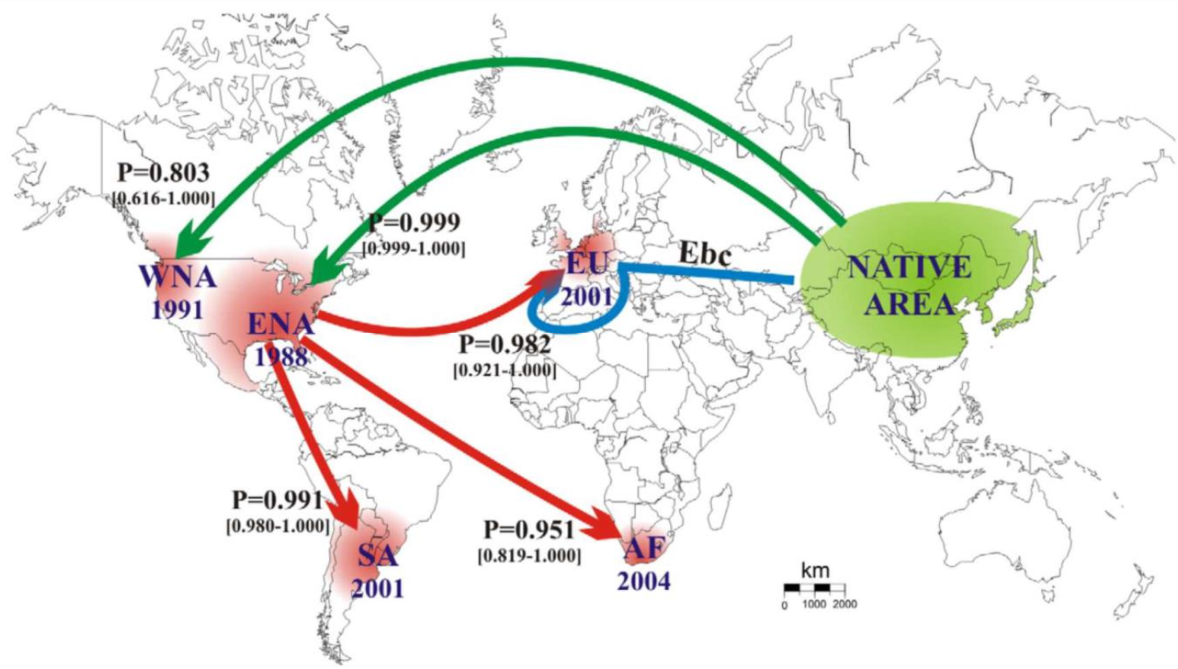

Figure IX.1 Spread of *Harmonia axyridis* (Lombaert et al. 2010)

to population reductions (or effects of similar severity); and only one case of an alleged extinction was found but the supporting evidence was poor. The authors do highlight that their data set may not reflect a complete picture with some effects underreported. This is particularly true of early classical biological control releases which were generally more polyphagous. Low impacts are, however, consistent with the fact that there are no native arthropods considered to have been negatively impacted by biocontrol agents in the IUCN Red data list of threatened species (Collen et al. 2012). Other reviews support the view non-target suppression of native species populations by released biocontrol agents are rare given the number of arthropod agents introduced (van Lenteren et al., 2006a, b; Parry, 2008; Kenis et al., 2009; Hajek et al., 2016).

A new recent review has been made to globally summarize all known direct non-target impacts from weed biocontrol agents deliberately introduced (Hinz et al., in press). Of 457 agents intentionally released until 2008, 60 (13.1%) have been recorded attacking non-target species in the field. Of 1,517 releases made using the 457 agent species, 122 (8.0%) resulted in non-target impacts. Both proportions have declined over time. Of the 457 agents, 67 (14.7%) spread naturally or were accidentally moved to other countries, and of these, 14 (20.9%) have caused non-target impacts. The number of agents and releases with non-target impacts per country/geographic region increased with the total number of agents released or releases made in that country/geographic region. Weed biocontrol programs in Australia have resulted in a lower than average level of non-target impacts. Three quarters of all non-target impacts cases occurred on plant species in the same family as the target weed. Approximately half of non-target impacts cases were predicted or predictable. In the majority of unpredicted cases (93.5%), the respective non-target plant species had not been tested pre-release. There were only four cases of 'false negatives' (< 1%), where the impacted plant species had been tested pre-release and deemed not at risk. As a measure of persistence and severity of non-target impacts, we distinguished between collateral damage (nibbling on non-target species in a different family than the target after mass outbreaks), spillover (temporally and spatially restricted development on non-targets) and sustained attack (persistent with potential negative effects on the population growth rate of non-targets). Of all non-target impacts cases, 43.9% were spillover, 32.6% sustained damage, and 14.4% were collateral damage. All agents causing sustained attack were released prior to 1996. Only two intentionally released agents, *Rhinocyllus conicus* Frölich and *Larinus carlinae* (Fabricius) (Curculionidae), and one agent which spread unintentionally, *Cactoblastis cactorum* (Berg) (Pyralidae), have been shown to potentially cause negative non-target impacts at the population level. The incidences of unpredicted non-target attack of intentionally released weed biocontrol agents decreased over time and this trend is predicted to continue with the systematic inclusion of molecular tools, behavioral studies, chemical ecology, and future scientific and analytical advancements. What is most needed is more systematic post-release monitoring to compare with pre-release host range testing to further advance the predictability of host use of biocontrol agents (Hinz et al., in press).

Another systematic recent review focused on non-target impacts from weed biocontrol agents on non-target plants and found significant non-target impacts to be rare (Suckling and Sforza, 2014)[44]. The magnitude of direct impact of 43 biocontrol agents on 140 non-target plants was retrospectively categorized using a risk management framework for ecological impacts of invasive species (minimal, minor, moderate, major, massive). The vast majority of agents

[44] https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/iasem-usa-bio-15-en.pdf

introduced for classical biological control of weeds (99% of 512 agents released) have had no known significant adverse effects on non-target plants thus far; major effects suppressing non-target plant populations could be expected to be detectable. Most direct non-target impacts on plants (91.6%) were categorized as minimal or minor in magnitude with no known adverse long-term impact on non-target plant populations, but a few cacti and thistles are affected at moderate (n = 3), major (n = 7) to massive (n = 1) scale. The largest direct impacts are also from two agents (*C. cactorum* on native cacti and *R. conicus* on native thistles), but these introductions would not be permitted today as more balanced attitudes exist to plant biodiversity, driven by both society and the scientific community. This analysis showed (as far as is known), that weed biocontrol agents have a biosafety track record of >99% of cases avoiding significant non-target impacts on plant populations. Some impacts could have been overlooked, but this seems unlikely to change the basic distribution of very limited adverse effects. Fewer non-target impacts can be expected in future because of improved risk assessment science and incorporation of wider values. Failure to use biological control represents a significant opportunity cost from the certainty of ongoing adverse impacts from invasive plants.

It seems likely that a review of the degree of genetic isolation in weed biocontrol targets from valued taxa would help to identify whether this is a valid approach to minimize non-target risks (Pemberton, 2000). Selecting targets that are distantly-related to valued taxa would identify easier targets, but there are plenty of examples of agents that are specific to the target weed and do not attack congeneric plants [e.g. *Tectococcus ovatus* Hempel (Eriococcidae)] attacks strawberry guava and does not attack common guava). Target selection should include the importance of the weed and the number of valued and native closely-related species. Provided host specificity testing is done appropriately weeds that are closely-related to crops or native taxa can be safely targeted. Consideration of the phylogenetic distance between the target and any potential biocontrol agents and closely related native species helps predict the likelihood level of non-target impacts as specialized biocontrol agents distantly related to native species likely to be encountered are less likely to infiltrate such native communities (Hoddle, 2004).

A common concern about unexpected direct non-target impacts is that biocontrol agents will evolve quickly following introduction into the new invaded environment and increase or alter their fundamental host range (the definition of which the focus of conservative host specificity testing is aimed at defining and within which population survival is possible). While evolutionary change is rarely predictable without a fully understanding of available selection pressures on the agent from the new environment or if the target rapidly declines in abundance, there are no cases of a specialist biocontrol agent rapidly evolving to change its fundamental host range following release (Van Klinken and Edwards, 2002). All cases of direct non-target impacts can be entirely explained through a rigorous experimental understanding of a biocontrol agent's host range (Marohasy, 1996; Secord and Kareiva, 1996). Indeed phylogenetic trees of specialist natural enemies suggest host shifts to broaden host range, where they occur (and specialization is generally a one way path) are of the order of once in 10-100,000 years (Van Klinken and Edwards, 2002). This is outside the timescale of concerns about the management of invasive species impacts.

B. Indirect non-target impacts

Indirect effects are defined as non-target population mediated through the interaction of two or more species to produce measurable changes in community structure or ecosystem function. Indirect effects from biological control have received considerably less attention than direct effects, most probably because they are less obvious and more difficult to measure. Indeed indirect non-target impacts can manifested themselves in many different ways (Hajek et al., 2016). The few examples of indirect non-target impacts that exist in weed biocontrol include indirect interactions via resource competition (Louda et al., 1997), apparent competition (Carvalheiro et al., 2008), second-order apparent competition (Pearson and Callaway, 2008) and ecological replacement (Pearson and Callaway, 2003; Duddley and Bean, 2012). It has been proposed that studying food webs in the native range of the biocontrol agent prior to release could predict the structure of food webs in the introduced range post-release (Veldtman et al., 2011). In addition, both Pearson and Callaway (2003) and Carvalheiro et al. (2008) suggested that ineffective biocontrol agents that are unable to reduce target weed densities and that remain highly abundant are the most likely source of indirect effects. Considering agent effectiveness or efficacy as part of the selection process is therefore another important criterion in the risk assessment of biocontrol agents. Additional cases including cases of indirect non-target impacts from arthropod biological control have been reviewed by McCoy and Frank (2010) and Simberloff (2012).

Opinions on the importance of indirect effects vary, however, with some authors characterizing them as at least as important as direct effects (Pearson and Callaway, 2003), while others suggest that their importance may be exaggerated, especially with respect to the biological control of insects (Thomas et al., 2004). The most recent classic case of indirect non-target impacts in classical biological control has been the halting of the biological control programme against invasive saltcedars, *Tamarix* spp. (Tamaricaceae), in southwestern USA, because of risks to the endangered southwestern willow flycatcher, *Empidonax traillii extimus* Audubon (Tyrannidae), which nests in saltcedars where they have replaced native willow shrub nesting sites. The concern is that biological control of saltcedars would remove nesting habitat before the native vegetation could be restored. The case remains controversial even ten years after an effective leaf beetle biocontrol agent was released. This is a case of a weed ecologically replacing a native species as a resource for another native species and illustrates the need to think very carefully about alien plants in the management of native ecological communities (Dunwiddie and Rogers, 2017).

C. Summary of non-target impacts

The evidence suggests nearly all recent biological control introductions of highly specific biocontrol agents made following internationally accepted Pest Risk Analysis-based risk assessment processes have not caused a quantified effect on non-target species, even closely related to the target species. Is this however due to their lack of existence or to a lack of targeted assessments?

Non-target impacts are more likely in older pre-PRA biological control introductions when more polyphagous biocontrol agents were used (Hinz et al., in press). However, when long periods of time have passed since release, it is harder to assess impacts due to lack of pre-release data (Kenis et al., 2009). Another difficulty in assessing especially indirect non-target effects of biocontrol releases is the many ways non-target impacts can manifest (Parry, 2008; Kenis et al., 2009).

Critics of classical biological control consider the lack of evidence for non-target impacts is due to poor post-release evaluation (e.g. Lockwood, 2000). Certainly, there is a general paucity of resources available for quantitative post-release evaluation of most biological control programmes. An alternative view is that a lack of evidence for non-target effects is evidence such effects are largely ecologically insignificant. One would expect that especially non-target effects on rare and endangered species should not go undetected. Predicting and testing for indirect non-target impacts is challenging (Karban et al., 1994; Simberloff, 2012). However, a greater focus on temporal community changes rather than pairwise species interactions in both pre- and post-establishment monitoring of biological control introductions will be important to detect persistent impacts. It is vital therefore that effective evaluation of non-target impacts remain as much a priority as evaluation of the ecological and biodiversity benefits of classical biological control programmes. Clearly, the range of possible ecological feedbacks predicted by theory (Holt and Hochberg, 2001) and a few highly quoted examples (Pearson and Callaway, 2003; Simberloff, 2012), suggest that vigilance is warranted. It is however important to balance impact of the biocontrol agents with that of the target pests themselves and the damage caused by any other pest control options (Van Driesche, 2016).

X. FUTURE PROSPECTS

This technical report has reviewed the history of classical biological control against many different types of invasive alien species assessing the history of success and failure, the cost effectiveness of classical biological control for the management of invasive alien species across different target taxonomic groups and evidence of non-target impacts. There are types of invasive alien species where the targeting and success of biological control has a long history of success across many countries (plants and invertebrate pests). There are types of invasive alien species where biological control programmes have been much rarer and generally restricted to one or two countries (i.e. the control of key vertebrate invasive alien species with viral pathogens) because of differing perceptions of risk and the very limited availability of specific candidate biocontrol agents. There are also many types of invasive alien species where biological control has been occasionally proposed, but never successfully delivered through direct population suppression (pathogens, marine vertebrates and invertebrates).

The challenge for the biological control of invasive alien species threatening biodiversity and ecosystem services is to try and target different types of invaders, such as marine pests. For these there is a lack of relevant research, risk analysis protocols, and regulatory guidelines to support the possible future expansion of biological control into new contexts. It will be important to provide the relevant support for research to explore options to tackle a broader range of invasive species impacting biodiversity. Meanwhile current traditional classical biological control approaches can continue to be developed for the types of targets for which significant benefits have already been generated.

XI. CONCLUSION - IMPORTANT CONSIDERATIONS IN THE APPLICATION OF A CLASSICAL BIOLOGICAL CONTROL PROGRAM

Biocontrol agents have been used against invasive alien species for more than 100 years. The successful cases of classical biological control clearly show that it is a valuable approach in the right circumstances, however a comprehensive assessment of the risk of potential biocontrol agents for any given target is essential.

Recent historical biological control successes and a paucity of identified non-target impacts results from effective risk assessment protocols and regulatory processes. The decision to release a biocontrol agent must be made based on rigorous risk analysis - risk assessment, risk management and risk communication (Sheppard et al., 2003). Biological control programmes can, therefore, be a powerful method of managing invasive alien species because they are based on ecological principles (that the invasive species is impactful because they have been introduced without their specific and impactful natural enemies and biological control sets out to address this) and highly target specific and can be effective at continental scales at low long-term cost. Most effectively discussed and planned programmes are successful. While the costs of biological control programmes are not insignificant in the early phases (Figure XI.1), it is still much lower than the development and continuous use of conventional control techniques.

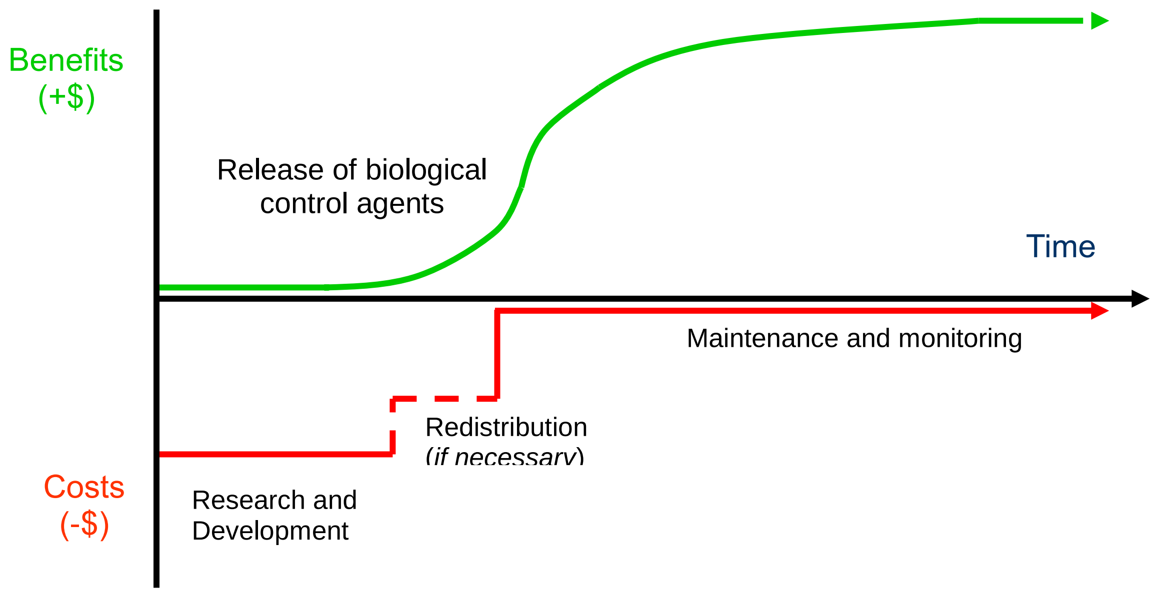

Figure XI.1 The schematic timelines of costs versus benefits in a classical biological control programme

Key components to be considered during a biological control programme include appropriate assessment of:

(a) Potential impacts (risks and benefits) on economic, environmental, social and cultural values and assets, including of local and indigenous communities;

(b) Prioritised target invasive alien species selection for biological control based on a) environmental impact, b) feasibility of biological control and c) likelihood of successful biological control (van Klinken et al., 2016);

(c) Biological control programme cost-benefit or cost-effectiveness analysis

(d) Collaboration and cooperation amongst stakeholders, government (NPPO) and non-government agencies and scientific and technical experts both nationally and internationally (RPPO) across agriculture environment and health throughout the process;

(e) Open and active dialogue/consultation with the public (stakeholders and non-stakeholders).

(f) Biological control cost effectiveness - investment in delivery versus likely benefit from control;

(g) Biocontrol agent selection based on a) likely level of specificity and b) expected level of efficacy (through native range field tests (Briese et al. 2005; Sheppard et al., 2006) and tests under appropriate containment conditions (Sheppard et al. 2005);

(h) Host-range/host-specificity of biocontrol agents against the targeted invasive alien species and closely related non-target species;

(i) Other non-target impacts in the recipient environment;

(j) Appropriate regulatory frameworks and Pest Risk Analysis processes for building the case for release and against which objective release decisions can be made – built around the IPPC-International Standards for Phytosanitary Measures or similar to them.

(k) Mechanisms to assist establishment and spread of the biocontrol agent to ensure effective control;

(l) Mechanisms or instruments to prevent the spread of biocontrol agents into areas/countries outside the scope of the PRA.

(m) Post release evaluation of environmental and native species benefits and assessment of any non-target impacts on related species or other species within the local ecological community/ecosystem.

A cost- benefit analysis or cost-effectiveness analysis should be undertaken where possible before initiating any classical biological control programme. Tools are available to assist this[45]. Explicitly capturing the monetary costs of application of biological control and benefits for environment, agriculture and cultural integrity can help to justify the necessary investment. Conducting a rigorous analysis requires consultations with stakeholders, e.g. relevant governmental sectors, farmers, land owners, indigenous peoples and local communities as necessary.

The safe and successful use of biocontrol agents requires rigorous science-based risk assessment on the host range of alien organisms and their potential impacts on biodiversity in the recipient environment. The importation and release of classical biocontrol agents requires close collaboration between the agricultural sector (government agriculture departments and regulators, National Plant Protection Organization, and industry stakeholders) and the environmental sector (government’s environment related departments and regulators, custodians of public land and conservation NGO’s). Inter-agency communication and collaboration are frequently limited for various reasons between these sectors in some jurisdictions. There are a number of publicly available and online publications (e.g. Winston et al., 2014), other information sources and databases of introduced and invasive species and known invasive species and any potential biocontrol agents to facilitate the delivery of biological control programmes including the application of rigorous risk analysis. Open access

[45] https://www.cbd.int/doc/meetings/ais/iasem-2015-01/official/iasem-2015-01-02-en.pdf

sources for such information and free sharing of research outcomes between jurisdictions involved in similar biological control programmes has been a strong historical basis for the mutual delivery of cost-effective benefits from classical biological control programs. Risks prior to release:

(a) Target not sufficiently impactful and the feasibility (can it be done) and likelihood (is it likely to work) of biological control success to justify investment in a biological control programme;

(b) Insufficient biocontrol agent host specificity or poor protocols for undertaking such risk assessment (Sheppard et al., 2003; 2005);

(a) Selection of ineffective agents due to a lack of understanding of target and agent biology and ecology ;

To overcome uncertainties (Liu et al., 2011a; 2011b) in the process of assessment, a platform for risk communication in which scientists, stakeholders and decision-makers can interact and discuss the uncertainties associated with biological invasions, such as Deliberative Multi-Criteria Evaluation (DMCE) can support prioritization of controls.

For biocontrol agent releases, as for all alien species introductions, risk management of biological control programs is important with planning for rapid response or eradication programs if necessary. Risks post release:

(a) Unexpected non-target impacts – failure of hosts specificity testing (e.g. failure to apply the most conservative starvation tests so biocontrol agent exhibits broader host range in the field at high densities post-release);

(b) Lack of impact – agent fails to establish or spread or was poorly selected based on a capacity to suppress the target;

(c) Insufficiency of monitoring post release to understand level of effectiveness and measure target and non-target impacts;

(d) Unexpected incompatibility of the biocontrol agent to the introduced environment - climate extremes (temperature drought), unintended impacts from native predator species (e.g. ants) or day length asynchronies with the native range.

Where outcomes are not satisfactory further research into identifying the reasons for failure is needed (Simberloff, 2012). Climate change is increasingly postulated as a potential disruptor of successful biological control outcome as conditions may disrupt the population equilibrium between agent and target where success is observed. ISPM 11 identifies climate change as an element to consider when evaluating the probability of establishment of a potential pest – when developing pest risk assessment, assessors often use climate modeling to evaluate this factor. There is little evidence to date that this is the case. Species distribution modelling already employed to understand biological invasions and pest outbreaks have and will be equally applicable to understanding biological control systems (Kriticos et al., 1999; 2009).

Recognizing the difficulty of eradication and the high cost of containment or conventional control of invasive alien species that are already established and widely spread in the open environment with high impact on biodiversity, economy and culture, the use of biocontrol agent should be considered as a potential self-sustaining and cost effective measure to control invasive alien species. It is therefore useful to consider biological control as a part of an integrated management programme on invasive alien species.

A common misconception and false expectation with classical biological control is that it will work like a "silver bullet" negating the need for ongoing or complementary control efforts against the target. While classical biological control is unique in providing the potential for continental and sustained target control with little long-term investment, in only a small percentage of cases does biological control provide complete control of the target under such circumstances. Best practice control measures for the target will need to continue to be applied both up until any biological control programme starts to show success and after, at least until widespread unassisted control is observed. The release of alien organisms as biocontrol agent on or near sacred sites and lands and waters traditionally occupied or used by indigenous peoples and local communities requires active engagement on such activities. Appropriate risk communication on both negative impact posed by invasive alien species and environmental and economic benefit of the use of biocontrol agent is essential to all stakeholders and the public at large.

Effective data collection and risk communication strategies are also required around the following:

(a) Release, redistribution, monitoring and evaluation of available biological agent as necessary;

(b) Adoption of an integrated active adaptive management approach – building understanding of how biological control can be complemented with the application of other target best practice management strategies and (e.g. pesticides) and ecosystem restoration activities with appropriate monitoring and adaptation of the control measures.

(e) Identify reasons why biological control is not working if necessary:

   (i) Biological and behavioral capacity of the agent to either achieve the densities or cause sufficient impact on the target – generally requires an ecological modelling approach;

   (ii) Sufficient genetic diversity of the biocontrol agents – generally requires an assessment of genetic diversity of the released population relative to the source population;

   (iii) Climatic and habitat suitability of the new environment for the biocontrol agent – generally requires and climate and habitat suitability modelling approach;

(iv) Resistance/tolerance of the target – if a target can easily sustain the level of damage inflicted by the biocontrol agent, agent populations may build up without suppressing the targets and pose a risk of non-target impacts which may need to be assessed;

The 100 year history, experience and many programme datasets from classical biological control programmes provides strong evidence that non-target risks can be effectively assessed and understood using the IPPC ISPM 3 (IPPC, 2017a) accepted guidelines on risk assessment through rigorous host specificity testing. Although the process of accurate risk assessment may take several years, even where variation in target susceptibility or agent virulence/specificity are observed successful outcomes are still reasonably likely.

XII. GLOSSARY OF TERMS USED IN THIS DOCUMENT

Alien species	"alien species" refers to a species, subspecies or lower taxon, introduced outside its natural past or present distribution; includes any part, gametes, seeds, eggs, or propagules of such species that might survive and subsequently reproduce(decision VI/23* annex)
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
FAO	Food and Agriculture Organization of the United Nations
Invasive alien species	"invasive alien species" means an alien species whose introduction and/or spread threaten biological diversity (For the purposes of the present guiding principles, the term "invasive alien species" shall be deemed the same as "alien invasive species" in decision V/8 of the Conference of the Parties to the Convention on Biological Diversity (decision VI/23* annex)
Inundative release	The release of large numbers of mass-produced biocontrol agents or beneficial organisms with the expectation of achieving a rapid effect. ISPM 3 (IPPC, 2017a)
Introduction	“introduction" refers to the movement by human agency, indirect or direct, of an alien species outside of its natural range (past or present). This movement can be either within a country or between countries or areas beyond national jurisdiction (decision VI/23* annex)
IOBC	International Organisation for Biological Control http://www.iobc-global.org/
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
ISSG	International Union for the Conservation of Nature, Species Survival Commission, Invasive Species Specialist Group (IUCN-SSC-ISSG)
Nagoya Protocol	The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity https://www.cbd.int/abs/
NPPO	National Plant Protection Organization

Parasite	An organism which lives on or in a larger organism, feeding upon it. ISPM 3 (IPPC, 2017a)
Parasitoid	An insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult. ISPM 3 (IPPC, 2017a).
Pest	Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. Note: In the IPPC, plant pest is sometimes used for the term pest (IPPC, 2017d)
Pest Risk Analysis	Risk analysis of the potential of an exotic species to become a pest in a new jurisdiction. Internationally recognized process under the IPPC ISPM 2.
Quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing or treatment (IPPC, 2017d)
Reference specimen	Specimen, from a population of a specific organism, conserved and accessible for the purpose of identification, verification or comparison. ISPM 3 (IPPC, 2017a)
Release (into the environment)	Intentional liberation of an organism into the environment ISPM 3 (IPPC, 2017a)
RPPO	Regional Plant Protection Organization
SBSTTA	CBD Subsidiary Body on Scientific, Technical and Technological Advice
SPS Agreement	The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures
Surveillance	An official process which collects and records data on pest presence or absence by survey, monitoring or other procedures [IPPC, 2016b]
WTO	The World Trade Organization (https://www.wto.org)

XIII. REFERENCES

Abe, T., Makino, S.I. and Okochi, I., 2010. Why have endemic pollinators declined on the Ogasawara Islands?. In *Restoring the Oceanic Island Ecosystem* (pp. 75-83). Springer, Tokyo.

Allendorf, F.W., 1991. Ecological and genetic effects of fish introductions: synthesis and recommendations. Canadian Journal of Fisheries and Aquatic Sciences 48(S1):178-181.

Bach, E., dos Santos Seger, G.D., de Carvalho Fernandes, G., Lisboa, B.B. and Passaglia, L.M.P., 2016. Evaluation of biological control and rhizosphere competence of plant growth promoting bacteria. Applied Soil Ecology 99:141-149.

Barbosa P., 1998. Conservation biological control. Academic Press, London.

Barton, J., 2004. How good are we at predicting the field host-range of fungal pathogens used for classical biological control of weeds? Biological Control 31: 99-122.

Barton, J., Fowler, S.V., Gianotti, A.F., Winks, C.J., De Beurs, M., Arnold, G.C. and Forrester, G., 2007. Successful biological control of mist flower (*Ageratina riparia*) in New Zealand: agent establishment, impact and benefits to the native flora. Biological Control 40(3):370-385.

Bae, S.J., Mohanta, T.K., Chung, J.Y., Ryu, M., Park, G., Shim, S., Hong, S.B., Seo, H., Bae, D.W., Bae, I. and Kim, J.J., 2016. Trichoderma metabolites as biological control agents against Phytophthora pathogens. Biological Control 92:128-138.

Beard, K.H. and Pitt, W.C., 2005. Potential consequences of the coqui frog invasion in Hawaii. Diversity and Distributions 11(5):427-433.

Bellows T.S. and Fisher T.W. (1999). Handbook of Biological Control: Principles and Applications of Biological Control. Academic Press, San Diego.

Better Border Biosecurity (B3) (2007). Biocontrol Information Resource for EPA Applicants (New Zealand). http://b3.net.nz/birea/index.php?page=background_biocontrol#ref234

Bigler, F., Babendreier, D., and Kuhlmann, U. (eds.), 2006. Environmental impact of invertebrates for biological control of arthropods: methods and risk assessment. CABI, Wallingford

Bloomer, J.P. and Bester, M.N., 1992. Control of feral cats on sub-antarctic Marion Island, Indian Ocean. Biological Conservation 60(3):211-219.

Boettner, G.H., Elkinton, J.S. and Boettner, C.J., 2000. Effects of a biological control introduction on three nontarget native species of saturniid moths. Conservation Biology 14:1798–1806

Briese, D.T., 2005. Translating host-specificity test results into the real world: the need to harmonize the yin and yang of current testing procedures. Biological Control 35(3):208-214.

Briese, D.T., Walker, A., 2002. A new perspective on the selection of test plants for evaluating the host-specificity of weed biological control agents: the case of *Deuterocampta quadrijuga*, a potential insect control agent of *Heliotropium amplexicaule*. Biological Control 25, 273-287.

Brochier, B., Vangeluwe, D. and Van den Berg, T., 2010. Alien invasive birds. Revue scientifique et technique 29(2) :217.

Brown, G. P., and R. Shine. 2016. Frogs in the spotlight: a 16-year survey of the abundance of native frogs and invasive cane toads on a floodplain in tropical Australia. Ecology and Evolution 6:4445-4457.

Charudattan, R., 2001. Biological control of weeds by means of plant pathogens: significance for integrated weed management in modern agro-ecology. Biological Control 46: 229-260.

Caltagirone L.E. (1981). Landmark examples in classical biological control. Annual Review of Entomology 26: 213-232.

Cassey, P., Blackburn, T.M., Sol, D., Duncan, R.P. and Lockwood, J.L., 2004. Global patterns of introduction effort and establishment success in birds. Proceedings of the Royal Society of London B: Biological Sciences, 271(Suppl 6):S405-S408.

Clout, M.N. and Russell, J.C., 2008. The invasion ecology of mammals: a global perspective. Wildlife Research 35(3):180-184.

Cock, M.J., van Lenteren, J.C., Brodeur, J., Barratt, B.I., Bigler, F., Bolckmans, K., Cônsoli, F.L., Haas, F., Mason, P.G. and Parra, J.R.P., 2010. Do new access and benefit sharing procedures under the convention on biological diversity threaten the future of biological control? BioControl 55(2):199-218.Cock, M.J.W., Day, R.K., Hinz, H.L., Pollard, K.M., Thomas, S.E., Williams, F.E., Witt, A.B.R. and Shaw, R.H.(2015). The impacts of some classical biological control successes. CAB Reviews 10 (042) DOI: 10.1079/PAVSNNR201510042

Cock, M.J.W., Murphy, S.T., Moses, T.K.K., Thompson, E., Murphy, R.J. and Francis, A.W., 2016. Trends in the classical biological control of insect pests by insects: an update of the BIOCAT database. BioControl, DOI: 10.1007/s10526-016-9726-3

Collen, B., Bohm, M., Kemp, R., and Baillie, J.E.M., 2012. Spineless: status and trends of the world's invertebrates. Zoological Society of London, London

Cooke, B.D., 2014. Australia's war against rabbits: the story of rabbit haemorrhagic disease. CSIRO PUBLISHING.

Cooke, B., Chudleigh, P., Simpson, S. and Saunders, G., 2013. The economic benefits of the biological control of rabbits in Australia, 1950–2011. Australian Economic History Review, 53(1):91-107.

Courchamp, F., Chapuis, J.L. and Pascal, M., 2003. Mammal invaders on islands: impact, control and control impact. Biological Reviews, 78(3):347-383.

Cowie, R.H., 2001. Can snails ever be effective and safe biocontrol agents? Int ernational Journal of Pest Management 47:23–24.

Cox, T.E., Strive, T., Mutze, G., West, P. and Saunders, G. 2013. Benefits of Rabbit Biocontrol in Australia. PestSmart Toolkit publication, Invasive Animals Cooperative Research Centre, Canberra, Australia (www.feral.org.au/PestSmart).

Crane, M.S., and Eaton, Â. T., 1997. Spring viraemia of carp virus (*Rhabdovirus carpio*): a biological control agent. Pages 87-107 in J. Roberts and R. Tilzey, eds. Controlling carp: exploring the options for Australia. Murray-Darling Basin Comm., Canberra, Australia.

Cullen, J., 1988. Current problems in host-specificity screening. In: Del Fosse, E.S., (Ed.), Proceedings of the VII international symposium on biological control of weeds, pp. 27-36.

Cullen, J.M., Sheppard, A.W., and Palmer, W.A. (in press). 115 Years of Biological Control of Weeds in Australia. Austral Entomology ?????

Davis, A.S., Landis, D.A., Nuzzo, V., Blossey, B., Gerber, E., and Hinz, H.L, 2006. Demographic models inform selection of biocontrol agents for garlic mustard (*Alliaria petiolata*). Ecological Applications 16: 2399-2410.

Denham, A.J. and Auld, T.D., 2004. Survival and recruitment of seedlings and suckers of trees and shrubs of the Australian arid zone following habitat management and the outbreak of Rabbit Calicivirus Disease (RCD). Austral Ecology, 29(5):585-599.

Dubey, S. and Shine, R., 2008. Origin of the parasites of an invading species, the Australian cane toad (Bufo marinus): are the lungworms Australian or American?. Molecular Ecology, 17(20):4418-4424.

Dunwiddie, P.W. and Rogers, D.L., 2017. Rare species and aliens: reconsidering non‐native plants in the management of natural areas. Restoration Ecology, 25(S2)

Eden, J.S., Kovaliski, J., Duckworth, J.A., Swain, G., Mahar, J.E., Strive, T. and Holmes, E.C., 2015. Comparative phylodynamics of rabbit hemorrhagic disease virus in Australia and New Zealand. Journal of Virology 89(18):: 9548-9558.

Edwards, R.J., Tuipulotu, D.E., Amos, T.G. , O'Meally, D., Richardson, M.F., Russell, T.L., Vallinoto, M., Carneiro, M., Ferrand, N., Wilkins, M.R., Sequeira, F., Rollins, L.A., Holmes, E.C., Shine, R. and White, P.A. 2018. Draft genome assembly of the invasive cane toad, *Rhinella marina*. GigaScience 7: 1–13.

Elkinton, J.S. and Boettner, G.H., 2012. Benefits and harm caused by the introduced generalist tachinid, Compsilura concinnata, in North America. Biocontrol 57:277–288

Evans, E.W., 2004 Habitat displacement of North American ladybirds by an introduced species. Ecology 85:637–647

FAO, 1992. Towards Integrated Commodity and Pest Management in Grain Storage. Accessible from http://www.fao.org/docrep/x5048e/x5048E00.htm#Contents

FAO, 1995. Code of conduct for the import and release of exotic biological control agents. Report of the conference of the FAO – Twenty-eight session. http://www.fao.org/docrep/x5585E/x5585e0i.htm, Accessed 23 October, 2012.

Fenner, F. and Myers, K., 1978. Myxoma viruses and myxomatosis in retrospect: the first quarter century of a new disease. In: Kurstak, E., Maramorosch, K. (Eds.) Viruses and the Environment. Academic Press, New York. Pp. 539-570.

Gassmann, A., 1996. Classical biological control of weeds with insects: a case for emphasizing agent demography. In Proceedings of the IX International Symposium on Biological Control of Weeds (pp. 171-175). University of Cape Town Rondebosch, South Africa.

Gong, W., Sinden, J., Braysher, M.L., Jones, R. and Wales, N.S., 2009. The economic impacts of vertebrate pests in Australia (p. 60). Canberra: Invasive Animals Cooperative Research Centre. https://www.researchgate.net/profile/Mike_Braysher/publication/253858624_The_Economic_Impact_of_Vertebrate_Pests_in_Australia/links/02e7e53b21528c192a000000.pdf

Greathead, D.J and Greathead, A.H., 1992. Biological control of insect pests by insect parasitoids and predators: the BIOCAT database. Biocontrol News and Information 13 (4) pp61N-68N.

Haas, D. and Défago, G., 2005. Biological control of soil-borne pathogens by fluorescent pseudomonads. Nature Reviews Microbiology, 3(4), p.307.

Hajek, A.E., Hurley, B.P., Kenis, M., Garnas, J.R., Bush, S.J., Wingfield, M.J., Van Lenteren, J.C. and Cock, M.J., 2016. Exotic biological control agents: A solution or contribution to arthropod invasions? Biological invasions 18(4): 953-969.

Hall, R.N., Mahar, J.E., Haboury, S., Stevens, V., Holmes, E.C. and Strive, T., 2015. Emerging rabbit hemorrhagic disease virus 2 (RHDVb), Australia. Emerging Infectious Diseases 21(12), p.2276.

Hamilton, P.B., Stevens, J.R., Holz, P., Boag, B., Cooke, B. and Gibson, W.C., 2005. The inadvertent introduction into Australia of *Trypanosoma nabiasi*, the trypanosome of the European rabbit (*Oryctolagus cuniculus*), and its potential for biocontrol. Molecular Ecology 14(10): 3167-3175.

Harman, G.E., Howell, C.R., Viterbo, A., Chet, I. and Lorito, M., 2004. Trichoderma species—opportunistic, avirulent plant symbionts. Nature Reviews Microbiology 2(1): 43.

Harris, P. and Peschken, D., 1971. *Hypericum perforatum* L., St. John's Wort (Hyperiaceae). Pp. 89-94 In: Biological Control Programmes Against Insects and Weeds in Canada 1959- 1968. Technical Communication No. 4, Commonwealth Institute of Biological Control, Trinidad. CommonwealtH Agricultural Bureaux, Farnham Royal, Slough SL2 3BN, England

Haselmayer, J. and Jamieson, I.G., 2001. Increased predation on pukeko eggs after the application of rabbit control measures. New Zealand Journal of Ecology:89-93.

Hinz H.L., Winston, R.L., Schwarzländer, M. (in press) How safe is weed biological control? A global review of direct non-target attack. The Quarterly Review of Biology.

Hoddle, M.S., 2004. Restoring balance: using exotic natural enemies to control invasive exotic species. Conservation Biology 18: 38-49.

Hoddle, M.S., 2006. Historical review of control programs for *Levuana iridescens* (Lepidoptera: Zygaenidae) in Fiji and examination of possible extinction of this moth by *Bessa remota* (Diptera: Tachinidae). Pacific Science 60:439–453

Holt, R.D. and Hochberg, M., 2001. Indirect interactions, community modules and biological control: a theoretical perspective. In: Wajnberg, E., Scott, J.K. and Quimby, P.C. (eds.) Evaluating indirect ecological effects of biological control. CABI, Wallingford, pp 13–37

Hopper, K.R. and Roush, R.T., 1993. Mate finding, dispersal, number released, and the success of biological control introductions. Ecological Entomology 18(4)::321-331.

Howard, W.E., 1967, March. Biological control of vertebrate pests. In Proceedings of the 3rd Vertebrate Pest Conference (1967) (p. 29).

Howarth, F. G., 1991. Environmental impacts of classical biological control. Annual Review of Entomology 36: 485-509.

Howarth, F.G., 1999. Environmental risks of biological control of vertebrates. Problem Snake Management: The Habu and the Brown Treesnake. Cornell University Press, USA, pp.399-410.

Huffaker, C.B. and Messenger, P.S. (eds.),1976. Theory and Practice of Biological Control. Academic Press, New York.

IPPC (International Plant protection Convention) (2016a). International Standards for Phytosanitary Measures (ISPM) No. 2: "Framework for Pest Risk Analysis Food and Agriculture Organization of the United nations, Rome https://www.ippc.int/en/core-activities/standards-setting/ispms/ ; https://www.ippc.int/en/publications/592/

IPPC (International Plant protection Convention) (2016b). International Standards for Phytosanitary Measures (ISPM) No. 6: "Guidelines for surveillance" Food and Agriculture Organization of the United nations, Rome https://www.ippc.int/en/core-activities/standards-setting/ispms/ ; https://www.ippc.int/en/publications/615/

IPPC (International Plant protection Convention) (2017a). International Standards for Phytosanitary Measures (ISPM) No. 3: Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms. Food and Agriculture Organization of the United nations, Rome https://www.ippc.int/en/core-activities/standards-setting/ispms/ ; https://www.ippc.int/en/publications/600/

IPPC (International Plant protection Convention) (2017b). International Standards for Phytosanitary Measures (ISPM) No. 11: " Pest Risk Analysis for Quarantine Pests" Food and Agriculture Organization of the United nations, Rome https://www.ippc.int/en/core-activities/standards-setting/ispms/ ; https://www.ippc.int/en/publications/639/

IPPC (International Plant protection Convention) (2017c). International Standards for Phytosanitary Measures (ISPM) No. 20: “Guidelines for a phytosanitary import regulatory system Food and Agriculture Organization of the United nations, Rome https://www.ippc.int/en/core-activities/standards-setting/ispms/ ; https://www.ippc.int/en/publications/602/

IPPC (International Plant protection Convention) (2017d). International Standards for Phytosanitary Measures (ISPM) No. 5: " Glossary of phytosanitary terms (as adopted by CPM-11 and CPM-12 ink amendments)" Food and Agriculture Organization of the United nations, Rome. https://www.ippc.int/en/core-activities/standards-setting/ispms/ ; https://www.ippc.int/en/publications/622/

Jäkel, T., Burgstaller, H. and Frank, W., 1996. Sarcocystis singaporensis: studies on host specificity, pathogenicity, and potential use as a biocontrol agent of wild rats. The Journal of Parasitology 82(2)::280-287.

Jäkel, T., Mouaxengcha, K., Nuber, U. and Douangboupha, B., 2016. Integrated rodent management in outbreak-prone upland rice growing areas of Northern Laos. Crop Protection 79:34-42.

Jarvis, P.J., Fowler, S.V., Paynter, Q., Syrett, P., 2006. Predicting the economic benefits and costs of introducing new biological control agents for Scotch broom Cytisus scoparius into New Zealand. Biological Control 39: 135-146.

Julien M, McFadyen R and Cullen J. 2012. Biological Control of Weeds in Australia. CSIRO Publishing, Melbourne, Australia.

Kairo, M.T.K., Cock, M.J.W., Quinlan, M.M. (2003). An assessment of the use of the code of conduct for the import and release of exotic biological control agents (ISPM no. 3) since its endorsement as an international standard. Biocontrol News and Information24 (1): 15N-27N.

Karban R, Hougen-Eitzmann D, English-Loeb G (1994) Predator-mediated apparent competition between two herbivores that feed on grapevines. Oecologia 97:508–511

Kark, S., Solarz, W., Chiron, F., Clergeau, P. and Shirley, S., 2009. Alien birds, amphibians and reptiles of Europe. In Handbook of alien species in Europe (pp. 105-118). Springer, Dordrecht.

Kenis, M., Auger-Rozenberg, M.A., Roques, A., Timms, L., Péré, C., Cock, M.J.W., Settele, J., Augustin, S. and Lopez-Vaamonde, C., 2009. Ecological effects of invasive alien insects. Biological Invasions 11:21–45.

Kerr, P., Donnelly, T., 2013. Viral Infections of Rabbits. Veterinary Clinics of North America: Exotic Animal Practice 16(2): 437-468.

Koch, R.L., 2003. The multicolored Asian lady beetle, Harmonia axyridis: a review of its biology, uses in biological control, and non-target impacts. Journal of Insect Science 3(32):1-16.

Kraus, F., 2008. Alien reptiles and amphibians: a scientific compendium and analysis (Vol. 4). Springer Science & Business Media.

Kraus, F., 2009. Global trends in alien reptiles and amphibians. Aliens: The Invasive Species Bulletin 28: 13-18.

Kraus, F., 2015. Impacts from invasive reptiles and amphibians. Annual Review of Ecology, Evolution, and Systematics 46:75-97.

Kriticos, D., Brown, J., Radford, I. and Nicholas, M., 1999. Plant population ecology and biological control: *Acacia nilotica* as a case study. Biological Control 16: 230–239.

Kriticos, D.J., Watt, M.S., Withers, T.M., Leriche, A. and Watson, M.C., 2009. A process-based population dynamics model to explore target and non-target impacts of a biological control agent. Ecological Modelling 220(17):2035-2050.

Kuris AM (2003) Did biological control cause extinction of the coconut moth, *Levuana iridescens*, in Fiji? Biological Invasions 5:133–141

Lafferty, K.D. and Kuris, A.M., 1996. Biological control of marine pests. Ecology 77(7):1989-2000.

Lever, C. 2002. Naturalized fishes of the world. Academic Press, New York.

Lighten, J. and van Oosterhout, C. 2017. Biocontrol of common carp in Australia poses risks to biosecurity. Nature Ecology and Evolution 1: 87.

Liu S, et al., 2011a. An integrated decision-support approach in prioritizing risks of non-indigenousspecies in the face of high uncertainty. Ecological Economics 70: 1924–1930.

Liu S. et al., 2011b. Incorporating uncertainty and social values in managing invasive alien species: a deliberative multi-criteria evaluation approach. Biological Invasions 13:2323–2337.

Lockwood, J.A., 2000. Nontarget effects of biological control: what are we trying to miss? In: Follett, P.A. and Duan, J.J. (eds) Nontarget effects of biological control. Kluwer Acad Publ, Dordrecht, pp 15–30

Lombaert, E., Guillemaud, T., Cornuet, J.-M., Malausa, T., Facon, B. and Estoup, A., 2010. Bridgehead Effect in the Worldwide Invasion of the Biocontrol Harlequin Ladybird. PLoS ONE 5(3): e9743. doi:10.1371/journal.pone.0009743

Lough, R.S., 2009. The current state of rabbit management in New Zealand. Report for MAF Biosecurity. Wellington, New Zealand. https://www.mpi.govt.nz/dmsdocument/16870-the-current-state-of-rabbit-management-in-new-zealand-issues-options-and-recommendations-for-the-future.

Lynch, L.D. and Thomas, M.B. (2000). Non-target effects in the biocontrol of insects with insects, nematodes and microbial agents: the evidence. Biocontrol News and Information 21 (4): 117N – 130N.

Mack, R.N., Simberloff, D., Mark Lonsdale, W., Evans, H., Clout, M. and Bazzaz, F.A., 2000. Biotic invasions: causes, epidemiology, global consequences, and control. Ecological Applications 10(3):689-710.

Magasi, L.P. and Syme, P.D., 1984. *Gilpinia hercyniae* (Hartig), Eurpean spruce sawfly (Hymenoptera: Diprionidae). In: Kelleher, J.S. and Hulme, M.A. (eds.) Biological Control Programmes Against Insects and Weeds in Canada1969-1980. Commonwealth Agricultural Bureaux, Farnham Royal, UK. pp295-297.

Mahar, J.E., Hall, R.N., Peacock, D., Kovaliski, J., Piper, M., Mourant, R., Huang, N., Campbell, S., Gu, X., Read, A. and Urakova, N., 2018. Rabbit hemorrhagic disease virus 2 (RHDV2; GI. 2) is replacing endemic strains of RHDV in the Australian landscape within 18 months of its arrival. *Journal of virology*, *92*(2), pp.e01374-17.

Marohasy, J., 1996. Host shifts in biological weed control: real problems, semantic difficulties or poor science? International Journal of Pest Management 42(2):71-75.

Marr, S.R., Johnson, S.A., Hara, A.H. and McGarrity, M.E., 2010. Preliminary evaluation of the potential of the helminth parasite *Rhabdias elegans* as a biological control agent for invasive Puerto Rican coquís (*Eleutherodactylus coqui*) in Hawaii. Biological Control 54(2):69-74.

Marshall, J., Davison, A.J., Kopf, R.K., Boutier, M., Stevenson, P. and Vanderplasschen, A. 2018. Biocontrol of invasive carp: Risks abound. Science 359: 877.

Mason, P.G. and Huber, J.T. (eds.), 2002. Biological control programmes in Canada, 1981-2000. CABI.

Mason, P.G., Flanders, R.G. and Arrendondo-Bernal, H.A., 2005. How can legislation facilitate the use of biological control of arthropods in North America? In Proceedings of the 2nd International Symposium on Biological control of Arthropods, Davos, Switzerland, 12-16 September 2005 (compiler Hoddle M), pp. 701-714. United States Department of Agriculture, Forest Service, Morgantown, WV, FHTET-2005-08, Vol II.

Mason, P.G., Kabaluk, J.T., Spencer, B.and Gillespie, D.R., 2013. Regulation of biological control in Canada. In: Mason, P.G. and Gillespie, D.R. (eds.) Biological Control Programmes in Canada 2001-2012 pp. 1–5. CAB International Publishing, Wallingford, Oxon (UK).

Mason, P.G., De Clerck-Floate, R.A., Gallant, B., Floate, K.D., Gillespie, D.R., Bourchier, R., Douglas, H., Vincent, C. and Boivin, G., 2017. Guide for the First-time Importation and Release of Arthropod Biological Control Agents in Canada. AAFC Publication No. 12700E, 171p.

Mason, P.G., Cock, M.J.W., Barratt, B.I.P,, Klapwijk, J.N., van Lenteren, J.C., Brodeur, J., Hoelmer, K.A. and Heimpel, G.E., 2018. Best practices for the use and exchange of invertebrate biological control genetic resources relevant for food and agriculture. BioControl 63:149-154 DOI : 10.1007/s10526-017-9810-3

McClay, A.S. and Balciunas, J.K., 2005. The role of pre-release efficacy assessment in selecting classical biological control agents for weeds—applying the Anna Karenina principle. Biological control, 35(3):197-207.

McColl, K.A., Cooke, B.D. and Sunarto, A., 2014. Viral biocontrol of invasive vertebrates: Lessons from the past applied to cyprinid herpesvirus-3 and carp (Cyprinus carpio) control in Australia. Biological Control 72:109-117.

McColl, K.A., Sunarto, A., Slater ,J., Bell, K., Asmus, M., Fulton, W., Hall, K., Brown, P., Gilligan, D., Hoad, J., Williams, L.M. and Crane, M.St.J., 2017. Cyprinid herpesvirus 3 as a potential biological control agent for carp (Cyprinus carpio) in Australia: susceptibility of non-target species. Journal of Fish Diseases 40:1141-1153.

McColl, K.A., Sheppard, A.W. and Barwick, M., 2017. Safe and effective biocontrol of common carp. Nature ecology & evolution, 1(5), p.0134.

McColl, K.A., Sunarto, A. and Neave, M.J., 2018. Biocontrol of carp: more than just a herpesvirus. Frontiers in microbiology, 9, p.2288.

McCoy, E. and Frank, J., 2010. How should the risk associated with the introduction of biological control agents be estimated? Agriculture and Forest Entomology 12:1–8.

McEvoy, P. B. and Coombs, E. M., 1999. Biological control of plant invaders: regional patterns, field experiments, and structured population models. Ecological Applications 9:387-401.

McFadyen, R.E.C., 1998. Biological control of weeds. Annual Review of Entomology 43(1):369-393.

Moodie, E., 1995. The potential for biological control of feral cats in Australia. New South Wales National Parks and Wildlife Service. https://www.pestsmart.org.au/wp-content/uploads/2014/12/Moodie1995_cat_biocontrol_review.pdf.

Mooney, C. 2010. Do Scientists Understand the Public? American Academy of Arts & Sciences, Washington DC. http://www.amacad.org/pdfs/scientistsUnderstand.pdf accessed 6 July, 2010.

Moran, V.C., Hoffmann, J.H. and Zimmermann, H.G., 2013. 100 years of biological control of invasive alien plants in South Africa: History, practice and achievements. S Afr J Sci. 109, 1-6. http://dx.doi.org/10.1590/sajs.2013/a0022

Morin, L., Reid, A.M., Sims-Chilton, N.M., Buckley, Y.M., Dhileepan, K., Hastwell, G.T., Nordblom, T.L. and Raghu, S., 2009. Review of approaches to evaluate the effectiveness of weed biological control

Müller-Schärer, H. and Schaffner, U., 2008. Classical biological control : exploiting enemy escape to manage plant invasions. Biological Invasions 10, 859-874.

NAPPO (2015a) Regional Standards for Phytosanitary Measures (RSPM), No. 7: "Guidelines for Petition for First Release of Non-indigenous Phytophagous or Phytopathogenic Biological Control Agents". http://www.nappo.org/english/standards-and-protocols/regional-phytosanitary-standards-rspms/rspm-07/and

NAPPO (2015b) Regional Standards for Phytosanitary Measures (RSPM), No. 12: "Guidelines for Petition for First Release of Nonindigenous Entomophagous Biological Control Agents". http://www.nappo.org/english/standards-and-protocols/regional-phytosanitary-standards-rspms/rspm-12/

NAPPO (2015c) Regional Standards for Phytosanitary Measures (RSPM), No. 26: "Certification of commercial arthropod biological control agents or non-Apis pollinators moving into NAPPO member countries" http://www.nappo.org/english/standards-and-protocols/regional-phytosanitary-standards-rspms/rspm-26/

Nettles, V.F., Corn, J.L., Erickson, G.A. and Jessup, D.A., 1989. A survey of wild swine in the United States for evidence of hog cholera. Journal of Wildlife Diseases 25(1):61-65.

Norbury, G., Heyward, R. and Parkes, J., 2002. Short-term ecological effects of rabbit haemorrhagic disease in the short-tussock grasslands of the South Island, New Zealand. Wildlife Research 29(6):599-604.

Noyes, J.S. 1994. The reliability of published host-parasitoid records: a taxonomist's view. Norwegian Journal of Agricultural Sciences, Supplement No. 16: 59-69

Page, A.R. and Lacey, K.L., 2006. Economic Impact Assessment of Australian Weed Biological Control. CRC for Australian Weed Management Technical Series No. 10, Glen Osmond, Australia <http://www.southwestnrm.org.au/sites/default/files/uploads/ihub/page-ar-lacey-kl-2006-economic-impact-assessment-australian-weed-biological-control.pdf >.

Pal, K.K. and Gardener, B.M., 2006. Biological control of plant pathogens. The plant health instructor, 2, pp.1117-1142.

Pallister, J., Goldie, S., Coupar, B., Shiell, B., Michalski, W.P., Siddon, N. and Hyatt, A., 2007. Bohle iridovirus as a vector for heterologous gene expression. Journal ofVvirological Methods, 146(1-2):419-423.

Parkes, J. and Murphy, E., 2003. Management of introduced mammals in New Zealand. New Zealand Journal of Zoology 30(4):335-359.

Parkes, J.P., Glentworth, B. and Sullivan, G., 2009. Changes in immunity to rabbit haemorrhagic disease virus, and in abundance and rates of increase of wild rabbits in Mackenzie Basin, New Zealand. Wildlife Research 35(8):775-779.

Parry, D., 2008 Beyond Pandora's Box: quantitatively evaluating non-target effects of parasitoids in classical biological control. Biological Invasions 11:47–58.

Paynter, Q., Forgie, S.A., Winks, C.J., Peterson, P.G., Ward, D.F., Nicholson, L., Van Zoelen, R., 2012a. Biotic resistance: Facilitation between invasive Homoptera and invasive ants limits the establishment of an introduced weed biocontrol agent in New Zealand. Biological Control 63: 188-194.

Paynter, Q., Fowler, S.V., Gourlay, A.H., Groenteman, R., Peterson, P., Smith, L., Winks, C.J., 2010. Predicting parasitoid accumulation on biological control agents of weeds. Journal of Applied Ecology 47: 575-582.

Paynter, Q., Fowler, S.V., Hugh Gourlay, A., Peterson, P.G., Smith, L.A., Winks, C.J., 2015. Relative performance on test and target plants in laboratory tests predicts the risk of non-target attack in the field for arthropod weed biocontrol agents. Biological Control 80: 133-142.

Paynter, Q., Overton, J.M., Hill, R.L., Bellgard, S.E., Dawson, M.I., 2012b. Plant traits predict the success of weed biocontrol. Journal of Applied Ecology 49: 1140-1148.

Paynter, Q.E., Fowler, S.V., Gourlay, A.H., Haines, M.L., Harman, H.M., Hona, S.R., Peterson, P.G., Smith, L.A., Wilson-Davey, J.A., Winks, C.J., Withers, T.M., 2004. Safety in New Zealand weed biocontrol: A nationwide survey for impacts on non-target plants. New Zealand Plant Protection 57:102-107.

Pearson, D.E. and Callaway, R.M., 2003. Indirect effects of host-specific biological control agents. Trends in Ecology and Evolution 18:456–461.

Pemberton, R.W., 2000. Predictable risk to native plants in weed biological control. Oecologia 125: 489-494.

Pimentel, D., Zuniga, R. and Morrison, D., 2005. Update on the environmental and economic costs associated with alien-invasive species in the United States. Ecological Economics 52(3): pp.273-288.

Pipalova, I., 2006. A review of grass carp use for aquatic weed control and its impact on water bodies. Journal of Aquatic Plant Management 44(1):1-12.

Pitt, W., Vice, D. and Pitzler, M., 2005. Challenges of invasive reptiles and amphibians. In: Proceedings of the 11th Wildlife Damage Management Conference. In: Nolte, D.L. and K.A. Fagerstone, K.A. (eds.). https://digitalcommons.unl.edu/icwdm_wdmconfproc/84/

Pitt, W.C., 2012. Management of invasive coqui frog populations in Hawaii. Outlooks on Pest Management 23(4):166-169.

Prathapan, K.D., Pethiyagoda, R., Bawa, K.S., Raven, P.H. and Rajan, P.D., 2018. When the cure kills—CBD limits biodiversity research. Science, 360(6396), pp.1405-1406

Pratt C.F. et al., 2014. Action 3.2 Demonstration Projects: Demonstrate the use of the Azolla weevil *Stenopelmus rufinasus* for the control of the floating weed *Azolla filiculoides* in UK, Belgium, France & Netherlands. RINSE partner report.

Morin, L., Reid, A.M., Sims-Chilton, N.M., Buckley, Y.M., Dhileepan, K., Hastwell, G.T., Nordblom, T.L. and Raghu, S., 2009. Review of approaches to evaluate the effectiveness of weed biological control agents. Biological Control 51(1):1-15.

Rathore, G., Kumar, G., Swaminathan, T.R. and Swain, P., 2012. Koi herpes virus: a review and risk assessment of Indian aquaculture. Indian Journal of Virology 23(2):124-133.

Rauzon, M.J., 1985. Feral cats on Jarvis Island: their effects and their eradication. Atoll Research Bulletin 282. The Smithsonian Institution. Washington DC. https://repository.si.edu/bitstream/handle/10088/5889/00282.pdf.

Reid, A.M., Morin, L., Downey, P.O., French, K. and Virtue, J.G., 2009. Does invasive plant management aid the restoration of natural ecosystems?. Biological Conservation 142(10):2342-2349.

Reid, T., Ward-Fear ,G., Schwarzkopf, L., Greenlees, M.J., Phillips, B.L., Brown, G., Clulow, S., Webb, J., Capon, R., Sheppard, A., Strive, T., Tizard, M. and Shine, R., 2017. New weapons in the toad toolkit: A review of methods to control and mitigate the biodiversity impacts of invasive cane toads (Rhinella marina) Quarterly Review of Biology 92: 124-149. (IP 5).

Richardson, A.J., Bakun, A., Hays, G.C. and Gibbons, M.J., 2009. The jellyfish joyride: causes, consequences and management responses to a more gelatinous future. Trends in ecology and evolution, 24(6), pp.312-322.

Rodda, G.H. and Savidge, J.A., 2007. Biology and impacts of Pacific island invasive species. 2. Boiga irregularis, the brown tree snake (Reptilia: Colubridae). Pacific Science, 61(3), pp.307-324.

Rowe, G. and L. J. Frewer. 2005. A typology of public engagement mechanisms. Science, Technology and Human Values 30: 251-290.

Roy, H.E., Adriaens, T., Isaac, N.J.B., Kenis, M., Onkelinx, T., San Martin, G., Brown, P.M.J., Hautier, L., Poland, R., Roy, D.B., Comont, R., Eschen, R., Frost, R., Zindel, R., Van Vlaenderen, J., Nedvěd, O., Ravn, H.P., Grégoire, J.C., de Biseau, J.C. and Maes, D., 2012, Invasive alien predator causes rapid declines of native European ladybirds. Diversity and Distribution 18:717–725.

Sands, D.P.A., Lukins, R.G. and Snowball, G.J., 1986. Agents introduced into Australia for biological control of *Gascardia destructor* (Newstead) (Hemiptera: Coccidae). Journal of the Australian Entomological Society 25: 51-59.

Saunders, G., Cooke, B., McColl, K., Shine, R. and Peacock, T., 2010. Modern approaches for the biological control of vertebrate pests: an Australian perspective. Biological Control 52(3):288-295.

Schwarzländer, M., Hinz, H.L., Winston, R. L., Day, M.D., 2018. Biological control of weeds: an analyiss of introductions, rates of establishment and estimates of success, worldwide. BioControl 63: 319-331.

Secord, D., 2003. Biological control of marine invasive species: cautionary tales and land-based lessons. In Marine Bioinvasions: Patterns, Processes and Perspectives (pp. 117-131). Springer, Dordrecht.

Secord, D. and Kareiva, P., 1996. Perils and pitfalls in the host specificity paradigm. BioScience 46(6):448-453.

Secretariat of the Convention on Biological Diversity (2011) Nagoya protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the Convention on Biological Diversity: text and annex. Convention on Biological Diversity, United Nations, Montreal, Canada, 25p

Shafland, P.L., 1995. Introduction and establishment of a successful butterfly peacock fishery in southeast Florida canals. In American Fisheries Society Symposium (Vol. 15, pp. 443-451).

Shanmuganathan, T., Pallister, J., Doody, S., McCallum, H., Robinson, T., Sheppard, A., Hardy, C., Halliday, D., Venables, D., Voysey, R. and Strive, T., 2010. Biological control of the cane toad in Australia: a review. Animal Conservation, 13(s1), pp.16-23.

Sharma, R.R., Singh, D. and Singh, R., 2009. Biological control of postharvest diseases of fruits and vegetables by microbial antagonists: A review. Biological Control 50(3):205-221.

Shea, K. and Possingham, H.P., 2000. Optimal release strategies for biological control agents: an application of stochastic dynamic programming to population management. Journal of Applied Ecology 37(1):77-86.

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

Sheppard, A.W., van Klinken, R. and Heard, T., 2005. Scientific advances in the analysis of direct risks of weed biological control agents to nontarget plants. Biological Control 35: 215-226.

Sheppard, A.W., Haines, M. and Thomann, T., 2006 Native range research assists risk analysis for non-targets in weed biological control: the cautionary tale of the broom seed beetle. Australian Journal of Entomology 45: 292-297.

Shine, R., 2010. The ecological impact of invasive cane toads (*Bufo marinus*) in Australia. Quarterly Review of Biology 85:253–291.

Shrader-Frechette, K. and McCoy, E.D., 1993. Method in Ecology: Strategies for Conservation. Cambridge University Press, Cambridge, UK

Singleton, G.R., 1994. The prospects and associated challenges for the biological control of rodents. Proceedings of the Sixteenth Vertebrate Pest Conference (1994). 54. http://digitalcommons.unl.edu/vpc16/54

Singleton, G.R. and McCallum, H.I., 1990. The potential of *Capillaria hepatica* to control mouse plagues. Parasitology Today 6(6):190-193.

Singleton, G.R. and Chambers, L.K., 1996. A manipulative field experiment to examine the effect of Capillaria hepatica (Nematoda) on wild mouse populations in southern Australia. International Journal for Parasitology 26(4):383-398.

Simberloff, D., 2012 Risks of biological control for conservation purposes. Biocontrol 57:263–276.

Simberloff, D., and P. Stiling . 1996. How risky is biological control? Ecology 77: 1965–1974.

Simberloff, D., Dayan, T., Jones, C. and Ogura, G., 2000. Character displacement and release in the small Indian mongoose, *Herpestes javanicus*. Ecology 81(8):2086-2099.

Songa, W. (2004). Kenya regulations for importation of biological control agents. In: Wabule, M.N., Ngaruiya, P.N.; Kimmins, F.K. and Silverside, P.J. Registration for Biocontrol Agents in Kenya. Proceedings of a Workshop, 14-16 May 2003, Nakuru, Kenya. KARI/PCPB, Nairobi, Kenya, and Natural Resources International Ltd., Aylesford, UK. pp 75-78.

Stiling, P. and Cornelissen, T., 2005. What makes a successful biocontrol agent? A meta-analysis of biological control agent performance. Biological Control 34(3):236-246.

Stirling, G.R., 2017. Biological control of plant-parasitic nematodes. In Diseases of nematodes (pp. 103-150). CRC Press.

Stokes, V.L., Banks, P.B., Pech, R.P. and Spratt, D.M., 2009. Competition in an invaded rodent community reveals black rats as a threat to native bush rats in littoral rainforest of south‐eastern Australia. Journal of Applied Ecology 46(6):1239-1247.

Strong, D. R. and Pemberton, R.W., 2000. Biological control of invading species: Risk and reform. Science 288: 1969-1970.

Suckling, D.M. and Sforza, R.F.H., 2014. What magnitude are observed non-target impacts from weed biocontrol? PloS one 9, e84847.

TAG (2014) Technical Advisory Group for Biological Control Agents of Weeds Manual. United States Department of Agriculture, TOC-2.

Taylor, A., McCallum, H.I., Watson, G. and Grigg, G.C., 2017. Impact of cane toads on a community of Australian native frogs, determined by 10 years of automated identification and logging of calling behaviour. Journal of Applied Ecology 54(6):2000-2010.

Teem, J.L., Gutierrez, J.B. and Parshad, R.D., 2014. A comparison of the Trojan Y Chromosome and daughterless carp eradication strategies. Biological invasions 16(6):1217-1230.

Thomas MB, Casula P, Wilby A (2004) Biological control and indirect effects. Trends in Ecololgy and Evolution 19:61.

Thresher, R.E., Hayes, K., Bax, N.J., Teem, J., Benfey, T.J. and Gould, F., 2014. Genetic control of invasive fish: technological options and its role in integrated pest management. Biological Invasions 16(6):1201-1216. https://doi.org/10.1007/s10530-017-1655-2

Thresher, R.E., Allman, J. and Stremick-Thompson, L. (2018) Impacts of an invasive virus (CyHV-3) on established invasive populations of common carp (Cyprinus carpio) in North America. Biological Invasions:1-16.

Thum, R., Paynter, Q., Volkl, W., Hoffmann, K.H., 1997. Ant homoptera phytophage plant interactions: Are ant-tended homoptera good for biological control? Mitteilungen Der Deutschen Gesellschaft Fur Allgemeine Und Agewandte Entomologie 11: 725-728.

Tompkins, D.M. and Begon, M., 1999. Parasites can regulate wildlife populations. Parasitology Today 15(8):311-313.

Tompkins, D.M. and Veltman, C.J., 2006. Unexpected Consequences Of Vertebrate Pest Control: Predictions From A Four‐Species Community Model. Ecological Applications 16(3):1050-1061.

Tracey, J.B. and Mary, B., 2006. Managing bird damage to fruit and other horticultural crops. Commonwealth Government-Department of Agriculture, Fisheries and Forestry-Bureau of Rural Sciences.

van Emden H.F., 2003. Conservation biological control: from theory to practice. In: Proceedings of the 1st International Symposium on Biological Control of Arthropods, R. Van Driesche (Ed.) United States Department of Agriculture Forest Service, Washington, USA

Van Driesche, R.G., 1994. Classical biological control of environmental pests. Florida Entomologist 77: 20-33.

Van Driesche, R.G. and Bellows, JR. T.S., 1996. Biological Control. Chapman & Hall, New York.

Van Driesche, R. and Hoddle, M., 2009. Control of pests and weeds by natural enemies: an introduction to biological control. John Wiley & Sons.

Van Driesche, R.G., Carruthers, R.I., Center, T., Hoddle, M.S., Hough-Goldstein, J., Morin, L., Smith, L., Wagner, D.L., et al., (2010). Classical biological control for the protection of natural ecosystems. Biological Control 54: S2-S33. DOI: 10.1016/j.biocontrol.2010.03.003.

Van Driesch R (2016) Integrating Biological Control into Conservation Practice. Springer.

Van Klinken, R.D. and Edwards, O.R., 2002. Is host ‐ specificity of weed biological control agents likely to evolve rapidly following establishment?. Ecology Letters 5(4):590-596.

van Klinken, R.D., Colasanti, R., Buckley, Y.M., 2008. How sensitive is weed invasion to seed predation? In: Julien, M.H., Sforza, R., Bon, M.C., Evans, H.C., Hatcher, P.E., Hinz, H.L., Rector, B.G., (Eds.), Proceedings of the XII International Symposium on Biological Control of Weeds. CABI International, Wallingford, UK, pp. 52-55.

van Klinken RD, Morin L, Sheppard, AW, Raghu S. (2016) Experts know more than just facts: eliciting functional understanding to help prioritise weed biological control targets. Biological Invasions 18: 2853–2870

van Lenteren, J.C., 2003. Quality control and production of biological control agents: theory and testing procedures. CABI Publishing.

van Lenteren, J.C., Bale, J., Bigler, F., Hokkanen, H.M.T. and Loomans, A.J.M., 2006a. Assessing risks of releasing exotic biological control agents of arthropod pests. Annual Review of Entomology 51:609–634.

van Lenteren, J.C., Cock, M.J.W., Hoffmeister, T.S. and Sands, D.P.A., 2006b. Host specificity in arthropod biological control, methods for testing and interpretation of the data. In: Bigler, F., Babendreier, D. and Kuhlmann, U. (eds.) Environmental impact of invertebrates for biological control of arthropods: methods and risk assessment. CABI, Wallingford, pp 38–63

Van Rensburg, P.J.J., Skinner, J.D. and Van Aarde, R.J., 1987. Effects of feline panleucopaenia on the population characteristics of feral cats on Marion Island. Journal of Applied Ecology:63-73.

Vitousek, P.M., Antonio, C.M., Loope, L.L. and Westbrooks, R., 1996. Biological invasions as global environmental change. American scientist 84(5):468.

Wapshere, A.J., 1974. A strategy for evaluating the safety of organisms for biological weed control. Annals of Applied Biology 77: 201-211.

White, E.M., Wilson, J.C. and Clarke, A.R., 2006. Biotic indirect effects: a neglected concept in invasion biology. Diversity and Distribution 12:443–455.

Williams, F., Eschen, R., Harris, A., Djeddour, D., Pratt, C., Shaw, R.S., Varia, S., Lamontagne-Godwin, J., Thomas, S.E. and Murphy, S.T., 2010. The economic cost of invasive non-native species on Great Britain. CABI Proj No VM10066:1-99.

Wilson F., 1960. A review of the biological control of insects and weeds in Australia and Australian New Guinea. Commonwealth Agricultural Bureaux, Farnham Royal. 102 pp.

Winston, R.L. Schwarzländer, M., Hinz, H.L., Day, M.D., Cock, M.J.W., and Julien, M.H. (eds,). 2014. Biological Control of Weeds: A World Catalogue of Agents and Their Target Weeds, 5th edition. USDA Forest Service, Forest Health Technology Enterprise Team, Morgantown, West Virginia. FHTET-2014-04. 838 p.

Zeddies, J., Schaab, R.P., Neuenschwander, P. and Herren, H.R. (2001). Economics of biological control of cassava mealybug in Africa. Agricultural Economics 24: 209-219.

Zachariades, C., Paterson, I.D., Strathie, L.W., Hill, M.P. and van Wilgen, B.W. (2017). Biological control as a management tool for suppression of invasive alien plants in South Africa. Bothalia 47 (2), https://doi.org/10.4102/abc.v47i2.2142