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EXPERT MEETING ON ALIEN SPECIES IN WILDLIFE
TRADE, EXPERIENCES IN THE USE OF BIOLOGICAL
CONTROL AGENTS AND DEVELOPMENT OF
DECISION SUPPORT TOOLS FOR MANAGEMENT OF
INVASIVE ALIEN SPECIES

Montreal, Canada, 28-30 October 2015
Item 3 of the provisional agenda

SUMMARY SYNTHESIS OF INFORMATION ON THE USE OF BIOLOGICAL CONTROL AGENTS AGAINST INVASIVE ALIEN SPECIES

Note by the Executive Secretary

I. INTRODUCTION

1. In paragraph 9(g) of decision XII/17, the Conference of the Parties to the Convention on Biological Diversity (CBD) requested the Executive Secretary to compile, in collaboration with the International Union for Conservation of Nature (IUCN) and through the Global Invasive Alien Species Information Partnership, information from Parties, scientific institutions, and other relevant organizations, on experiences in the use of biological control agents against invasive alien species, in particular the release in the wild of alien species for this purpose, including positive and negative cases and cases of the application of appropriate risk assessment, and to submit a synthesis of this information to the Subsidiary Body on Scientific, Technical and Technological Advice prior to the thirteenth meeting of the Conference of the Parties, and to make this information available through the clearing-house mechanism.

2. Accordingly, the Executive Secretary sent notification 2015-052 to Parties, other Governments and relevant organizations inviting submissions of information on experiences in the use of biocontrol agents against invasive alien species. The following Parties, other Governments, relevant organizations and experts, Australia, Bahrain, Belgium, Canada, Colombia, Democratic Republic of Congo, European Union, Finland, France, Gabon, Guatemala, Israel, Japan, Mexico, Myanmar, Namibia, New Zealand, Norway, Peru, South Africa, Sweden, South Africa, United Kingdom of Great Britain and Northern Ireland, United States of America, Asia-Pacific Forest Invasive Species Network (APFISN), Centre for Agriculture and Biosciences International (CABI), Commonwealth Scientific and Industrial Research Organization (CSIRO), Délégation à la Recherche, Government of French Polynesia, Papeete, Tahiti, French Polynesia, Estonian Marine Institute (EMI), Insituo de Investigación de la Amazonía Peruana, International Organization for Biological Control, National Institute of Oceanography of Israel, International Union of Forest Research Organizations (IUFRO), Landcare Research in New Zealand, Ornamental Aquatic Trade Association and Pet Industry Joint Advisory Council (PIJAC) submitted information, which is accessible on the CBD website at <http://www.cbd.int/invasive/iasem-2015-01-submissions/default.shtml>. The Secretariat acknowledges with gratitude the contributions of invasive species experts in the IUCN Invasive Species Specialist Group and CABI, specifically Drs. Andy Sheppard, Phil Cowan, Quentin Paynter and Sean T. Murphy, in finalizing this note and supporting documentation.

3. Based on the information above and other peer-reviewed publications submitted by experts this note reviews the definition of biological control and scope of the expert meeting (section II), and presents information on experiences of Parties, other Governments and relevant organizations (section III). Section IV provides information on existing international standards related to biological control. Section V summarizes the findings and conclusion as a basis for further discussion. A glossary of terms is attached to this document as an annex.

II. SCOPE OF THE SESSION ON BIOLOGICAL CONTROL

A. Scope of the session on the use of biological control agents for control of invasive alien species

4. The session on biological control will review the use of biological control agents to control invasive alien species, in order to prepare a synthesis of available information for consideration by the Subsidiary Body on Technical and Scientific and Technological Advice at its twentieth meeting (Montreal, Canada, from 25 to 29 April 2016).

5. In accordance with paragraph 9(g) of decision XII/17 the expert meeting focuses on the application of alien (non-native) organisms in the control of invasive alien species that threaten ecosystems, habitats or (native) species in the environment, taking also into account the knowledge accumulated in the use of biological control agents in agricultural pest management.

B. Definition of biological control

6. Biological control, often referred to “biocontrol” or “BC”, is defined as “a method of reducing or eliminating damage inflicted by a pest by means of a biological agent, traditionally a parasite or a predator, or by the introduction of a disease where the causal organism is specific in action”.¹

7. There are three major strategies of biological control depending on the way of introduction or origin of biological control agents²:

(a) *Classical biological control*: host-specific natural enemies from the country of origin of the pest or weed are identified, and one or more are imported and released to control the pest. It is expected that the biological control agent will establish permanently from the relatively small founder populations released, and that they will reproduce and spread;³

(b) *Augmentative biological control*: Relatively few natural enemies, either native or introduced organisms, may be released at a critical time of the season (inoculative release) or literally millions may be released (inundative release). Additionally, the condition of the recipient environment (e.g. field or green house) may be modified to favour or augment the natural enemies;

(c) *Conservation biological control*: this strategy is focused on enhancing naturally-occurring biological control. For example, crops can be sown with strips or borders of plants that are beneficial to existing natural enemies serving as a refuge or source of food so that they can increase their abundance⁴.

¹ FAO 1992. Towards Integrated Commodity and Pest Management in Grain Storage. Accessible from <http://www.fao.org/docrep/x5048e/x5048E00.htm#Contents>

² The text was extracted and summarized by the Secretariat from the definition used in Biocontrol Information Resource for EPA Applicants (New Zealand) http://b3.net.nz/birea/index.php?page=background_biocontrol#ref234

³For general texts see Caltagirone L.E. (1981). Landmark examples in classical biological control. Annual Review of Entomology 26: 213-232. (1981) and Bellows T.S. and Fisher T.W. (1999). Handbook of Biological Control: Principles and Applications of Biological Control. Academic Press, San Diego.

⁴ Barbosa P. (1998). Conservation biological control. Academic Press, London. and 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

8. For the purposes of the expert meeting, other biological substances, such as genetically modified plants that produce some pesticidal protein, and biochemical molecules that may control some invasive alien species⁵ are not considered as biological control agents.

C. Taxonomic range

9. Regarding the agents used for biological control of invasive alien species, including pests and weeds, a wide range of taxa that can replicate and are likely to establish in the recipient environment have been used. For example:

(a) Micro-organisms, e.g. *Bacillus thuringiensis* (bacteria) against moths, butterflies, beetles and flies; *Beauveria bassiana* (fungus) against white flies, thrips, aphids and weevils; rabbit haemorrhagic disease virus (RHDV) against European rabbits in Australia, and plant pathogenic fungi used to control weeds;

(b) Animal species as predators or herbivores of weeds (e.g. lady bugs against aphids, mites, scale insects; entomopathogenic nematodes against insect pests; *Cactoblastis* moths to control prickly pear) or parasitoid insects (e.g. Ichneumonid wasps against caterpillars of butterflies and moths);

(c) Plant species as naturally-occurring repellent and attracting pests to trap the targeted pests (e.g. velvet bean, *Mucuna pruriens* against blady grass, *Imperata cylindrica*).

10. The expert meeting is expected to consider all relevant taxa as candidates of classical biological control agents, as appropriate.

III. CASES OF BIOLOGICAL CONTROLS AGAINST INVASIVE ALIEN SPECIES

11. In this section the information submitted by Parties and experts is summarized. The original submissions are accessible at <https://www.cbd.int/invasive/iasem-2015-01-submissions/default.shtml> . Some updates were provided by experts on cases that are advanced.

A. Examples of successful biological controls⁶

12. In Australia biological control of Prickly Pear, *Opuntia stricta*, using the *Cactoblastis* moth, *Cactoblastis cactorum* has managed Prickly Pear populations to well under economic thresholds for more than 80 years, generating \$3 billion AUD benefits, with no off-target effects due to the specificity of the moth larvae's diet.

13. Along with the successful control of numerous cactus species, the State of Queensland Government has used biological control successfully controlled rubbervine, groundsel bush, noogoora burr and *Mimosa diplotricha* using biological control. Several other species such as crofton weed, *Ageratina adenophora* and parthenium weed, *Parthenium* spp. have also been significantly impacted by the introduction of biological control agents. In addition to research on weed biological control, the

⁵ (a) Plant-Incorporated-Protectants (PIPs) that are pesticidal substances. For example, genetically modified plants that produce some pesticidal protein from genetic material transferred into the plant, such as delta endotoxin of *Bacillus thuringiensis* (or Bt). The plant, instead of the Bt bacterium, synthesizes the substance that destroys the pest.

(b) Biochemical pesticides that are naturally occurring substances that control pests by non-toxic mechanisms (e.g. insect sex pheromones, various scented plant extracts that attract insect pests to traps) to be used for pest control or to supplement the activities of classical biological control.

The transboundary introductions of biological materials mentioned above (a) and (b) are overseen elsewhere. For example, PIPs produced using modern biotechnology are addressed under the Cartagena Protocol on Biosafety. FAO Guidance for Harmonizing Pesticide Regulatory Management in South East Asia provides general guidance on development of regulations on biochemical pesticides. The International Standard for Phytosanitary Measure (ISPM) No.14 on the use of integrated measures in a systems approach for pest risk management under the International Plant Protection Convention determines relevant development and evaluation of integrated measures in a systems approach.

⁶ Original submissions from Parties, organizations and experts can be found at <https://www.cbd.int/invasive/iasem-2015-01-submissions/default.shtml> .

Queensland Government, in conjunction with CSIRO under the banner of the CRC for Tropical Pest Management and the CRC for Australian Weed Management, developed strategies and improvements in both the science and processes of weed biological control in Australia. This has resulted in improvements to the way host specificity testing of potential biological control agents are conducted and numerous publications in international journals. In addition, the Queensland Government was involved in formal courses geared to overseas researchers, providing training in all aspects of weed biological control.

14. In Belgium, the Azolla weevil (*Stenopelmus rufinasus*) which is naturally occurring in the country was used for biological control of water fern, *Azolla filiculoides*, water fern, a species with documented impact on water quality, submerged plants and animals, drainage, pumps and filters, leisure and livestock. The method was previously used in South Africa after extensive safety testing and effective control was demonstrated in the period 2012-14 in several sites in Belgium, UK, Netherlands and France. The species was also provided to a citizen science early warning pilot project using a popular online recording tool for naturalist observers.⁷ It is considered that biocontrol of the invasive *A. filiculoides* using the weevil *S. rufinasus* is safe, effective, practical and financially viable⁸.

15. In Tahiti, French Polynesia, the alien invasive tree, *Miconia calvescens* DC (Melastomataceae), was well controlled after the release of a defoliating fungal pathogen *Colletotrichum gloeosporioides* f. sp. *miconiae* Killgore & L. Sugiyama. The results of five years of monitoring showed that total native and endemic species richness and plant cover increased in all sites and plots. Partial defoliation of *Miconia* canopy trees (between 6% and 36%) led to significant recruitment of light-demanding pioneer species, but also to the appearance of some semi-shade and shade tolerant rare endemic species. Native ferns and angiosperms remained dominant (ca. 80%) in the forest understorey during the monitoring period.

16. Many of the successful cases of biological control in New Zealand^{9, 10} are documented. These include the control of:

(a) **Nodding Thistle**, *Carduus nutans* by introduction of a receptacle weevil, *Rinocyllus conicus* and a gall fly, *Urophora solstitialis* to damage the seeds, and a crown weevil, *Trichosirocalus horridus*. A mathematical model has been developed that predicts nodding thistle population will decline if 65% or more of the seeds are destroyed. Levels of seed predation greater than this have already been observed in New Zealand. Combined with improved pasture management, this model explains why many people reported that nodding thistle is now declining through the country;

(b) **St. John's Wort**, *Hypericum perforatum* by introduction of St John's wort beetles, *Chrysolina hyperici* in 1943, and *Chrysolina quadrigemina* in 1965 and a gall midge *Zeuxidiplosis giardi* released in 1961. The weed has declined to the point where it is no longer considered a problem. A recent economic analysis estimated the cost benefit ratio of this programme ranges from c. 11:1 to 100:1 and an NPV of NZ\$150M-1.5 billion, depending on assumptions made regarding the rate of spread of the weed;

(c) **Ragwort**, *Jacobaea vulgaris* by introduction of Cinnabar moth, *Tyria jacobaeae* in 1929; a seedfly, *Botanophila jacobaeae* in 1936 and the ragwort flea beetle *Longitarsus jacobaeae*, which was released in 1983 and has been highly successful, dramatically reducing ragwort populations throughout much of New Zealand, often only 4-5 years after release. A recent economic analysis estimated the cost benefit ratio of this programme to be 14.1:1 and an NPV of NZ\$1.1 billion;

(d) **Alligator weed**, *Alternanthera philoxeroides* by introduction of a beetle, *Agasicle hygrophia* and a moth, *Arcola malloi*, that defoliate and mine the plant were released during the 1980s. These agents have not proved to be effective at controlling terrestrial infestations or aquatic

⁷ <http://waarnemingen.be/exoten>; <http://waarnemingen.be/exo/be/nl/6452.pdf>

⁸ 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.

⁹ http://www.landcareresearch.co.nz/_data/assets/pdf_file/0010/20512/Biological_Control_Success_Stories.pdf

¹⁰ http://www.landcareresearch.co.nz/_data/assets/pdf_file/0017/20519/How_Safe_are_Biological_Control_Agents.pdf

infestations that are regularly flooded or frosted, but they have controlled mats of the weed on lakes and ponds;

(e) **Mist flower**, The smut fungus was associated with a c. 98% reduction in mist flower cover and was so successful that the status of a rare plant *Hebe acutiflora*, which was threatened by smothering mistflower, was changed from 'endangered' to 'range restricted'.¹¹

17. In St. Helena, a scale insect (*Orthezia insignis*) infested gumwoods. *O. insignis* had a history of successful biological control in Hawaii, and several African countries through the introduction of the predatory South American coccinellid beetle, *Hyperaspis pantherina*. The life history and environmental safety of the predator were studied in quarantine in the UK, and in 1993 the St. Helena government gave permission for its introduction onto the island. The beetles, *H. pantherina* were used to establish a laboratory colony, from which over 5000 beetles were released from June 1993 to February 1994. Monitoring was undertaken using visual counts of *O. insignis* and *H. pantherina* on 300 labelled branchlets on the gumwood trees. There have been no further problems reported with the scale on St. Helena since 1995 as shown in the figure below.¹²

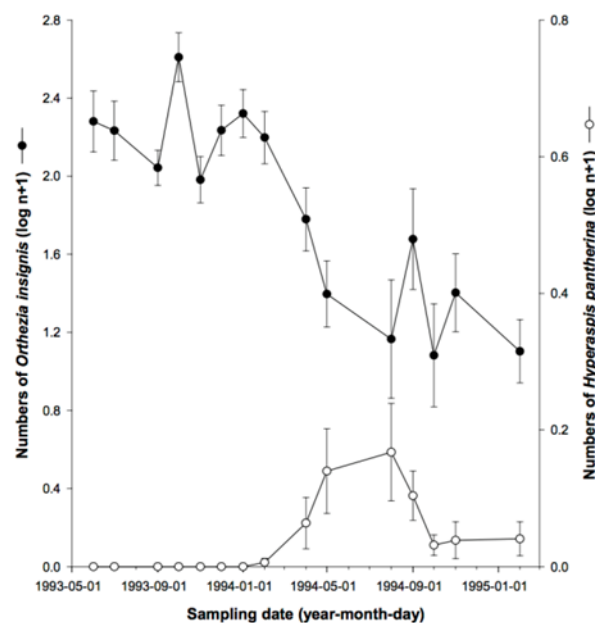


Figure 1. The mean numbers of *O. insignis* and *H. pantherina* on the labelled shoots of initially severely and moderately infested gumwood trees at Peak Dale. Error bars show the standard error for each mean, calculated on log-transformed data

18. In recent years, the United Kingdom has been funding research on biological control of five plant species. The work started in 2003 and the overall cost has been £3 million. The positive cases include:

(a) **Himalayan balsam**, *Impatiens glandulifera*. Following extensive host range and safety testing of a number of agents, one (the rust fungus *Puccinia komarovii* var *glanduliferae*) was deemed safe to release and this took place in 2014 under a strict monitoring regime. In the first year of monitoring infection was found on balsam plants adjacent to the infected release plants, and the rust was found to overwinter in the field under experimental conditions. These are encouraging sign of potential establishment and future spread. In 2015 a more extensive release programme is underway at 25 sites in England and Wales; spread is being monitored.

(b) **Australian swamp stonecrop** (*Crassula helmsii*). After a prioritization process where several Australian arthropod and fungal natural enemies were evaluated, the galling mite, *Aculus* sp.

¹¹ Winston, R.L., Schwarzländer, M., Hinz, H.L., Day, M.D., Cock, M.J.W., Julien, M.H., 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 pp.

¹² <http://www.bugwood.org/arthropod2005/vol1/2b.pdf>

has been selected as the most promising natural enemy to control *Crassula helmsii*. A large proportion of the safety testing has been undertaken indicating that the host specificity of this mite is high. Life history studies are also underway and these data will be compiled in a pest risk assessment which will be produced in 2016 with the view to making experimental releases in 2016/2017.

19. In Australia Wild European rabbits, *Oryctolagus cuniculus*, are serious agricultural and environmental pests. Myxoma virus and rabbit haemorrhagic disease virus have been used as biocontrol agents to reduce impacts.¹³ As shown in the diagram below the economic benefits of the biological control of rabbits in Australia, 1950–2011 could be counted as a successful case. Although rabbits gained disease resistance and showed greater potential for increase, significant counter-measures were taken in agricultural areas to keep rabbits down. The rise of rabbits in arid pastoral areas where control measures were unaffordable would have had relatively small economic impact on a national scale because those areas do not contribute as heavily to agricultural production as higher rainfall zones.¹⁴

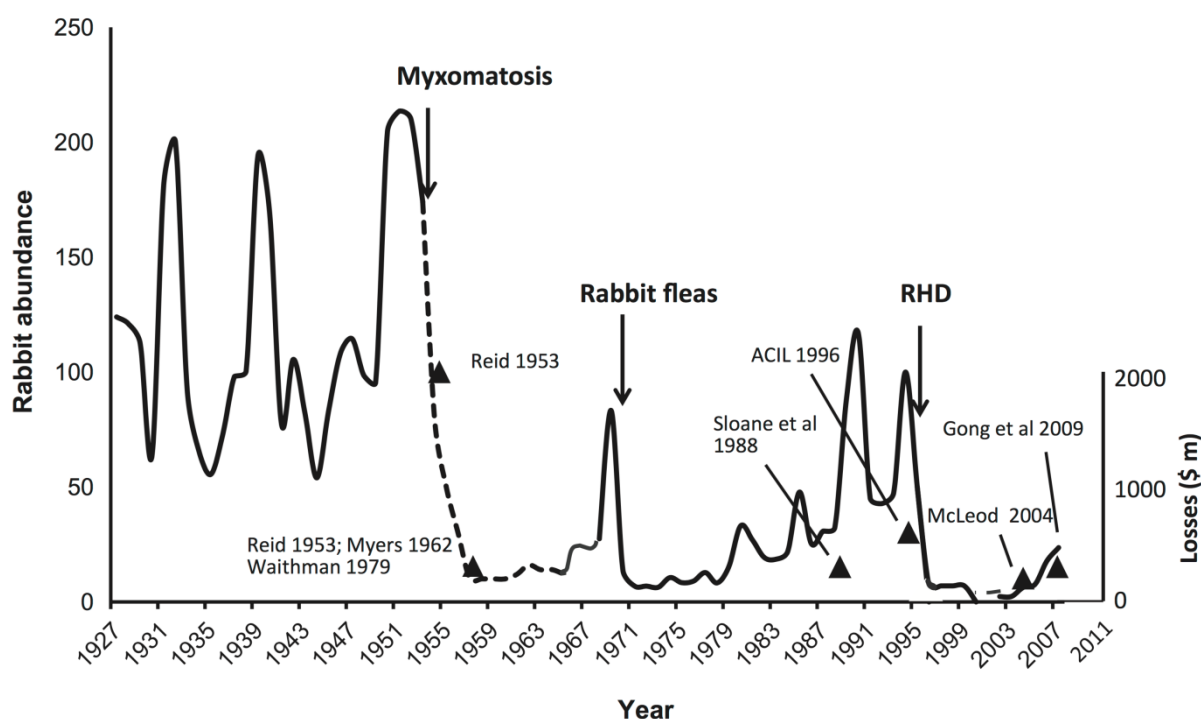


Figure 2. Diagram showing how rabbit abundance in semi-arid South Australia has varied through time in response to the release of biological control agents. The estimated Australia-wide economic losses to rabbits (black triangles) are also shown. Scale for losses shown on right-hand side of figure.

Figure adapted from Saunders *et al.*

B. Examples of limited success or failure of biological controls, including non-target attack

20. The mikania weed, *Mikania micrantha*, a perennial plant of neotropical origin, is a major threat to natural and plantation forests and agricultural systems in Asia and the Pacific. In India it is a serious weed in the south-eastern and north-eastern states. The efficacy of herbicides to control mikania weed is short lived, and manual weeding is labour intensive and expensive. In this context, the rust fungus *Puccinia spegazzinii* de Toni, from Trinidad, shown to be highly specific and damaging to mikania weed, was assessed for its control. Following a consultation process with the Ministry of Agriculture, Government of India and other local stakeholders, the rust was imported in

¹³ Cookie B. et al 2013 Australian Economic History Review, 53 (1) 91-107 See also, <http://www.invasiveanimals.com/publications/research/>

¹⁴ <https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/Expert%20Submissions/Sheppard/iasem-expert-sheppard-bio-06-en.pdf>

2004 into the quarantine facility at the National Bureau of Plant Genetic Resources in New Delhi. After additional host-specificity testing, field release was permitted by the Government of India in 2005. The rust was first released in tea gardens in Assam (north-east India) in October 2005 but did not establish, most likely due to the presence of a biotype of the weed that was partially resistant to the rust pathotype used. In Kerala (south-west India), releases of the rust were initially made in agricultural systems in August 2006, followed by forest sites. These releases are now considered to be successful. The rust has spread and is persisting.

21. The cactus moth, *C. cactorum* Berg., from South America, was widely used as a biological control species against prickly pear (*Opuntia* sp.), though in the Florida peninsula and in several Caribbean islands it became a threat to some desert plants of North America. Due to the social, economic and ecological damage it would cause to the cacti in Mexico, the Mexican official standard NOM-EM-040-FITO-2003 that prevents the introduction, establishment and spread of the cactus moth was published in Mexico. Coupled with this effort, in liaison with international organizations, a technical education campaign was begun aimed at monitoring cacti in order to have an early warning system throughout the country. In August 2006 the presence of the cactus moth was detected Isla Mujeres and Quintana Roo. Fortunately, a timely response resulted in the successful eradication of *C. cactorum* on Isla Mujeres and Isla Contoy, subsequently. The eradication campaign was conducted in collaboration with national (SAGARPA and CONAFOR) and international organizations (IAEA, USDA and NAPPO), which developed pheromone traps and conducted technical training for eradication. Since February 20, 2007 no adult males have been detected on Isla Mujeres and since 5th of March of that year no eggs masses have been found in sentinel cacti or traps.

22. In Myanmar the apple snail (*Pomacea canaliculata*) was introduced in Inlay Lake to control the spreading of water hyacinth (*Eichhornia crassipes*). It suppressed water hyacinth but also became a pest. Currently, both snail and water hyacinth are widely distributed in the wetland.

23. In France¹⁵ the Asian lady beetle, *Harmonia axyridis* Pallas (Coleoptera: Coccinellidae) was introduced deliberately for experiments as biological control agent against aphids in 1980. A method of mass rearing was then developed at the Antibes Institut National de la Recherche Agronomique (INRA) and the species was released in cultures in 1995. To achieve the required effectiveness repeated releases of the beetles were needed and the cost of biological control quickly became large. Then, the INRA research has been directed towards selecting a sedentary ladybug, which is unable to fly and its spread is expected to be limited. As shown in the map below (Figure 3), the introduced *Harmonia axyridis* has spread to a wide range of locations around the world. This illustrates one of the risks of inadvertent spread which is inherent in biological controls.

¹⁵ <https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/iasem-france-bio-02-fr.pdf>

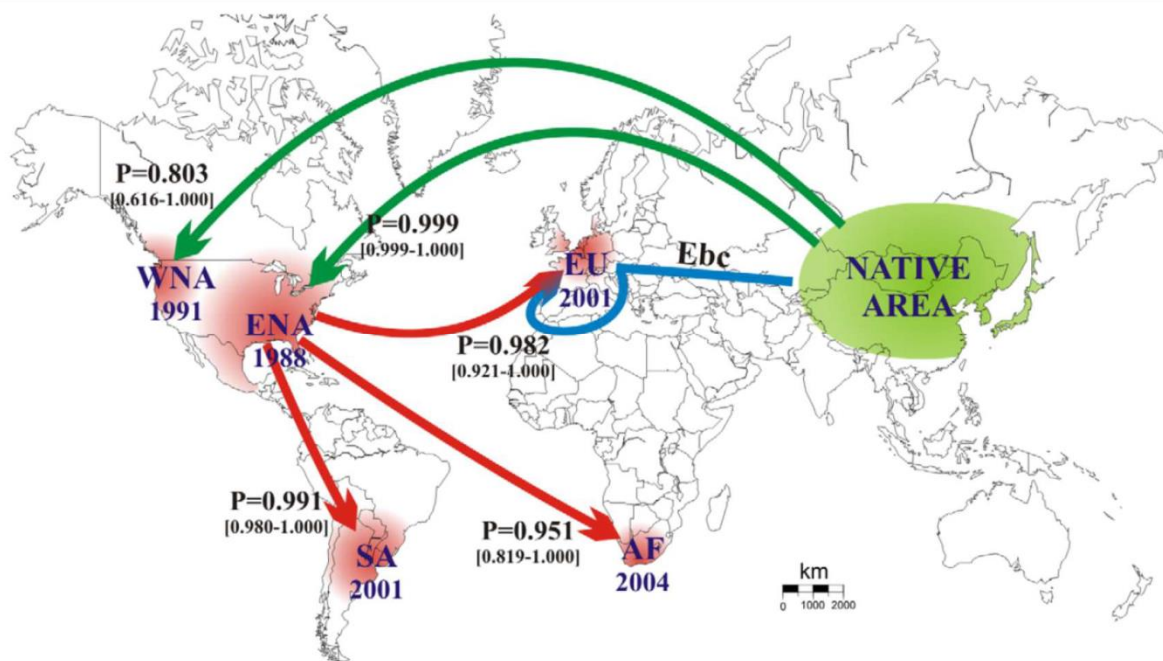


Figure 3. Spread of *Harmonia axyridis*¹⁶

24. In Gabon¹⁷ electric ant, *Wasmannia auropunctata* was introduced as a biological control agent for some insect pests controls, such as cocoa capsids (Hemiptera; Miridae) in Cameroon and some voluntary introduction in Gabon has conducted. With no native competitors in Gabon, *W. auropunctata* has spread progressively throughout the country, threatening the animal biodiversity and human health. The occurrence of *W. auropunctata* at Lopé was first recorded in 1982, in the garage area of a logging camp recently abandoned, which later became the first gorilla study area of the Station d'Etudes des Gorilles et Chimpanzés (SEGC). Villagers confirmed that *W. auropunctata* was absent locally until logging roads were drawn during the 1970s.

25. In Sweden a bacterial alien species *Phasmarhabditis hermaphrodita*, lethal to snails and slugs is sold to the general public for use in gardens to control Spanish slug, *Arion vulgaris* that has considerable economic impact in both gardens and agricultural field. Infestations of *A. vulgaris* may in some areas even affect property values. However, *P. hermaphrodita* impacts not specifically to *A. vulgaris* and thus it is suspected that *P. hermaphrodita* affect snails and slugs in the families of Milacidae, Limacidae and Arionidae. *P. hermaphrodita* was approved for use as a molluscicide in 2008 by the Swedish Chemicals Inspection. The experiences showed that the use of *P. hermaphrodita* was somewhat successful for controlling juvenile Spanish slug but it is not effective for adults. No studies in the effect of *P. hermaphrodita* on biological diversity in Sweden have been found by a literature search. This biocontrol agent is suspected that it negatively affects populations of native snails and slugs, but it is difficult to distinguish between other effects, such as some molluscicide and effects of *A. vulgaris* on native snails and slugs through predation and competition.

26. In the UK a control of Floating pennywort, *Hydrocotyle ranunculoides* has been conducted in recent years. Preliminary field and lab observations in Floating pennywort's native range of Argentina in the 1980's by the USDA had highlighted the potential of a weevil, *Listronotus elongatus* against Floating pennywort. A scoping survey visit to Argentina by CABI in 2006 confirmed that the weevil had a huge impact on the plant in the field and appeared highly host specific and further surveys in 2010 also identified a promising leaf/petiole mining fly and a number of damaging pathogens. From

¹⁶ Lombaert E., Guillemaud T., Cornuet J.-M., Malausa T., Facon B. & 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

¹⁷ <https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/iasem-gabon-bio-01-en.pdf>

2010-15, collaborations with the South American Biocontrol Laboratory (USDA-ARS-SABCL), now FuEDEI (Foundation for the Study of Invasive Species), allowed for a few exports of the weevil and pathogens despite protracted delays in licensing. Host range testing of the weevil and pathogens against 79 species of closely related and/or economically important non-target plants of relevance to the UK and Europe have been ongoing. Results indicate that the leafspots and rust pathogen are not suitably specific. However in 2016, a pest risk assessment for the weevil will be produced with the view to making experimental releases in 2016/2017 should the weevil's specificity prove sufficiently high. Specificity studies on the fly, *Hydrellia* sp. will resume in the fall 2015 in Argentina in parallel, pending export approval to the UK.

C. Examples of evidence on non-target impacts in research

27. To date there have been more than 1000 biocontrol programmes for more than 224 weed species worldwide, using 551 different agents (insects, mites, and fungi) worldwide¹⁸, and for the vast majority no unpredicted non-target attack has occurred. There are only eight reports of insect agents attacking non-target plants that were not predicted by safety-testing prior to release, (which was generally inadequate by modern standards), including two cases in New Zealand (Table 1.). Most of these attacks were only transitory, 'spill-over' attack, a phenomenon that is occasionally seen when plant-feeding species colonize a new habitat, and have not caused significant economic losses or environmental damage.

28. Of the 26 fungal pathogens that have been released for biocontrol worldwide none have caused unexpected non-target damage.

Table 1: Observed non-target attack in New Zealand

Species introduced	Observed
Alligator Weed beetle, <i>Agasicles hygrophila</i>	<u>Yes, minor spillover (rare)</u>
Alligator Weed Moth, <i>Arcola malloi</i>	No
Blackberry Rust, <i>Phragmidium violaceum</i> *	<u>Yes, minor spillover</u>
Boneseed leafroller, <i>Tortrix</i> sp. s.l. ' <i>chrysanthemoides</i> '	No
Broom Seed Beetle, <i>Bruchidius villosus</i>	<u>Yes, minor impacts on minor fodder plant</u>
Buddleia weevil, <i>Cleopus japonicas</i>	No
Californian Thistle Rust, <i>Puccinia punctiformis</i> *	No
Canada thistle leaf-beetle, <i>Lema cyanella</i>	No
Cinnabar Moth, <i>Tyria jacobaeae</i>	<u>Yes, minor spillover on native plants</u>
Gorse hard shoot moth, <i>Pempelia genistella</i>	No
Gorse Pod Moth, <i>Cydia succedana</i>	<u>Minor unpredicted impacts on other weeds</u>
Gorse Seed Weevil, <i>Exapion ulicis</i>	No
Gorse soft shoot moth, <i>Agonopterix umbellana</i>	No
Gorse Spider Mite, <i>Tetranychus lintearius</i>	No
Gorse thrips, <i>Sericothrips staphylinus</i>	No
Greater St John's Wort Beetle, <i>Chrysolina quadrigemina</i>	No
Green thistle beetle, <i>Cassida rubiginosa</i>	<u>Yes, minor spillover on globe artichoke</u>
Heather Beetle, <i>Lochmaea suturalis</i>	No
Hieracium gall midge, <i>Macrolabis pilosellae</i>	No
Hieracium gall wasp, <i>Aulacidea subterminalis</i>	No
Hieracium Rust, <i>Puccinia hieracii</i> var. <i>piloselloidarum</i> *	No
Lesser St John's Wort Beetle, <i>Chrysolina hyperici</i>	<u>Yes, minimal impacts on native plants</u>

¹⁸ Winston, R.L., Schwarzländer, M., Hinz, H.L., Day, M.D., Cock, M.J.W., Julien, M.H., 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 pp.

Mexican Devil Gall Fly, <i>Procecidochares utilis</i>	No
Mist Flower Fungus, <i>Entyloma ageratinae</i>	No
Mist Flower Gall Fly, <i>Procecidochares alani</i>	No
Nodding Thistle Crown Weevil, <i>Trichosirocalus horridus</i>	No
Nodding Thistle Gall Fly, <i>Urophora solstitialis</i>	No
Nodding Thistle Receptacle Weevil, <i>Rhinocyllus conicus</i>	No
Old Man's Beard Leaf Fungus, <i>Phoma clematidina</i>	No
Old Man's Beard Leaf Miner, <i>Phytomyza vitalbae</i>	<u>Yes, minor spillover on native plants</u>
Ragwort Flea Beetle, <i>Longitarsus jacobaeae</i>	No
Ragwort plume moth, <i>Platyptilia isodactyla</i>	No
Ragwort Seedfly, <i>Botanophila jacobaeae</i>	No
Scotch Thistle Gall Fly, <i>Urophora stylata</i>	No
St John's Wort Gall Midge, <i>Zeuxidiplosis giardi</i>	No
Woolly nightshade lace bug, <i>Gargaphia decoris</i>	No

*adventive species, not deliberately introduced as weed biocontrol agents

29. Overall the benefits gained from releasing biological control agents have far outweighed any damage caused. In the biological control of weeds, researchers are continually reviewing the knowledge gained from both past experience and new studies to refine best practice, develop more sophisticated tests that more accurately reflect real-life situations, and improve their interpretation of the results obtained.

30. New Zealand is the only country in which extensive nationwide follow up surveys have been undertaken to check for non-target damage, countering potential criticism that the detected cases may be a fraction of those which have occurred. So far 32 invertebrate agents and 5 fungal agents (including three self-introduced species for which host-range testing data were available) have been surveyed and results have provided additional assurance that current best practice host-testing is a good indicator of what will happen in the field. Non-target attack was generally absent, even when some might have been expected (Table 1). Seven of 34 species deliberately released for weed biocontrol in New Zealand attack non-target plants. Of these, three cases were due to deficiencies in the host-test plant lists that were developed prior to the adoption of the Wapshere 'centrifugal' phylogenetic method¹⁹ for selecting test plants, resulting in key plant species being omitted from testing:

31. Alligator weed beetles *Agasicles hygrophila* were once seen feeding on *Alternanthera nahui* at Lake Waiporohita in northern New Zealand. This plant species was not included in the original host-range testing. Retrospective testing indicated that *A. hygrophila* will feed and oviposit on *A. nahui*, but this plant cannot support full development of *A. hygrophila* as it lacks hollow stems in which pupation takes place. Moreover, *A. hygrophila* has high humidity requirements and only attacks floating alligator weed and *A. nahui* usually grows in situations that are too dry for *A. hygrophila*. The spill over attack was associated with flooding at the lake edge, so that plants that would normally have been growing on dry land were partially submerged. It is likely that approval to release *A. hygrophila* would still be granted under modern regulatory procedures in New Zealand, as the degree of spill-over attack is predictably trivial.

32. Cinnabar moth, *Tyria jacobaeae* larvae will occasionally 'spill-over' onto attack native fireweeds *Senecio minimus* and *S. biserratus*. The attack is minor as the adult moth does not lay eggs on the non-target plants, so only plants growing in close proximity to defoliated ragwort, *Jacobaea vulgaris* plants are attacked by hungry larvae wandering in search of food. Eight native *Senecio*

¹⁹ Aa assessment method on host-range based on the degree of phylogenetic separation from the target weed rather than by taxonomic circumscription.

species were tested before cinnabar moth was released in 1929, but recent advances in phylogenetics using molecular techniques have shown these species to be quite distantly related to ragwort and inappropriate species to use for host testing. The attacked plant species were omitted from testing in 1929 but have since been shown to be relatively closely-related to ragwort. Molecular plant phylogenetics has since revolutionized host-plant selection making such omission of key test plants unlikely nowadays.

33. The lesser St John's wort beetle, *Chrysolina hyperici* attacks native *Hypericum involutum* in New Zealand. This native species was not included in host-range testing performed in the 1940s, but retrospective host-range testing revealed that attack on *H. involutum* was predictable. Further investigations have found that non-target attack is rare and has no impact on *H. involutum* populations.

34. Two cases of non-target attack were explained by flaws in host-range testing protocols, which have subsequently been corrected:

(a) Broom seed beetles, *Bruchidius villosus* are attacking tree lucerne, *Cytisus proliferus* seed, although again this is not significant to the plant. This was not predicted from the results of 'choice' specificity tests (given a choice between broom and tree lucerne, beetles only attacked broom). However, in New Zealand, tree lucerne produces pods before broom. This 'no choice' scenario was not tested in pre-release feeding trials, as 'choice' tests at the time were considered to be more useful. Retrospective testing indicated that 'no-choice' tests, had they been performed, would have predicted the risk to tree lucerne and 'no choice' tests are always included now when is potential for such a 'no choice' situation to arise;

(b) The gorse pod moth, *Cydia succedana* is attacking several introduced legumes that are closely-related to the target weed including Scotch broom, *Cytisus scoparius*, French broom, *Genista monspessulana*, tree lupin, *Lupinus arboreus* and trefoils, *Lotus* spp. Field studies have revealed that gorse pod moth activity in New Zealand is often poorly synchronized with gorse flowering and non-target attack was most prevalent when gorse flowers and pods were absent. Furthermore, although original specificity tests were performed on moths sourced from England, moths of Portuguese provenance were also released into New Zealand to improve genetic diversity. Testing has since revealed that the Portuguese moths have a slightly wider host-range than the UK moths. As a result no agents would ever be released from a population that had not been thoroughly tested, even if it is the same species.

35. Finally, two species were found to cause minor spill-over attack which was predicted (approval to release the agents was given on the basis that the potential benefits of releasing the agent outweighed the potential negative impacts; see the sub-section D. below on the national legislation in New Zealand):

(a) The Old man's beard leaf miner, *Phytomyza vitalbae* will occasionally 'spill-over' onto a species of native *Clematis*, *C. foetida* (and on one occasion *C. forsteri*). The damage is trivial and only occurs in relatively close proximity to old man's beard because female old man's beard leaf miners are infertile if they do not feed on old man's beard;

(b) The Green thistle beetle, *Cassida rubiginosa*, was released in New Zealand despite the potential for non-target attack on some ornamental species and globe artichoke *Cynara scolymus*. Field surveys have found some spillover feeding on globe artichoke growing in close proximity to the target weed Canada thistle *Cirsium arvense*. The attack was not sustained and very minor.

36. The blackberry rust, *Phragmidium violaceum* has self-introduced to New Zealand. Testing carried out before the rust was released in Australia and suggested that native *Rubus* and some cultivated thornless blackberry species here might be attacked. However, some very minor 'spill-over' damage has only been observed once on native bush lawyer, *R. cissoides* growing in close proximity to heavily infested blackberry plants.

37. A number of other species where the potential for minor non-target attack was predicted, prior to agent release, do not attack non-target plants in the field (e.g. Gorse Spider Mite, *Tetranychus lintearius*, Heather Beetle, *Lochmaea suturalis*, Ragwort Flea Beetle, *Longitarsus jacobaeae*) indicating that host-range testing predictions have often been conservative. A promising methodology for investigating whether a plant is likely to be a field host was recently developed which compares the relative performance (e.g. percentage survival) of a candidate agent on test plant species and the target weed.

38. As well as direct effects (the biocontrol agent damages another plant) it is possible that there could be indirect non-target effects on ecosystems when the biocontrol agent becomes a food source, competitor, or disease vector. These are also referred to as 'ripple' or 'downstream' effects and may be positive or negative. Currently, many believe that such intricate and often subtle effects are impossible to assess given the current level of knowledge of ecosystem function, but they are considered before biocontrol agents are released. Moreover, a method for predicting the potential for biocontrol agents to be subject to parasitism was recently developed in New Zealand and has been used to prioritize candidate biocontrol agents (on the basis that parasitized agents are more likely to fail and potentially contribute to negative ripple effects). However, ripple effects mediated by parasitoids appear to be minor in New Zealand. For example, the old man's beard leafminer shares parasitoids with a native leafminer and there is no evidence for increasing levels of parasitism of native leafminer mines, or for a reduction in native leafminer abundance with increasing proximity to old man's beard infestations. Further research into food webs is being undertaken and may allow better predictive models to be developed in the future.

39. Successfully controlling a weed could be a negative outcome if it led to soil erosion or replacement by a worse weed. However, we know of no examples in New Zealand where this has occurred, and it has been rarely reported globally. The largest indirect effect caused by biocontrol agents is likely to be the restoration of native habitats as a result of a reduction in the problem weed.

D. Expert reviews of biological controls regarding their impacts

40. A systematic review²⁰ focused by plant on non-target impacts from agents deliberately introduced for the biological control of weeds found significant non-target impacts to be rare. 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 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 from two agents (*Cactoblastis cactorum* on native cacti and *Rhinocyllus 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. An analysis²¹ showed (as far as is known), that weed biological control 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 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 weeds. It is recommended that a simple five-step scale be used to better communicate the risk of consequences from both action (classical biological control) and no action (ongoing impacts from invasive weeds).

²⁰ <https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/iasem-usa-bio-15-en.pdf>

²¹ Suckling DM, Sforza RFH (2014) What Magnitude Are Observed Non-Target Impacts from Weed Biocontrol? PLoS ONE 9(1): e84847. doi:10.1371/journal.pone.0084847

41. 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 risks²². 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* attacks strawberry guava and does not attack common guava). Provided host-range testing is done appropriately plants that are closely-related to crops or native taxa can be safely targeted. Target selection has to include weed importance and difficult species that are closely-related to valued should not be ignored. In addition, consideration of the insect and plant families involved in non-target effects warrants further effort. Ecological cascades may require further investigation although there are already studies indicate that biological control programmes result in less reticulate trophic relationship than natural food webs of native insects, and that specialized natural enemies are less likely to infiltrate native communities²³.

E. Examples of effective legislative, policy or regulatory framework at the national level

Australia:

42. Australia is one of few countries to have biological control legislation: the Biological Control Act (1984) with parallel Acts in each Australian sub-national jurisdiction. 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 biological control agent releases. When it is applied, targets and agents are declared under the Biological Control Act, leading to a requirement of a public enquiry to consider risks, costs, and benefits.

43. The Guidelines for the Introduction of Exotic BCAs for the Control of Weeds and Plant Pests define a process managed through the National Biosecurity Committee and its various subcommittees, which involves preparing a nomination for the weed or feral animal species of interest and submitting it for approval as a target of biological control. The target must be approved by the National Biosecurity Committee before permission to release a biological control agent is sought.

44. Under current regulatory arrangements, before a biological control agent can be released into the environment, it must be established via scientific risk assessment that the risks associated with release are very low or negligible. This is consistent with Australia's appropriate level of protection (ALOP).²⁴

45. Risk assessments are led by the Department of Agriculture and carried out by scientific and technical experts, in consultation with scientific specialists and other stakeholders. Part of this assessment is 'host specificity testing' undertaken by the researcher, which ensures the proposed control agent is specific only to the target species. A host specificity test involves the exposure of species similar to the target to the control agent, within a quarantine containment facility (required infrastructure to undertake a biological control program). Off-target effects are the key consideration in biological control risk assessment. Based on the risk assessment, the Department of Agriculture may provide a recommendation to allow release if the risk is considered to be acceptable. For proposed plant controls, the Department of Agriculture has produced revised Guidelines for the Introduction of Exotic Biological Control Agents for the Control of Weeds and Pest Plants to assist researchers and importers understand the risk assessment process.²⁵

46. Approval of animal biological control agents is also required under the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act), and this is administered by the Australian Government Department of the Environment. The Department manages a process that allows a 'testing permit' to be issued for the importation of specimens into quarantine-approved facilities for conducting tests to obtain information for assessing potential impacts of the species on the Australian environment. A testing permit is only issued if it can be demonstrated that the

²² Pemberton, R.W. (2000) Predictable risk to native plants in weed biological control. *Oecologia*, 125, 489-494

²³ Hoddle, M. S. (2004) *Conservation Biology*, 18(1), 61-65

²⁴ <http://www.agriculture.gov.au/market-access-trade/sps>

²⁵ http://www.agriculture.gov.au/biosecurity/risk-analysis/reviews/biological-controlagents/protocol_for_biological_control_agents

information cannot be obtained without conducting the tests in Australia. Further, under Section 303EE (4) of the EPBC Act, a risk analysis report prepared by the Department of Agriculture may be used by the Environment Minister in making a determination to include the species on the List of Specimens Taken to be Suitable for Live Import (the live import list). Once host specificity testing is completed, biological control agents are assessed under the EPBC Act, under which the Environment Minister makes a determination whether or not to include the species on the allowed live import list.

New Zealand:

47. Introductions in New Zealand are now regulated under the Hazardous Substances and New Organisms Act 1996 (HSNO). The legislation is strongly focused on the health and safety of people and the environment. HSNO is implemented by the Environmental Protection Authority, 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.

48. For biological control agents, the emphasis is mainly upon (a), (b), and (d). For biological control agent applications, the Authority makes decisions by evaluating risks, costs, and benefits of introducing the agent.

South Africa:

49. The introduction and release of biological control agents in South Africa is subject to the Agricultural Pests Act, No. 36 of 1983 which is administered by the Department of Agriculture, Forestry and Fisheries (DAFF) and the National Environmental Management Biodiversity Act (NEMBA), No. 24 of 2004 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 biological control agents by DAFF is in accordance with the International Plant Protection Convention and the relevant International Standards for Phytosanitary Measures developed by the Food and Agriculture Organization (FAO) of the United Nations.

50. In South Africa the process of issuing a permit requires the applicant to provide specific information on the target weed; the candidate biological control agent and the envisaged research; as well as a prediction on the potential impact of the biological control agent on the environment. Import permits for candidate biological control 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 biological control 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.

51. The NEMBA provides for the management and conservation of South Africa's biodiversity within the framework of the National Environmental Management Act, 1998. 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. The AIS Regulations are aimed at preventing the introduction of more species that may be potentially invasive in the country, as a first priority. The DEA also forms part of the Bio-control Release application Review committee, which is chaired by the South African National Biodiversity Institution (SANBI).

IV. EXISTING INTERNATIONAL REGULATORY FRAMEWORK ON BIOLOGICAL CONTROL AGENTS

A. International Standards for Phytosanitary Measures

52. Under the International Plant Protection Convention (IPPC) that is aimed at protecting cultivated and wild 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 WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) as the basis for phytosanitary measures to apply in trade.

53. The ISPM 2: 2007 *Framework for Pest Risk Analysis* 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 biological control 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.

54. Once the initiation stage has been completed, the provisions included in ISPM 11:2013 *Pest Risk Analysis for Quarantine Pests* should be considered as this standard provides detailed information on the integrated processes to be used for risk assessment and the selection of risk management options. It is to note that this standard includes provisions for pest risk assessment in relation to environmental risks, and this aspect covers environmental concerns related to the use of biological control agents.

55. As it relates specifically to biological control agents and other beneficial organisms, ISPM 3:2005 *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*²⁶ provides phytosanitary measures applicable for safe use of these organisms, with the scope of risk management related to their export, shipment, import and release. It outlines the related responsibilities of contracting parties to the IPPC, national plant protection organizations (NPPOs) or other responsible authorities, importers and exporters. The standard covers biological control agents capable of self-replication (including parasitoids, predators, parasites, nematodes, phytophagous organisms, and pathogens such as fungi, bacteria and viruses), as well as sterile insects and other beneficial organisms (such as mycorrhizae and pollinators), and includes those packaged or formulated as commercial products.²⁷

56. Some guidelines included in the standard might 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 biological control agents may primarily affect other non-target organisms, but thereby result in harmful effects on plant species, or plant health in habitats or ecosystems.

²⁶ https://www.ippc.int/static/media/files/publications/en/1323944456_ISPM_03_2003_En_2011-12-01_Refor.pdf

²⁷ ISPM No. 3 does not include living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control.

57. Under ISPM 3:2005 the NPPO or other responsible authority) should:

- (a) Carry out pest risk analysis prior to import or release of biological control 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 biological control agents and other beneficial organisms;
- (d) Ensure that biological control 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.

58. 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 biological control 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.

59. When evaluating an organism for its potential as a pest, a pest risk assessment should be conducted in accordance with stage 2 of the pest risk analysis process, for which details are provided ISPMs 2:2007²⁸ and 11:2004.²⁹ Consideration should be given to uncertainties and potential environmental consequences, as provided for in those standards. In addition to conducting a pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

60. 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.

61. If a pest risk analysis was not undertaken prior to import in accordance with ISPM 2:2007 and/or ISPM 11:2004, it should be undertaken prior to release, taking into account uncertainties, as provided for in those standards. As highlighted above, in addition to conducting pest risk assessment, contracting parties should also consider possible impacts on the environment, such as impacts on non-target invertebrates.

62. In addition to the above, ISPM 3:2005 indicates that the NPPOs or other responsible authority should implement the following measures:

²⁸ https://www.ippc.int/static/media/files/publications/en/1323944382_ISPM_02_2007_En_2011-12-01_Refor.pdf

²⁹ https://www.ippc.int/static/media/files/publications/en/2014/05/12/ispm_11_2013_en_2014-04-30.pdf

- (a) Quarantine of the cultured or reared biological control agents, for as long as considered necessary.
- (b) Preserving specimens of the biological control agents and their targeted species;
- (c) Documentary that are necessary for importing of biological control 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.

63. It is important to note that other ISPMs may be relevant and should be taken into consideration as it relates to biological control agents and other organisms. For instance, ISPM 6:2011 Guidelines for surveillance, which 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. Adopted ISPMs are available at <https://www.ippc.int/en/core-activities/standards-setting/ispm/>.

B. Application of the relevant ISPMs for the use of biological control agents against invasive alien species

64. As described in ISPM 3:2005, the role and responsibility of the NPPO (or other responsible authority) are core part of the risk management of biological control agents at the national level.

65. Phytosanitary concerns may include the possibility that newly introduced biological control agents may affect other non-target organisms, and thereby result in harmful effects on plant 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.

66. It is important to note that the scope of ISPM 3:2005 does not include living modified organisms, issues related to registration of biopesticides, or microbial agents intended for vertebrate pest control.

67. In assessing the pest risk (the risk of a biological control agent becoming harmful for plants) of biological control agents against invasive alien species, importing countries may require broader sense of 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 3:2005 stipulates that non-target organisms in the environment are such as invertebrates;

- (b) On habitats or ecosystems (Although ISPM 11: 2013 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 is not only with direct impact by the biological control agent but also with climate and landscape changes in some complex manner;

- (d) Related to the negative impact posed by biological control agents that are native to the country. Regarding the use of native species as biological control agents, ISPM 3:2005 considers only the risks posed by contaminated organisms and risk assessment on the environment is exemplified.

68. ISPM 20:2004 “*Guidelines for a phytosanitary import regulatory system*” indicates that contracting parties may make special provision for the import of biological control 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 authority.

V. CONCLUSION

A. Issues identified in the use of biological control agents

69. Biological control agents have been used against invasive alien species for more than 100 years. The successful cases of classical biological control submitted by Parties, other Governments, relevant international organizations and experts demonstrate that comprehensive assessment of the risk of alien organisms for biological control is essential.

70. In the successful cases, the risk assessment and risk management with options for rapid response or eradication of the biological control agent have been carefully considered. Some key points on risk assessment and management include:

- (a) Appropriate assessment on host-range and its specificity of a biological control agent against the targeted invasive alien species;
- (b) Appropriate assessment on non-target impacts in the recipient environment;
- (c) Appropriate assessment on establishment and spread of the biological control agent to ensure effective control;
- (d) Appropriate assessment on spread of the biological control agent to minimize the risk of inadvertent establishment in the areas where the impact is not known/assessed;
- (e) Appropriate assessment of potential impacts on economic, social, environment as well as culture, including the culture of indigenous peoples and local community;
- (f) Cost effectiveness of the use of biological control agent (investment in research vs benefit of release);
- (g) Participation of experts in the process of assessment and collaborative work between agricultural sector, such as NPPO and Regional Plant Protection Organization, and environment sector throughout the process;
- (h) Participation of and communicate with citizens, appropriate.

71. Prior to release the biological control agents some cases applied the agent in a contained condition (such as laboratories, glasshouses, zoos or field test sites) and monitored the efficacy and impact on the environment in particular against non-target species³⁰ to ensure safe use of the biological control agents that are new to the environment.

72. It is encouraged that once the biological control agent is released into the environment systematic monitoring on the ecosystem (including soil erosion), habitats and native species, in particular phylogenetically close species to the targeted invasive alien species were monitored. The monitoring also continued on efficacy of the biocontrol agent.

73. In cases where the efficacy is not sustained or not satisfactory, supplemental measures are applied and also research into the reason of failure should be conducted. Such practices include:

- (a) Continuous release of the biological agent (augmentative biological control);

³⁰ <http://www.epa.govt.nz/new-organisms/about/Pages/types-of-approvals.aspx>

- (b) Release of a new biological agent with appropriate risk assessment and monitoring;
- (c) Integrated management approach, such as the combination of biological control and the application of pesticide or herbicide with appropriate monitoring and adaptation of the control measures.
- (e) Research to identify the reason of failure:
 - (i) Review of species identification in the host organisms and the biological control agent in use (species or sometimes infra specific level);
 - (ii) Review of the assessment of host range specificity;
 - (iii) Review of change in characteristics/behavior of the released a biological control agent in the released environment;
 - (iv) Investigation on indirect effect (e.g. apparent competition,³¹ trophic cascade and indirect mutualism);

74. In the cases of failure or limited success of biological controls with impact on non-target species, the lessons learned include evidence of:

Prior to introduction:

- (a) Lack or insufficiency of risk assessment process (e.g. entomophagous insects with wide host range);
- (a) Lack or insufficiency of information to appropriately assess the risk of impact on non-target species;
- (b) Failure of decision not to release in case with minimal risk was identified but considered as acceptable risks;

Prior to and post introduction:

- (c) Lack or insufficiency of risk management plan to minimize the risk of alien species as biological control agent;
- (d) Lack or insufficiency of monitoring and rapid response to the negative impact on biodiversity;
- (e) Unpredicted change of behavior in agricultural pest control agents which turned out invasive alien species in the environment;
- (f) Climate change may result in unpredicted impact on the behavior of the introduced biological control agents in the field. This has to be included in the process of risk assessment.³²

75. In sum, the successful use of biological control agents requires rigorous science-based risk assessment on the host range of alien organisms and their potential impacts on biodiversity in the recipient environment.

76. The decision on a release of a biological control agent that is considered to be safe for release should be based on the result of risk analysis (risk assessment, risk management and risk communication). Continued research to monitor its efficiency and specificity should be conducted.

³¹ If a target host is attacked by a biological control agent but still maintains a substantial population, the target may subsidize the population of the agent, and may result in significant levels of attack on a non-target species.

³² 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

Where outcomes are not satisfactory further research into identifying the reasons for failure is needed.³³

77. To overcome uncertainties^{34,35} 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)^{34, 35} can support prioritization of controls.

78. Although biological control can be a powerful method of control against invasive alien species and successful cases are available, the cost for research to ensure its efficacy and safety is shown to be significant as shown in section III above. A separate analysis for the monetary costs of application of biological control and benefits for environment, agriculture and cultural integrity can help to justify the research cost.

79. To conduct a meaningful cost/benefit analysis, consultations with stakeholders, e.g. relevant governmental sectors, farmers, land owners, indigenous peoples and local communities, is necessary.^{35,36}

80. Recognizing the difficulty of eradication and the high cost of 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 biological control 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.

81. When the biological control agent(s) behaved in ways that deviate from the evidence of the assessment, contingency plans for taking management measures should be prepared:

(a) Augmentation of release of biological control agent may be considered with appropriate monitoring;

(b) Integrated pest management techniques could help to improve the efficacy of biological control agent;

(c) Continuous monitoring and rapid eradication should be included in the risk management strategy to address the risk of biological control agents becoming invasive;

(d) Regarding the range shifts associated with climate change, scientists pointed out that it could be profitably assessed by linking general circulation models to climatic envelope or other range prediction models that are already employed by both invasion biologists and biological control scientists.

82. The history of biological control indicates that the risk could have been assessed if the recording of host range and other environmental facts had been sufficiently carried out. Although the process of accurate risk assessment may take 5 to 10 years, and where changes in susceptibility or virulence of the targeted species has been observed during the period of trials, the reduction of efficacy does not eliminate the usefulness of biological control programmes, as some successful cases have shown, in particular when it was applied as part of an integrated approach.

³³ Simberloff D. *BioControl*(2012) 57:263-276

³⁴ Liu S, et al. (2011): An integrated decision-support approach in prioritizing risks of non-indigenous species in the face of high uncertainty. *Ecological Economics* 70 1924–1930

³⁵ Liu S. et al (2011): Incorporating uncertainty and social values in managing invasive alien species: a deliberative multi-criteria evaluation approach. *Biol Invasions* 13:2323–2337

C. Other challenges

83. The import of alien organisms for the purpose of biological control requires close collaboration between agriculture sector, in particular national and regional plant protection organizations, and environment sector. Inter-agency communication and collaboration are frequently limited for various reasons. For application of pest risk analysis including impact analysis on the environment further efforts to enhance collaboration between the relevant governmental sectors, as well as the expert community, is necessary. For trans-boundary movement of alien organisms the rules related to the trade facilitation under the World Trade Organization also apply. In the contexts above, safe trans-boundary movement of alien organisms as biological control agent and appropriate benefit sharing agreements under the existing national legislation should be facilitated.

84. Information sharing is a key for accurate risk assessment. Access to research publications and databases of introduced and invasive species has to be ensured, globally.

85. According to the International Organization for Biological Control, at least 7,000 introductions of biological control agents involving almost 2,700 species have been made worldwide. The most widely used biological control agents have been introduced into more than 50 countries. Biological control agents from 119 different countries of origin have been introduced into 146 different recipient countries. In the case of classical biological controls, a national or international research institute usually carries out the research. The sector has traditionally not applied intellectual property rights to regulate access to, or use of, classical biological control agents. It has usually made good practical sense to collaborate with a research organization 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 context of 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, It is reported³⁶ that access to genetic resources, including biological control agents, has become increasingly restrictive under the national legislation related to access to genetic resources as well as phytosanitary regulations.

86. The release of alien organisms as biological control agent on or near sacred sites and lands and waters traditionally occupied or used by indigenous peoples and local communities could be a challenge. Appropriate risk communication on both negative impact posed by invasive alien species and environmental and economic benefit of the use of biological control agent would be essential.

87. There are tools to conduct risk assessment and selection of risk reduction measures, as well as cost-benefit analysis. These are presented in another document for the Expert meeting (UNEP/CBD/IAS/EM/2015/XX the document symbol should be inserted here)

³⁶ <https://www.cbd.int/invasive/doc/meetings/isaem-2015-01/BIOCONTROL/other%20organizations/IOBC/iasem-org-iobc-bio-01-en.doc>

Annex

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 biological control agents or beneficial organisms with the expectation of achieving a rapid effect [ISPM 3, 1995; revised ISPM 3, 2005]
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)
IPPC	International Plant Protection Convention
ISPM	International Standard for Phytosanitary Measures
NPPO	National Plant Protection Organization
Parasite	An organism which lives on or in a larger organism, feeding upon it [ISPM 3, 1995]
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, 1995]
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 [FAO, 1990; revised FAO, 1995; IPPC, 1997; revised CPM, 2012]
Quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing or treatment [FAO, 1990; revised FAO, 1995; CEPF, 1999]
Reference specimen	Specimen, from a population of a specific organism, conserved and accessible for the purpose of identification, verification or comparison. [ISPM 3, 2005; revised CPM, 2009]

Release	(into the environment) Intentional liberation of an organism into the environment [ISPM 3, 1995; revised CPM, 2013]
RPPO	Regional Plant Protection Organization
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 [CEPM, 1996; revised CPM, 2015]
WTO	The World Trade Organization
