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Dear NISC Members:

On December 6, 2017, the Invasive Species Advisory Committee (ISAC) adopted three white papers, which include recommendations for consideration by the Council. Each paper is a direct response to guidance requested of ISAC to advance priorities set forth in the *2016–2018 NISC Management Plan*.

The white paper topics include:

- Advancing Federal-Tribal cooperation in addressing invasive species
- Exploring the application of advanced biotechnologies for the management of invasive species
- Evaluating the risk of managed relocation from an invasive species perspective

The papers are attached here for your reference and also available within the ISAC white paper archives: <https://www.doi.gov/invasivespecies/isac-resources>

The next ISAC meeting is tentatively scheduled to coincide with National Invasive Species Awareness Week (NISAW): February 27th–March 2nd at the National Museum of the American Indian in Washington, DC. More information will be forthcoming from the NISC Secretariat pending final DOI conference clearance.

If questions arise about the papers or the upcoming meeting, please feel free to reach out to me or Dr. Jamie K. Reaser, NISC Executive Director: jamie_reaser@ios.doi.gov.



Charles T. Bargeron
Chair, ISAC

ATTACHMENTS

1. White Paper, *Enhancing Federal-Tribal Coordination of Invasive Species*
2. White Paper, *Advancing Biotechnology Tools for Invasive Species Management*
3. White Paper, *Managed Relocation: Reducing the Risk of Biological Invasion*
4. Distribution List

Enhancing Federal-Tribal Coordination of Invasive Species

Submitted for consideration by the Invasive Species Advisory Committee (ISAC) Federal-Tribal Coordination Task Team

FINAL · APPROVED DECEMBER 6, 2017

INTRODUCTION

Invasive species are defined by the United States government to mean “with regard to a particular ecosystem, a non-native organism whose introduction causes or is likely to cause economic or environmental harm, or harm to human, animal, or plant health” (Executive Order [E.O.] 13751). The ecosystems to which invasive species are introduced or spread are not delimited by jurisdictional boundaries; they intersect with lands managed by federal, tribal, state, territorial, and county governments, as well as properties under private ownership. For this reason, effective coordination and cooperation across jurisdictions is of paramount importance in the prevention, eradication, and control of invasive species.

Federally recognized American Indian tribes are second only to the federal government in terms of the amount of land they manage; approximately 56.2 million acres are owned either by individual tribal members or the *tribe*; the title to which is held in *trust* by the federal government. Most *trust land* is within reservation boundaries, but *trust land* can also be off-reservation, or outside the boundaries of an Indian reservation. A large amount of additional land is owned and/or managed by Native Hawaiians and Alaska Native Corporations. For the purposes of this paper, these native land stewards will hereafter be referred to collectively as indigenous peoples.

Since its establishment in 1999, the National Invasive Species Council (NISC) has acknowledged the importance of working with indigenous peoples to address invasive species issues (E.O. 13112). To date, six representatives of federally recognized American Indian tribes have been appointed members of the non-governmental Invasive Species Advisory Committee (ISAC) which advises NISC. The 2016–2018 *NISC Management Plan* calls includes a priority action (2.5.1) to:

Develop recommendations for coordinating Federal agency activities to implement E.O. 13112 with Federally-recognized tribes, as well as Native Alaskan and Native Hawaiian communities.

Adopted on December 5th, 2016, E.O. 13751 reiterates that federal agencies are to:

Coordinate with and complement similar efforts of States, territories, federally recognized American Indian tribes, Alaska Native Corporations, Native Hawaiians, local governments, nongovernmental organizations, and the private sector.

In order to further these goals, a Federal-Tribal Coordination Task Team was established under the auspices of ISAC.¹ This paper reflects the work of that task team, including internal group discussions, informal consultations with other indigenous peoples, and literature review. The task team identified the following needs and recommendations to further strengthen coordination and cooperation between the U.S. government and indigenous peoples in their efforts to address a shared concern: the devastating impacts of invasive species on the environment and all who depend on it for their survival and quality of life. In order to be successful, coordination efforts between federal agencies and indigenous peoples to address invasive species will need to take into consideration land rights and claims; assure indigenous peoples free, prior, and informed consent; respect and facilitate the application of traditional ecological knowledge; and enable indigenous groups to build their own legal and technical capacities to address invasive species concerns.

¹ ISAC Members: Blaine Parker (Columbia River Inter-Tribal Fish Commission, Task Team Chair), Chuck Barger (University of Georgia), and Sean Southey (PCI Media Impact). Invited Resource Persons: Lori Buchanan (Molokai/Maui Invasive Species Committee, University of Hawaii Pacific Cooperative Studies Unit), Miles Falck (Great Lakes Indian Fish and Wildlife Commission, former ISAC member), Chris Fisher (Colville Confederated Tribes, former ISAC member), Joe Maroney (Kalispel Tribe of Indians), Mervin Wright (Pyramid Lake Paiute Tribe), and Gintas Zavadkas (employed by the Miccosukee Tribe of Indians of Florida during part of the project period). The NISC Secretariat and task team members are grateful to the Department of the Interior’s Bureau of Indian Affairs for enabling tribal representatives to serve as technical experts on the ISAC Federal-Tribal Task Team.

NEEDS AND OPPORTUNITIES

Engaging in Effective Consultation

Prior to implementing the recommendations called for in the 2016–2018 NISC Management Plan, NISC is to consult with federally recognized tribes pursuant to E.O. 13175. Signed on November 6, 2000, the executive order for the Consultation and Coordination with Indian Tribal Governments exists “to establish regular and meaningful consultation² and collaboration with tribal officials in the development of federal policies that have tribal implications, to strengthen the United States government-to-government relationships with Indian tribes, and to reduce the imposition of unfunded mandates upon Indian tribes.”

RECOMMENDATION #1

NISC will notify potentially impacted indigenous peoples when it is considering the actions set forth in its management plans and relevant executive orders, and consult with these entities upon commitment of federal resources to these actions. A three-phase consultation with affected indigenous peoples is encouraged, including *exploratory consultation* (to determine if an impact of the federal action is likely), *pre-consultation* (to establish technical-level cooperation), and *formal consultation* (a government-to-government consultation including relevant agreements for cooperative management of invasive species and invasion pathways).

Strengthening Invasive Species Management Planning

Federal, state, and territorial governments have developed numerous invasive species management plans to establish their goals and priorities for addressing invasive species in the United States. By comparison, relatively few invasive species management plans have been developed by indigenous peoples.³ Not only does this limit the capacity of indigenous people to prevent, eradicate, and control invasive species on the lands they steward, it impedes federal agencies from being able to readily identify opportunities for strengthening coordination and cooperation with indigenous people on shared priorities – by species, location, or pathway of concern. Federal technical and/or financial support could enable indigenous peoples to strengthen management planning, through plans

2 According to E.O. 13175, “consultation is a process that aims to create effective collaboration between the US government and the Indian Tribes. With a core purpose to inform federal decision-makers on Tribal matters to exercise their Trust Responsibilities effectively and honorably. Consultation is built upon clear, proactive government-to-government exchange of information and promotes enhanced communication that emphasizes trust, respect, and shared responsibility. Communication will be open and transparent without compromising the rights of Indian Tribes or the government-to-government consultation process.”

3 Exceptions are noted in Rau et al 2017: http://sites.dartmouth.edu/reo/files/2012/10/Reo_et_al_AIQ_invasive_species_2017.pdf

focused on invasive species, as well as by including invasive species in broader natural and cultural resource planning efforts. These federal investments would not only support federal trust responsibilities, they would serve as a wise investment in the protection of federal lands that might otherwise be subject to incursions of harmful organisms from lands under the stewardship of indigenous peoples who do not have the resources to eradicate or contain invasive species.

RECOMMENDATION #2

NISC will provide grants to indigenous peoples to support the development of invasive species plans, as well as the integration of the invasive species issue into broader natural and culture resource planning efforts, including those activities relevant to human health, safety, and livelihoods.⁴ These plans are to include an assessment of the needs and opportunities for strengthening coordination and cooperation between specific federal agencies and indigenous peoples in their efforts to prevent, eradicate, and control invasive species.⁵

Raising Awareness, Building Capacity, and Fostering Traditional Ecological Knowledge

Although invasive species can have profound impacts on cultural resources and identity,⁶ there has been relatively little focus on these human dimensions of the invasive species issue. This has slowed the recognition of indigenous peoples as key partners in federal efforts to protect shared national assets. It has also limited the potential application of traditional ecological knowledge as a means for preventing, eradicating, and controlling invasive species, as well as restoring the ecosystems they have impacted. There is a need for the Federal Government to foster opportunities for raising awareness of the full suite of impacts of invasive species on indigenous peoples, as well as the potential application of traditional ecological knowledge to management decision making. Federal agencies have trust responsibilities to protect resources of indigenous peoples and, therefore, have the need and inherent directive to provide training to indigenous peoples in currently recognized best practices for the prevention, eradication, and control of invasive species. Likewise, federal agency staff could improve

4 Refer to the Fire Chapter Part 90, Chapter 2 in the Indian Affairs Manual (IAM), Bureau of Indian Affairs: <https://www.bia.gov/sites/bia.gov/files/assets/public/raca/pdf/idco09179.pdf>; United States of America, U.S. Department of Agriculture, Office of Congressional and Intergovernmental Relations. (2007). *American Indians and Alaska Natives: A Guide to USDA Programs* (p. 19): <http://www.usda.gov/documents/AmerIndianNativeAlaskGuide-07%2011%2007.pdf>.

5 Although this paper is necessarily focused on federal-tribal coordination, coordination with state and county programs is also to be encouraged.

6 See, for example: Rau et al 2017: http://sites.dartmouth.edu/reo/files/2012/10/Reo_et_al_AIQ_invasive_species_2017.pdf; Ens et al. 2015: http://cmsdata.iucn.org/downloads/ens_et_al_2015_indigenous_people_and_invasive_species_iucn_cem_ecosystems_and_invasiv.pdf

their capacities to enact trust responsibilities by creating opportunities for indigenous peoples to provide training on the application of traditional ecological knowledge to invasive species management.

RECOMMENDATION #3

NISC will direct the NISC Secretariat to establish a virtual toolkit (“portal”) for the dissemination of information on the linkages between invasive species and indigenous peoples, to include but not be limited to grants information, management plans, educational and outreach materials, case studies, and scientific publications.

RECOMMENDATION #4 (A & B)

NISC will support (A) the creation of an annual national conference on the linkages between invasive species and indigenous peoples, as well as (B) direct federal agencies to mainstream the inclusion of indigenous peoples in invasive species training courses, workshops, outreach campaigns, and other education-oriented activities.⁷

RECOMMENDATION #5 (A & B)

NISC will (A) make training courses in invasive species prevention, eradication, and control available to indigenous peoples through grants and other types of support and, as feasible, (B) work with indigenous peoples to include traditional ecological knowledge in federal training course curricula.

Creating a NISC Secretariat Coordinating Position

Few Departments, Agencies, and Offices on the Council have staff whose work is at the interface of invasive species and indigenous peoples’ issues, no one in the Federal Government is specially charged with coordinating this work from a whole of government perspective. A full-time coordinating position is needed to fulfill the directives set forth in relevant executive orders, NISC management plans, and recommendations made herein.⁸

RECOMMENDATION #6

NISC will create a Federal-Tribal Coordinator position within the NISC Secretariat to increase communication, coordination, and cooperation between federal agencies and indigenous peoples as a standard practice in the prevention, eradication, and control of invasive species across shared landscapes.

⁷ Although indigenous peoples have participated in federally-associated coordinating mechanisms (e.g., ISAC and the Aquatic Nuisance Species Task Force) and special events, there has been relatively little effort to inform indigenous peoples of these opportunities or sponsor their participation.

⁸ While this position is focused on federal-tribal government coordination, coordination with state and local governments will be necessary for the effective implementation of invasive species projects on a landscape scale.

Advanced Biotechnology Tools for Invasive Species Management

Submitted for consideration by the Invasive Species Advisory Committee (ISAC) Advanced Biotechnology Task Team

FINAL · APPROVED DECEMBER 6, 2017

Increasingly, genetic tools are being used to detect and solve pressing environmental, social, and health-related challenges. It is clear that investments in technology innovation can be game changing, as advances in biotechnology may provide new methods to protect the nation's resources from the negative impacts of invasive species. The current toolbox of management options is recognizably insufficient to deal with many of the high-impact species that have been introduced. However, "surrendering" to these species is generally not a viable option from ecological, health, economic, socio-cultural, or political perspectives. Cost-efficient solutions to these "grand invasive species challenges" need to be found. Through processes that strategically alter an organism's genetic blueprint (aka genome), advanced biotechnologies may substantially improve our capacities to eradicate and/or control populations of invasive species.

Interest in the application of advanced genetic technologies is growing rapidly on national and international scales, across disciplines, and for parties affected by the impact of invasive species. As this interest grows, genetic technologies are quickly evolving with some raising questions over whether the potential risks are too high to warrant their use. Policy makers worldwide have expressed concern about the capacity of regulatory systems to keep pace with these technological advances and effectively address the societal concerns (known as "social license") that are inherent in the application of advanced genetic technologies, particularly when modified organisms are to be released. It is also important to note that the exploration of advanced genetic technologies is occurring in the midst of growing skepticism over both scientific and regulatory institutions. A single misstep in the development and application of advanced biotechnologies could fundamentally compromise social and political support for highly beneficial applications across a wide range of environmental, human health, and biodefense goals.

Clearly, there is a need to carefully explore the potential ecological, socio-economic, and political ramifications of using advanced genetic technologies to address invasive species. The National Invasive Species Council (NISC) has expressed this need through Action 6.3.1 of the 2016–2018 *NISC Management Plan*, which specifically calls for "an assessment of the potential ecological, socio-economic, and political benefits and costs

of gene editing technology in the context of invasive species prevention, eradication, and control" (NISC 2016). The objective of this paper is to support this assessment by providing recommendations to NISC on the further development and application of advanced biotechnologies for invasive species eradication and control.

POTENTIAL APPLICATIONS

The rapid pace of technology advancement in the field of genetics is giving rise to approaches for the eradication and control of invasive species. Work is already underway to investigate advanced biotechnology applications for public health, pest management, and biodiversity conservation, all of which show a range of possibilities for addressing invasive species (Harvey-Samuel et al. 2017, Piaggio et al. 2017). Some examples of current explorations include:

Genome Editing Genome editing is a technique that allows researchers to insert, delete, or modify DNA to silence, activate, or otherwise modify an organism's specific genetic characteristics. While the practice is not new (zinc finger nucleases [ZFNs] and transcription activator-like effector nucleases [TALENs] have been used since the late-1990s), the development and refinement of clustered regularly interspaced short palindromic repeats (CRISPR) combined with the Cas9 enzyme (CRISPR/Cas9) has rapidly transformed the field by increasing the specificity and efficiency of gene editing and decreasing costs by orders of magnitude (Vasiliou et al. 2016, Wang et al. 2016). Genome editing has a suite of potential uses and is currently being applied to human health and crop protection (e.g., vector-borne disease, crop pests). Future uses of genetic editing for invasive species management could include modifying:

- invertebrate pests for Sterile Insect Technique releases (e.g., mosquito eradication in Hawaii for eliminating avian malaria that is driving extinctions of Hawaiian endemic birds, Piaggio et al. 2017);
- introduced invertebrate pests so that they are unable to carry certain diseases, coupled with large scale releases of those modified pests to increase the proportion of the population carrying the trait (Sampath et al. 2015, Piaggio et al. 2017);

- native species to be resistant to disease (e.g., bats for white-nose syndrome, amphibians for the fungal disease chytridiomycosis, Thomas et al. 2013, Adams 2016); and
- crops and other valuable plants to confer disease resistance, or to produce insecticide variants for invertebrate pests (e.g., American chestnut and chestnut blight, Jacobs et al. 2013).

Gene Drives Gene drives further advance the use of genome editing by introducing a mechanism that promotes the inheritance of a particular gene to increase its prevalence in a population (Esvelt et al. 2014). Essentially, the process “drives” the desired genetic trait through subsequent generations of offspring from the modified individual(s). Gene drives occur naturally, but can now also be synthesized with CRISPR/Cas9. The use of gene drives provides the potential to modify sexually reproducing wild populations by design. Gene drives allow specific genes to be inserted, modified or deleted. For example, they can be used to modify populations to no longer carry a disease or to alter the sex ratio of all offspring to all male. Significant concern exists over the potential for gene drives to move beyond (or be moved beyond) their targeted population of an invasive species to affect that species where it is native (Noble et al. 2017).

To date, CRISPR gene drives have been synthesized in yeast, fruit flies and two species of mosquito (Di Carlo et al. 2015, NAS 2016). Specific potential applications include mosquito control to limit the transmission of malaria and other vector borne diseases, or to eradicate invasive rodents on islands.

RNA Interference Ribonucleic acid interference (RNAi) is a naturally occurring intracellular mechanism, which effectively “silences” targeted genes (Fire et al. 1998, EPA 2013). The process involves the introduction of double-stranded RNA into the cell, which results in the destruction of single stranded messenger RNA with the same nucleotide sequence. This type of targeted gene silencing can be used to provide resistance to pests and diseases, eliminate production of specific hormones, or can be a taxa-specific toxicant (Huvenne and Smagghe 2010, Xue et al. 2012, Casacuberta et al. 2015). As such, these new technologies have significant potential to improve targeted pest and invasive species control and replace certain use patterns of conventional and organic chemistries used for broad-spectrum pest control. Future uses for invasive species control could include:

- taxa-specific pesticides for use in baits and foliage sprays, or in applications to marine or freshwater systems to control invasive mollusks, fish, and introduced parasites of native fish (Heath et al. 2014, Owens and Malham 2015, Saleh et al. 2016);
- taxa-specific hormone suppressants in baits that would disrupt social dynamics or turn workers against queens, leading to colony collapse in invasive social invertebrates like ants; and
- modified invasive scale insects, such that invasive ants who share a symbiotic relationship with the scale are affected, but other scale predators or parasites are not affected.

ISSUES AND CONCERNS

As these advanced biotechnologies are developed, it is critical to have adequate decision support tools and methods that can identify, assess, and mitigate their potential risks in the research and development phase (e.g., laboratory conditions and field trials), as well as in their full-scale applications. A 2016 National Academy of Sciences (NAS) study included a number of recommendations relevant to the research phase and overall biosecurity, but increased attention is needed given ongoing evolution in the technology and regulatory requirements for assessing potential field-based applications (NAS 2016, Akbari et al. 2015). While this requires the development of new decision support tools, lessons learned and practices can also be derived from other fields of application.

Biosecurity: The 2016 NAS study included a significant focus on biosecurity, as well as recommendations for establishing confinement and containment protocols for laboratory and field-testing and release. The report outlines a step-wise approach similar to that used in the development of biocontrol agents. The steps include: preparation for research (phase 0); laboratory-based research (phase 1); field-based research (phase 2); staged environmental release (phase 3); and post-release surveillance (phase 4) (NAS 2016).

Risk Analysis: Research on advanced genetic technologies needs to proceed in a manner that identifies and assesses the relative risks at each stage of development (e.g., laboratory containment, clinical field trials) (Kuiken et al. 2014). Work is underway to strengthen risk identification, risk assessments, and population modeling capacities (Hayes et al. 2014, Casacuberta et al. 2015). This includes projects being undertaken by the U.S. Army Corps of Engineers (USACE) and Australia’s Commonwealth Scientific and Industrial Research Organisation (CSIRO). Ideally, this work will inform the development of standardized risk analysis procedures and guidelines for prioritizing advanced biotechnology applications to invasive species eradication and control.

Risk Mitigation: There is also a need to develop risk mitigation techniques, for example by making the advanced biotechnologies self-limiting. The inclusion of reversal drives or daisy chain drives into gene drives are possibilities that are currently being explored (Noble et al. 2016). Additionally, the Department of Defense’s Defense Advanced Research Projects Agency (DARPA) is funding the Safe Genes research program, which includes examination of controls for gene editing, application technologies, countermeasures and prophylaxis, and genetic remediation.

Governance: Policies and legal processes are shifting as regulators work to identify potential future technological applications and update existing rules accordingly (Marchant et al. 2013). The evolution of this regulatory process, most specifically associated with the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework), coincides with both an increase in the rate of technological change as well as an additional focus on the release of advanced biotechnologies for broader scale environmental applications (OSTP 1986, Oye et al. 2014). The movement beyond applications for medicines, food safety, and agriculture/

livestock has raised questions as to whether the three current regulatory agencies have the requisite studies, data and risk assessment methodologies necessary to evaluate applications for broader ecological purposes, such as invasive species control.

The Coordinated Framework is designed to balance regulation adequate to protect consumer health and the environment with regulatory flexibility to avoid impeding innovation, and it outlines oversight responsibilities given existing legal authorities exercised by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) and USDA's Animal and Plant Health Inspection Service (APHIS). (OSTP 1986). A 1992 update and another initiated in 2015 have endeavored to maintain flexibility as biotechnology has advanced in scope and application (OSTP 1992, Holdren et al. 2015).¹ Within these regulatory processes, there are triggers for engaging assessments related to the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA), however invasive species applications represent a divergence from the types of products and private sector applicants with which the regulatory agencies have traditionally dealt. There are also arguments that the United States regulatory system itself is overly complicated. For example, the company Oxitec submitted two similar applications for trials of genetically modified *Aedes aegyptii* mosquitoes and to diamondback moths. Despite the similarity of the technology used, the mosquito application was reviewed by the Food and Drug Administration (FDA) given its focus on human health, whereas the diamondback moth was reviewed by APHIS given the focus on plant health. This has prompted a request from some developers of advanced biotechnologies for more clarity on how those regulatory regimes apply to invasive species applications.

Public Engagement and Social License The most important long-term component for the successful use of advanced genetic technologies for invasive species eradication and control is public acceptance of the technology (Kuiken 2016). Failure to engage the public and foster support for real-world applications could leave these technologies sitting on the shelf despite their potential and significant investments in their

1 The 2015 update resulted in three documents relevant to potential future regulations:

- Modernizing the Regulatory System for Biotechnology Products: a draft update to the Coordinated Framework to clarify how the current authorities and responsibilities of EPA, FDA and USDA apply to different product (OSTP 2016a);
- National Strategy for Modernizing the Regulatory System for Biotechnology Products: A draft long-term strategy to ensure that the Federal regulatory system can efficiently assess any risks associated with future products of biotechnology. (OSTP 2016b); and
- Preparing for the Future Products of Biotechnology: an independent analysis of the future landscape of biotechnology products by the National Academy of Sciences, Engineering, and Medicine (NAS 2017)

In tandem with the development of these products, the EPA, FDA, and USDA are issuing guidance on how the update affects their own responsibilities and internal processes (see also Appendix I: Agencies and Statutes Regulating Biotechnology Products relevant to Invasive Species).

development. Key questions include: Who is responsible for public outreach and engagement, particularly for issues that extend beyond the scope of public input into federal regulatory approval processes? At what stage should engagement take place? How should public dialogue be structured? How should competing interests be addressed (e.g., greater public good vs. local interests; transparency vs. proprietary commercial information)?

It is also important to recognize the need for and benefits of public discourse over a range of ethical and social issues including: how values inform notions of benefits and costs, what constitutes socially acceptable thresholds of risk, linkages to social justice, environmental justice and intergenerational equity, and how to maintain public trust in both science as well as government (Hart Research Associates 2013, Pauwels 2013, Meghani 2014, Sharpe 2014, Sankar and Cho 2015, NAS 2016). There will not be a single answer to these questions, but the mechanism for dialogue and public engagement is still critical for vetting the development and potential application of these advanced technologies.

Classical Biological Control Classical biological control (biocontrol) is the use of an invasive species' natural enemies from its native range to control that invasive species in the new habitat that it has invaded (ISAC 2015, ISAC 2016). Parallels have been drawn between biocontrol and the use of genetically modified species as a control technique (the term genetic biocontrol has been used by some experts), given questions on any unintended impacts that the introduced organism could potentially have on non-target species and their ecosystems (Webber et al. 2015, NAS 2016, Piaggio et al. 2017). The identification, testing, and risk assessment of potential biocontrol agents is a rigorous regulatory process designed to ensure minimal to no non-target effects. Lessons can readily be applied from the long history of practice with classical biological controls. For example, biocontrol agents undergo an extensive process for risk analysis (Carruthers and D'Antonio 2005) and often include cost/benefit analyses as well (Jetter et al. 1997, de Lange 2010, McFadyen 2007). Of particular note is the use of a Technical Advisory Group for Biological Control Agents of Weeds (TAG) to provide guidance and serve as an interface between researchers and regulatory community (APHIS 2017).²



RECOMMENDATIONS TO NISC

We recommend that relevant NISC members work together to:

1. Foster the development of decision support tools and updated guidance for federal activities related to advanced biotechnology applications and invasive species, including:
 - prioritization frameworks to identify optimal targets (species and sites) for the application of advanced biotechnologies, and assessments of available and potential

2 The TAG includes representation from USDA, DOI, EPA, DOD/USACE as well as the National Plant Board, the Weed Science Society of America and the ARS Biological Control Documentation Center.

biotechnologies and their suitability for specific taxa/species in specific environments or under specific conditions (including climatic changes);

- updated guidance on confinement and containment protocols for laboratory and field testing and release;
 - standardized risk analysis frameworks addressing aspects of risk assessment, management and communications appropriate to the full R&D cycles (i.e., project conceptualization, problem formulation, laboratory testing, field trials, scaled environmental releases); and
 - evaluation of risk minimization and mitigation measures including physical, biogeographic, and temporal containment and application technologies.
2. Establish a multi-stakeholder technical advisory group focused on intentional environmental releases of advanced biotechnology applications. Modeled after the Technical Advisory Group for Biological Control Agents of Weeds, the group would identify emerging technical, social and environmental issues with their use and to help facilitate communication across the research, conservation and regulatory communities.
 3. Call for relevant federal agencies to undertake a periodic horizon-scanning exercise to identify anticipated developments in advanced biotechnologies and their applications to invasive species prevention, detection, eradication, and control and report their findings to NISC via its Secretariat. This would include identification of implications for social license, policy and regulatory reviews, and resources needed for stewardship.
 4. Direct the development and publication of guidance/best practices for developers of advanced biotechnology applications to invasive species to facilitate regulatory reviews, including clarity on regulatory jurisdictions, information/data necessary for reviews, and processes to interface with other relevant agencies where necessary and appropriate. The FDA, EPA, and USDA, as well as the Departments of Defense and the Interior have critically important roles in this process.
 5. Direct relevant agencies to develop and publish a process to assess the ethical, social and interjurisdictional (i.e., federal, state, tribal, territorial) dimensions of emerging advanced biotechnologies and their deployment. This could include best practices, public engagement, and securing social license.
 6. Enable relevant federal research and development agencies to support research into new platform-providing advanced biotechnologies that can be applied widely to different invasive species and incentivize the development of novel approaches for invasive species management including the use of grand challenges as mechanisms to drive the development of new technologies.



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APPENDIX I

Agencies and Statutes Regulating Biotechnology Products relevant to Invasive Species

AGENCY	STATUTE	OBJECTIVE	APPLICATION
EPA	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	Preventing unreasonable adverse impacts on the environment	Insect applications designed as a pesticide
EPA	Toxic Substances Control Act (TSCA)	Prevent the manufacture, processing, distribution in commerce, use, or disposal of chemical substances from presenting an unreasonable risk of injury to health or the environment	Catchall for applications not covered by other agencies or under other statutes
FDA	Federal Food, Drug, and Cosmetic Act (FD&CA)	Ensure human and animal drugs are safe and effective	Applications on rodents, fish and other animals, as well as on insects for health purposes
USDA	Plant Health Protection Act	Protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks	Plant applications that include a pest or noxious weed component

Derived from OSTP 2016b, which reviews statutes relevant to the full range of biotechnology products.

Managed Relocation: Reducing the Risk of Biological Invasion

Submitted for consideration by the Invasive Species Advisory Committee (ISAC) Managed Relocation Task Team

FINAL · APPROVED DECEMBER 6, 2017



INTRODUCTION

Managed relocation is the intentional relocation of populations of native wildlife to habitats that they do not now live in as a hedge against hypothetical changes in their current ranges. This proposed scheme has been proposed as one tactic to perhaps minimize the risk of extinctions of species owing to changing climate (cf. Aitken and Bemmels 2016; Fordham et al. 2012; Gallagher et al. 2015; Loss et al. 2011; Vitt et al. 2009).¹ This contrasts with the relocation of wildlife to locations whose habitat has been degraded or destroyed (Miller et al. 2012; Seddon et al. 2014a; Seddon et al. 2014b). Although intended to advance conservation goals, there are substantive concerns about the ethical foundation, social acceptability, ecological wisdom, and practical capacity of engaging in management relocation (Maier and Simberloff 2016; Ricciardi and Simberloff 2009a; Schwartz et al. 2012). The feasibility concerns are largely governed by limits on ecological knowledge and legal and funding constraints. Thus, although increasingly popular in concept, managed relocation will not be practical as a broadly exercised extinction mitigation strategy (Maier and Simberloff 2016).

A key concern about the managed relocation scheme is the risk of ecological damage that might be caused by the translocation of species to novel ecosystems (Maier and Simberloff 2016; Ricciardi and Simberloff 2009b). Intentional introductions of non-native species have often resulted in unexpected and adverse outcomes (Mack et al. 2000), potentially amounting to billions of dollars in damages and other losses (Pimentel et al. 2001). These impacts may become readily evident, subtly accumulate over time, or emerge suddenly following a long, apparently benign lag time (Simberloff 2009). The current understanding of ecological systems has provided weak evidence for gauging the risk of translocated organisms to the recipient ecosystems (Ricciardi and Simberloff 2009a).

Invasive species are defined by the United States government to mean “with regard to a particular ecosystem, a non-native organism whose introduction causes or is likely to cause economic or environmental harm, or harm to human, animal, or plant health.”² Any organism that is relocated to a novel ecosystem is thereby non-native has the potential to become an invasive species and/or spread “hitching” invasive species (e.g., pathogens, parasites, or propagative material).

Regardless of the how often the introduction of non-native species cause ecological harm, the degree of harm suggests that introducing them poses sufficient ecological risk to the integrity of natural systems that local, national, and international governing bodies need to establish policies that constrain species introductions (Lodge et al. 2006). However, there is not now any cohesive policy at any level of governance to guide the conditions under which managed relocation might be acceptable or what might be the consequences of interested parties engaging in unsanctioned managed relocation efforts (Klenk and Larson 2015; Kostyack et al. 2011; Schwartz et al. 2012; Shirey and Lamberti 2010).

Recognizing the risks posed by invasive species to national security, federal assets, and the well-being of the American public, Section 4(d) of Executive Order (E.O.) 13112³ called for the National Invasive Species Council (NISC) to:

Develop, in consultation with the Council on Environmental Quality (CEQ), guidance to Federal agencies pursuant to the National Environmental Quality Act (NEPA) on prevention and control of invasive species, including the procurement, use, and maintenance of native species as they affect invasive species.

The 2016-2018 NISC Management Plan⁴ thus called for the following actions:

Action 4.1: In keeping with NEPA requirements, develop a general introductory document and associated annexes that provide

¹ The scientific literature generally refers to intentional translocation of species outside a species’ historic range for the purpose of conservation as managed relocation (Richardson et al. 2009), assisted migration (McLachlan et al. 2007), or assisted colonization (Hoegh-Guldberg et al. 2008). For consistency, “managed relocation” is used throughout this paper.

² <https://www.doi.gov/invasivespecies/management-plan-and-executive-order>

³ <https://www.doi.gov/invasivespecies/management-plan-and-executive-order>

⁴ <https://www.doi.gov/invasivespecies/management-plan-and-executive-order>

effective guidance for the prevention, eradication, and control of invasive species, as well as the restoration of impacted habitats. Each annex will provide guidance on a specific aspect of the invasive species issue. The first annexes are to be developed within the scope of this NISC Management Plan, but annexes may be included as needed dictate and resources permit. The initial annexes include:

- Action 4.1.1: Use of native seed/plants in habitat restoration;
- Action 4.1.2: Movement of watercraft among water bodies; and
- Action 4.1.3: Reducing the risk of biological invasion via managed relocation

In order to further Action 4.1.3, a Managed Relocation Task Team was established under the auspices of ISAC.⁵ This paper reflects the work of that task team, including internal group discussions, expert consultations, and literature review. The Task Team considered two parallel bodies of science to inform the analysis: a) the species translocation literature (Schwartz and Martin 2013; Seddon 2010), particularly as it relates to changing climates⁶ and b) a parallel, more empirically rich and much larger⁷ literature on the harmful consequences of invasive species on ecosystems (Mack et al. 2000) and on prediction and management of the risks of invasion (Hulme 2009; Kolar and Lodge 2002; Simberloff 2009; Thuiller et al. 2005). See Annex I for examples of managed relocation scenarios, Annex II for a list of referenced literature, and additional as citations for further reading.

The task team offers the following key finding and recommendation to strengthen federal capacities to reduce the risk of biological invasion being facilitated through managed relocation practices.



KEY FINDING

Any organism that is relocated to a novel ecosystem has the potential to become an invasive species or spread “hitching” invasive species, or both. Managed Relocation is not congruent with Executive Order 13112 to the extent that it might facilitate “economic or environmental harm or harm to human, animal, or plant health.” Consequently, the actions by federal agencies or those entities supported by federal funding to engage in

⁵ ISAC Members: Edward E. Clark, Jr. (Wildlife Center of Virginia), Dan Simberloff (University of Tennessee), Mark Schwartz (University of California – Davis), Brent Stewart (Hubbs-SeaWorld Research Institute), and John Peter Thompson (Maryland Nursery and Landscape Association). The NISC Secretariat and task team members are grateful to the National Park Service for enabling the participation of technical experts on the ISAC Managed Relocation Task Team.

⁶ An ISI Web of Science search on the terms “assisted migration” or “assisted colonization” or “managed relocation” on 28 April 2017 returned 539 peer reviewed journal articles, 444 since 2010.

⁷ An ISI Web of Science search on the terms “invasion” or “invasive” or “non-native” and “threat” and “species” or “ecosystem” or “biodiversity” conducted on 28 April 2017 returned 3,496 papers, 2,358 since 2010.

managed relocation need to be addressed in a manner consistent with E.O. 13751 Section 3. (3), which compels Agencies to:

Refrain from authorizing, funding, or implementing actions that are likely to cause or promote the introduction, establishment, or spread and invasive species in the United States, unless pursuant to guidelines that it has prescribed, the agency has determined and made public its determination that the benefits of such actions clearly outweigh the potential harm caused by invasive species; and that all feasible and prudent measures to minimize risk of harm will be taken in conjunction with these actions.



RECOMMENDATION

Develop a clear national policy for managed relocation consistent with agency duties as set forth in E.O. 13751. This may be best accomplished through a Presidential Memorandum or CEQ-published NEPA guidance document that is further supported by agency-specific guidance.^{8,9}

The actions taken in response to this recommendation should be standardized and streamlined among all Federal Agencies even though perhaps challenging at Department and Agency levels. Proposals for managed relocation are likely to vary substantially in goals, locations, species, relevant authorities, agency jurisdictions, and available management resources. Public resource managers might propose actions that range from translocating genotypes across portions of species ranges (e.g., tree seed zones) to transferring suites of species in an effort to migrate ecosystems. Similarly, the rationale for such actions may range from reducing extinction risk among endangered species to altering forest composition for timber production or adjusting the composition of zooxanthellae to increase resilience of coral to bleaching.

Good governance requires that the evidence presented by the proponent of managed relocation is evaluated by a qualified, neutral third-party. Therefore, any evaluation and approval actions made in accordance with national or agency-specific policies, or both, should be conducted through an external review process.

At a minimum, the national policy and any supporting policies should:

- A. *Limit the use* of managed relocation to extra-ordinary circumstances;

⁸ It is particularly important that the U.S. Fish and Wildlife Service develop explicit guidelines for when and how species listed under the Endangered Species Act or Migratory Bird Treaty Act may be the focus of managed relocation. Since migratory birds are not typically range-limited, the national guidelines should preclude them for managed relocation.

⁹ Although this paper is necessarily focused on federal policy, coordination with state, territory, and tribal governments is strongly encouraged. In the context of native species management, non-federal agencies frequently have authorities that exceed those of the federal government.

**Scenarios***Meeting Public Land Management Objectives*

Public agencies and their partners might engage in managed relocation to meet various public land management objectives. Fish introductions into fishless montane lakes was sponsored by many state fish and game agencies during the 20th century (Casal 2006). From a federal perspective, the practice has been endorsed, or at least tolerated, throughout the National Park System to the extent that numerous parks now contain non-native trout in formerly fishless lakes. The ecological cost of these introductions has been high (Eilers et al. 2007), and those same agencies are now spending limited conservation resources removing non-native fish from lakes to restore their former fishless nature (Hoffman et al. 2004) and protect amphibians and reptiles from fish-transmitted diseases (Hoffman et al. 2004). Despite lessons learned regarding the harm caused by introducing fish into fishless lakes, bull trout were moved into a fishless lake, for the purpose of bull trout conservation, by Glacier National Parks as recently as 2015 (Galloway et al. 2016).

Private Landowner Effects on Public Lands

Private land managers have the capacity to affect public lands by introducing non-native species to their property with little or no ecological justification. These species may spread onto federal lands creating a potential need for land managers to either declare the species an invasive species or of conservation value. The Torreya Guardians began a program to actively spread *Torreya taxifolia* more than a decade ago (<http://www.torreyaguardians.org>). The group began with an effort to expand this species' range from northern Florida and southern Georgia over 600 km northward to North Carolina. The group has continued the spread of *T. taxifolia* as far north as Michigan and New Hampshire and west to Oregon with apparently no effort for ecological justification. In all cases the group has endorsed private plantings of this federally listed endangered tree species on private lands in a manner that is ecologically unjustified and risky, though they have not violated any rules or guidelines adopted by any governing body.

Advancing Commercial Interests

Natural resource-based industries (especially horticulture, forestry, and aquaculture/commercial fisheries) are engaging in mass relocation of species for economic gains (Benito-Garzon et al. 2013; Dumroese et al. 2015; Fady et al. 2016; Fontaine and Larson 2016; Klenk and Larson 2015; Pedlar et al. 2011; Pedlar et al. 2012; Williams and Dumroese 2013; Winder et al. 2011). When biological invasion results from these translocations, the economic benefits to a relative few may result in substantial, long-term costs to the public. Federal partnership with private land managers are needed to help minimize the risk of managed relocation activities by private sector groups on neighboring public lands and, more broadly, the well-being of Americans.

- B. *Delineate conditions* that constitute legitimate exceptions to E.O. 13571 (e.g., imminent extinction of a keystone species), recognizing that the national need that may supersede the caution imposed by the executive order;¹⁰
- C. Develop a clear and consistent *definition of actions* and *definition of reasonable expected benefit* that, among other things, address the need for enacting this extreme management measure;
- D. Require a *standardized risk assessment* that evaluates the potential:¹¹
 - 1. degradation of recipient ecosystems caused by the introduced species
 - 2. resulting in losses of other native species or diminishment of valued ecosystem services;
 - 3. degradation of adjoining ecosystems caused by the introduced species expanding its distribution resulting in losses of other native species or diminishment of valued ecosystem services;
 - 4. degradation of the recipient ecosystem caused by associated pests or pathogens accidentally moved with the target species resulting in unwanted disease or damage to resident native species;
 - 5. risk that moving individuals of a species further degrades the potential of that species to persist within its historic distribution; and
 - 6. risk that moving individuals of non-local genotypes drives undesirable evolutionary trajectories through mixing with local genotypes;
- E. Require a *monitoring and safeguard plan* that establishes protocols that evaluates each of the five risk actors (above) in addition to the success or failure of the action on the target species. The safeguard component should address containment, or elimination of the translocated species in the event that the prescribed monitoring demonstrated that risk factors were larger than originally estimated and that ecosystem damage exceeds the benefits gained through the translocation. The critical nature of this policy component means that a funding must be established and dedicated to support post-release monitoring and enacting safeguard measures. The temporal delimitation for enacting monitoring and safeguarding practices should be context-specific and articulated clearly in the plan; and
- F. Identify measures to be taken if the guidelines are violated.

¹⁰ It is clear from this literature that there are several opinions among biologists regarding the need, the criteria by which to judge a project supportable, and the likely consequences of engaging in managed relocation (Javeline et al. 2015).

¹¹ There are models for managing risks associated with introducing species to novel ecosystems. These risk management strategies mostly deal with decisions to release biocontrol agents. This literature provides a foundation to guide decisions where compelling need suggests managed relocation despite the risk (see Annex II for relevant literature).

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