



U.S. DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
OFFICE OF OCEANIC AND ATMOSPHERIC RESEARCH
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23 October 2009

Susan Mangin, Executive Secretary
Aquatic Nuisance Species Task Force
U.S. Fish and Wildlife Service
4401 North Fairfax Drive
Arlington, VA 22203

Dear Susan,

I am pleased to submit the proposed revised Research Protocol (Attachment 2) to the Task Force with the recommendation of the Research Committee that it be adopted to replace the existing 1994 version ("Protocol for Evaluating Research Proposals Concerning Aquatic Nonindigenous Species"). This new version is substantially the same as submitted for Task Force comments in May 2009, which was distributed to all Task Force members. In addition, I solicited comments from 27 other academic, state, and federal scientists.

In total four comments were received from Task Force agency and external reviewers (Attachment 1). Relatively minor content changes and some content reorganization were made in response to those comments and then the final draft was resent to the Research Committee for their final approval. Two additional comments were received from Research Committee members and acted upon. The attached version is recommended by the entire Research Committee.

I would be remiss if I did not reiterate the continuing concern of Research Committee members over the lack of a clear commitment by Task Force members to include use of the Protocol as part of their RFP requirements. One Research Committee member restated it in his response to the proposed final version – see Attachment 2, Research Committee Member #1 (non-federal). His comments mirror those stated by several Committee members.

As you know, I will be stepping down as Research Committee Chair and stepping off the Committee in the near future. However, if there is anything further that needs to be done prior to selection of a new Chair, please do not hesitate to ask.

Sincerely, and with best wishes for continued progress by the Task Force,

A handwritten signature in black ink that reads "David F. Reid".

David F. Reid, Ph.D
Chair, Research Committee

Attachments



Attachment 1

Summary of Comments Received After May 2009

Canadian Scientist

"I wanted to let you know I did read through the draft research risk assessment protocol, but other than some minor grammatical/editorial issues (esp. standardization in the references) - I have no comments. I felt that everything of potential concern was covered in the protocol. Thanks for the opportunity to look it over."

Response: Minor editing changes made.

Regional Non-profit Environmental Program Coordinator

"I recently reviewed the Federal ANS Research Risk Assessment Procedure document. My only comment is a question about whether the research risk assessment protocol might include a question(s) related to the likelihood of control/management of a species should it escape."

Response: The likelihood of control and management is not a factor the Research Committee believes should be a consideration when deciding if Containment Plans should be required, which is the purpose of the Risk Analysis. NANPCA (1990) specifically directs that the Protocol be established "to ensure that research activities carried out under this subtitle do not result in the introduction of aquatic nuisance species to waters of the United States." Thus the potential for control and management is not an appropriate consideration and could cloud the intent.

Commissioner of a State Agency

"General comments:

1) The terms "nuisance," and "nonindigenous" are used interchangeably and this is confusing. In strictly reading the draft, the risk assessment could be interpreted as applying only to "invasive" or "nuisance" species. Essentially, a decision would have to be made by the researcher that the species in question poses a risk to human health, environment or economic activities before invoking the protocol. Rather than leaving that decision to the researcher and in instances where biological or ecological information is limited or unavailable, the term "nonindigenous" should be substituted for the terms "nuisance" or "invasive," except in instances where use of invasive or nuisance is to clearly indicate a species that causes or may cause these risks.

Response: Where we thought appropriate the terms "nuisance" and "invasive" were changed to "nonindigenous". However, since the word "nuisance" exists in both the original legislation (NANPCA, 1990) and the name of the Task Force, the word "nuisance" could not be entirely eliminated. Most remaining occurrences are in the Introduction section where terms are defined and discussed for clarification. Additional locations

where the term “nuisance” occurs are required to reflect titles, text related to the original statute, or where the intent of the text requires differentiation between “nonindigenous” and “nuisance”. The Research Committee had previously debated changing the proposed title of the protocol to “Federal Aquatic Nonindigenous Species (ANS) Research Risk Analysis Protocol”, but concluded that it should be consistent with the Task Force name.

2) While termed a “risk assessment,” the process consists of a risk assessment and then, if needed, risk management with the combined results communicated via various means. Given that this process consists of the three elements ascribed to risk analysis (risk assessment, risk management and risk communication) suggest using 'risk analysis.'

Response: the proposed name of the revised Protocol was changed to “Federal Aquatic Nuisance Species Research Risk Analysis Protocol.” Also, clarifying text related to the name change and the term “risk analysis’ was added to the “Background” section.

Specific comments:

Page 2 provides five qualifications which confuse the protocol. Suggest deleting this qualifying information. The researcher should be led in an uncompromised manner to the implementation of the risk analysis. In addition, most (if not all states) prohibit or control through permitting the release of nonnative species. The five qualifications hinge upon the presence or distribution of a nonnative species and presumably its benign effect. Benign or not, the movement to new locations or release of nonnative species may be an illegal activity and, in an abundance of caution, the researcher should implement this risk analysis to abide by state laws and/or prevent the spread of nonnative species.

Response: the text on which this concern was based was removed. The Committee notes that the opening sentence under responsibilities of the PI states “The Principal Investigator is responsible, along with his/her institution, for determining that the proposed research complies with all applicable local, state, and national laws and regulations.”

Page 7, Question 8: Please include a requirement that the regulations be described.

Response: Done

Additional reference:

Scarfe, A. D., C-S Lee, and P.J. O’Byran. 2006. Aquaculture Biosecurity: Prevention, Control and Eradication of Aquatic Animal Diseases. Blackwell Publishing Professional. Ames, Iowa.”

Response: this reference was already listed, but in a different format. The text was changed to the proposed format.

Academic Researcher

"At first I was concerned that microbes weren't even mentioned. Then I saw that the NIH guidelines were invoked, and subsequently this broad, general document had words now and then that clearly expand its scope to consider microorganisms. From the standpoint of

this microbial ecologist, the document's stipulations are flexible and acceptable. Overall, I think the document does a good job with the microbes and there is nothing that needs to be added."

No response required.

Research Committee Member #1 (non-federal)

"I read the Research Protocol from the perspective of a researcher who is preparing to submit a grant proposal to a federal agency. My primary concern, as a prospective researcher, was to find out what I need to do to meet the requirements of the funding agency. The first three pages of the document lead me to believe that I will be required to comply with the Research Protocol as a necessary prerequisite to funding. However, at the bottom of page 3 [under "Responsibilities/The Funding Agency"] it says-

"NANPCA (1990) Section 1202(f)(3) requires that competitive research grants authorized and funded under the Act be conditioned on use of the Protocol to ensure that any recipient of funds follows the protocol. It is the responsibility of funding agencies to determine the applicability of this requirement to any research they fund."

My first response is to check the RFP to see if there is any statement that says I'm required to comply with the Research Protocol. If there is not, I'm going to ignore the Research Protocol and instead put my effort into making the grant proposal meet the stated requirements in the RFP. I'm going to do this because I just don't have the time and effort to put into components of the grant application that don't increase the chances of getting it funded.

I understand that the ANSTF instructed the group [Research Committee] to write the Research Protocol as if compliance was required as a prerequisite to funding (even though federal agencies in practice would not actually make it a requirement for funding), but I think most researchers will avoid the additional trouble of risk assessment, institutional review and HACCP if it isn't required. I think the Research Protocol as it stands presently satisfies the directive of ANSTF, but I also think it is unlikely to actually change the behavior of researchers in the end. In my opinion, that will not happen unless the funding agencies state that compliance to the Research Protocol is a requirement for funding in their respective RFPs.

I do not have any suggestions or changes to make in the document. I think it will be a valuable guide for those that are inclined to police themselves with respect to their research programs."

Response: primary concern reiterated in cover letter.

Research Committee Member #2 (non-federal)

"A comment for consideration in the last bullet of the containment plan. Should it include a reference to personnel? I was at a meeting today that referenced scuba and snorkel as data/species gathering techniques and that personnel were cleansed as well as gear prior to moving to the next water. Adding "and personnel" after the parentheses "...waders)"

would address this. Otherwise the risk analysis protocol appears to be quite comprehensive.”

Response: The text of the specified bullet was expanded as follows (bold indicates new text inserted in response to this comment):

*Take precautions when moving field gear (e.g., boats, trailers, nets, waders, **scuba, snorkeling and similar personal gear**, etc.) between locations if transport of nonindigenous species is possible. **Field personnel should also be checked if the situation dictates. For example, someone snorkeling in a body of water infested with a species like Cercopagis pengoi, the fishhook waterflea, could easily carry a significant number of those organisms caught up in their hair and clothing. Even though adults of that species would quickly die out of water, they could be carrying eggs that can remain viable after such exposure.** Procedures such as visual inspection, washing, removal of plant material or sediments, drying, and disinfection can reduce the probability of moving organisms between field sites.*

Attachment 2

**Proposed Revised
Federal Aquatic Nuisance Species (ANS) Research Risk Analysis Protocol**

October 2009

Prepared by the Research Committee of the ANS Task Force

Reid, David F.	U.S. Dept of Commerce (National Oceanic & Atmospheric Administration), Chair
Beck, Linda	Western Regional Panel (U.S. Fish & Wildlife Service)
Bowers, Michael	U.S. Dept of Agriculture (Cooperative State Research, Education, and Extension Service)
Cofrancesco, Al	U.S. Dept of Defense (U.S. Army Corps of Engineers)
Everett, Richard	U.S. Dept of Homeland Security (U.S. Coast Guard)
Gross, Sharon	U.S. Dept of Interior (U.S. Geological Survey)
Hill, Jeff	University of Florida Tropical Aquaculture Laboratory
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Moy, Phil	Great Lakes ANS Panel (University of Wisconsin Sea Grant)
Pederson, Judy	Northeast ANS Panel (MIT Sea Grant College Program)
Slacum, Julie	Mid-Atlantic Regional Panel (U.S. Fish & Wildlife Service)
Teem, John	Gulf and South Atlantic Regional Panel/National Aquaculture Association (Florida Department of Agriculture and Consumer Services)
Thompson, Sue A.	Mississippi River Basin Panel (Pennsylvania Fish and Boat Commission)

FEDERAL AQUATIC NUISANCE SPECIES (ANS) RESEARCH RISK ANALYSIS PROTOCOL

AQUATIC NUISANCE SPECIES TASK FORCE (ANSTF)

[DATE]

Introduction

This document is required by the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (“NANPCA,” Public Law 101-646, 104 STAT. 4671, 16 USC 4701-4741), as amended (National Invasive Species Act, 1996). Section 1202(f)(2) directs the Aquatic Nuisance Species Task Force (ANSTF) to establish a protocol “to ensure that research activities carried out under this subtitle do not result in the introduction of aquatic nuisance species to waters of the United States.”

Responsibility for actual use of this Protocol is specified in Section (f)(3): “*The Task Force shall allocate funds authorized under this Act for competitive research grants to study all aspects of aquatic nuisance species, which shall be administered through the National Sea Grant College Program and the Cooperative Fishery and Wildlife Research Units. Grants shall be conditioned to ensure that any recipient of funds follows the protocol established under paragraph (2) of this subsection.*”

Throughout this document both the descriptors “nonindigenous” and/or “nuisance” are used when referring to aquatic species that are the target of this risk analysis. Language used in the NANPCA (1990) differentiates between a nonindigenous species and a nuisance species, with a “nonindigenous” label being solely based on the historic range of the species, while a “nuisance” designation is based on a species being both nonindigenous AND potentially harmful (“threatens the diversity or abundance of native species or the ecological stability of infested waters, or commercial, agricultural, aquacultural or recreational activities dependent on such waters”). The ANSTF Research Committee adopted a precautionary approach by targeting this risk analysis to all aquatic nonindigenous species research, regardless of the “nuisance” designation. The intent of the procedures outlined herein is to minimize to the extent practicable the risk of release and spread of aquatic nonindigenous species into areas they do not yet inhabit, since any nonindigenous species may become a nuisance species. Not only is it often not possible to be sure that a species won’t become a nuisance (as defined) in the future, the possession and/or release of nonindigenous species may be illegal under various federal, state or local laws which may or may not differentiate between nonindigenous and nuisance species.

Background

This document (“the Protocol”) replaces the previously established “Protocol for Evaluating Research Proposals Concerning Aquatic Nonindigenous Species” (ANSTF, July 1994). It applies only to research involving aquatic nonindigenous species (ANS)

and is designed to reduce the risk that research activities may cause introduction or spread of such aquatic species. Other potential means of introduction, such as bait movement, aquaria disposal, ballast water discharge, movement of recreational boats, movement of fishing gear, horticultural sales, etc., are not addressed here.

The original “Research Protocol,” adopted in draft form in 1992, was finalized and published by the ANSTF in July 1994. In 2008 the ANSTF requested the Research Committee (a Committee of the ANSTF) to evaluate and recommend revisions to the 1994 Protocol, as needed. According to the Society for Risk Analysis (SRA, <http://www.sra.org>), the elements or components of a “risk analysis” include risk assessment, risk characterization, risk communication, risk management, and policy relating to risk. This revised protocol incorporates three of those elements – it requires a risk assessment (Part I) and then, if needed, establishment and implementation of a risk management plan (Part II), with the combined results communicated to the funding agency as part of the proposal and funding process. Therefore this revised Protocol is renamed “Federal Aquatic Nuisance Species Research Risk Analysis Protocol.” It was adopted by the ANSTF [enter date adopted by ANSTF].

Therefore this revised Protocol is renamed “Federal Aquatic Nuisance Species Research Risk Analysis Protocol” and was adopted by the ANSTF [enter date adopted by ANSTF].

This protocol supplements, but does not replace, other existing Federal guidelines established to control activities with specific major classes of organisms. This document does not eliminate or in any way affect requirements of the National Environmental Policy Act (NEPA, 1970, [42 U.S.C. 4321 et seq.]).

The incorporation of a “Hazard Analysis and Critical Control Point (HACCP)” approach for prevention planning and developing Containment Plans specific to particular research activities is encouraged. Information about the use of HACCP is available at <http://www.seagrant.umn.edu/ais/haccp> and a web site detailing the application HACCP to natural resource pathways plus a link to download a HACCP wizard that helps create HACCP plans, can be found at: <http://www.haccp-nrm.org/>

Federal ANS Research Risk Analysis Protocol

The Federal ANS Research Risk Analysis Protocol consists of a risk assessment (risk characterization and communication, Part I, below) to be completed by the Principal Investigator to evaluate proposed research for its potential to result in the introduction or spread of aquatic nonindigenous species to or within the waters of the United States.

If indicated by the risk assessment (Part I), the Principal Investigator must develop risk management plans by developing and documenting Containment Plans (Part II). Containment Plans specify and describe the Standard Operating Procedures that will be used throughout the research project to prevent escape or unintentional transfer of aquatic nonindigenous organisms by the research activities conducted under the

project. Due to the number of federally funded programs and facilities and the differing characteristics and distributions of potential research organisms and types of research, it is impractical to specify a generic Containment Plan that would be suitable for every situation.

Responsibilities

1. The Principal Investigator (PI)

The Principal Investigator is responsible, along with his/her institution, for determining that the proposed research complies with all applicable local, state, and national laws and regulations.

Under the Protocol, the Principal Investigator is responsible for

- Conducting and documenting the research risk analysis outlined in this document.
- Including the completed risk assessment (Part I) as part of the research proposal.
- If Part I indicates the need for Containment Plans, a statement must be included with Part I that the appropriate Containment Plans will be prepared and implemented by the Principal Investigator prior to initiation of the research. See Appendix IV.

Containment Plans should document 1) the control and containment procedures that will be used during research and throughout the time that the species is present and viable - this will usually be accomplished by attaching appropriate Containment Plans, 2) a training plan to assure that all staff associated with the research are aware of the Containment Plan and the Standard Operating Procedures for conducting the research, and 3) upon completion of the study the research organisms will be humanely euthanized and disposed of properly.

2. The Research Institution

An authorized administrative representative of the Research Institution other than the PI and from the chain of authority above the PI (such as a Department Chair, Section Chief, Director, etc.) must provide a signed statement as part of the proposal cover pages acknowledging that

1. The Research Institution has reviewed and approves the proposed research and the Federal ANS Research Risk Analysis Protocol documentation completed by the Principal Investigator, and,
2. Based on the outcome of the risk assessment (Part I of the Protocol), creation and implementation of appropriate Containment Plans to prevent the introduction of aquatic nonindigenous species to the waters of the United States will be implemented by the Principal Investigator prior to initiation of the research.

3. The Research Institution and the PI are responsible for complying with all applicable local, state, and national laws and regulations related to possession of nonindigenous species. The researcher and/or research institution is responsible for contacting the appropriate state and federal agencies to obtain permits, as required, for transporting and possessing the species of interest.
4. The Principal Investigator and his/her Research Institution are responsible for ensuring that students and staff involved with this research comply with all provisions of the appropriate Containment Plans and legal requirements associated with this research.

3. The Funding Agency

NANPCA (1990) Section 1202(f)(3) requires that competitive research grants authorized and funded under the Act be conditioned on use of the Protocol to ensure that any recipient of funds follows the protocol. It is the responsibility of funding agencies to determine the applicability of this requirement to any research they fund.

PART I**Risk Assessment**

Sufficient information and detail must be provided to enable the funding agency program manager and/or proposal reviewers to evaluate the accuracy and completeness of the risk assessment and the need for Containment Plans.

Answer each of the following questions in writing. Provide enough detail so that a reviewer can evaluate and understand the basis for your answers. Use additional pages as needed.

(Questions 1-4 relate to the risk of introduction)

1. Will the research involve ONLY the use of preserved samples of water, sediment, and/or biota?

YES NO

YES: Score = 0; Proceed directly to Question 3

NO: Score = +1

Score, Q1: _____

Proceed to Next Question.

* * * * *

2. Are any nonindigenous disease-causing parasites, pathogens, or other disease-causing agents known to be carried by the species to be used in this research, not already in the ecosystem(s) where the research will be conducted, and OIE (*World Organisation for Animal Health*, http://www.oie.int/eng/en_index.htm) reportable or known to be harmful to the health of native and/or stocked species?

YES NO

YES: Score = +1; prevention/containment procedures are required.

NO: Score = 0

Score, Q2: _____

Proceed to Next Question.

* * * * *

3. Will this research involve transportation of unpreserved water, sediment, and/or biological samples or specimens in any life stage between or through water bodies or ecosystems not interconnected with the source ecosystem of the samples?

YES NO

YES: Score = +1; preventive/protective shipping and transportation procedures may be required.

NO: Score = 0

Score, Q3: _____

Proceed to Next Question.

* * * * *

4. Will this research involve use of field sampling equipment that is, has been, or will be used in different natural water bodies and/or sediments located in unconnected ecosystems?

YES NO

YES: Score = +1; appropriate field equipment decontamination procedures are required; development of a HACCP plan for field gear should be considered.

NO: Score =0

Score, Q4: _____

Sum of Scores Q1-4: _____

If the Sum of Scores for Questions 1-4 is "0", STOP HERE - you do not need to take further action. There is low risk that the research activities would result in the introduction or spread of aquatic nonindigenous species, or expose the ecosystem to associated diseases, parasites, or pathogens.

If the Sum of Scores for Questions 1-4 is >0, proceed to the next question.

* * * * *

(Questions 5-7 relate to the risk of establishment)

5. Are there reasons to conclude that the nonindigenous species used in this research **cannot survive and/or reproduce** in any of the ecosystems, watersheds, or drainage networks through which or where live or unpreserved samples will be transported, used or stored for this research?

YES NO

YES: Score = 0

If Yes, please attach a narrative that provides the basis for this answer.

NO: Score = +1

Score, Q5: _____

Proceed to next Question

* * * * *

6. Are there reasons to conclude that the nonindigenous species used in this research would **NOT** become aquatic nuisance species, as defined by NANPCA (1990, as amended), if it/they escaped or were released? (Note: this does not refer to survival,

rather, the likelihood that the species could or will become an aquatic nuisance as defined by NANPCA Section 1003).

YES NO

Yes: Score = -1; There is low risk that the research activities under this project will result in the establishment or spread of an aquatic nuisance species.

If Yes, please attach a narrative that provides the basis for this answer.

NO: Score = +1

Score, Q6: _____

Proceed to next Question

* * * * *

7. What was your answer to Question 2?

YES NO

YES: Score = +1; prevention/containment procedures are required, even if the host species is believed or known not likely to become established or become a nuisance if released, unless the samples will be preserved at the site of collection in a manner that is known to also kill or deactivate viruses and other pathogens.

NO: Score = 0

Score, Q7: _____

* * * * *

(Question 8 establishes if there are existing regulations that require use of specific containment procedures)

8. Are collection, possession, and/or transportation of any of the species to be used in this research regulated by any local, state or federal laws?

YES NO

YES: Score = +6

If "Yes" please attach a citation and brief description/summary of the applicable regulations.

NO: Score = 0

Score, Q8: _____

Sum of Scores Q5-8: _____

If the Sum of Scores, Questions 5-8 is "≤0", NO Containment Plan is needed and no further action is required. However, to avoid the spread of nonindigenous species by incidental means during the conduct of this research, care should be taken to decontaminate all field equipment by appropriate means before reusing it in another ecosystem. Development of a HACCP plan for field gear is recommended.

If the Sum of Scores, Questions 5-8 is >0, but less than +5 and the proposed research is selected for Federal funding, the PI is responsible for developing and documenting appropriate Containment Plans prior to initiation of research.

If the Sum of Scores, Questions 5-8 is +5 or greater and the proposed research is selected for Federal funding, it is the responsibility of the PI and his/her research institution to assure that the research meets all legal requirements for permits and for implementation of any containment procedures specified in regulations.

- If there are applicable containment procedures that are already specified by local, state or federal regulatory agencies, they should be identified by reference in the proposal.
- The existence of legally mandated or specified containment requirements does not preclude the need for the PI and his/her research institution to develop, document, and implement additional Containment Plans that are identified as necessary by this Risk Assessment.

PART II

Containment Plan(s)

If the outcome of the risk assessment (Part I) indicates the need for Containment Plans, the Principal Investigator is responsible for developing and implementing a plan to prevent nonindigenous species from escaping or being accidentally released, and for decontaminating associated equipment. The specific procedures will depend on the species involved, their life stages and sizes, the characteristics of the research location(s) with regard to the species' critical environmental factors and the potential for the species to survive and reproduce in that/those locale(s). If any of the species is or is known to carry nonindigenous disease-causing parasites, pathogens, or other disease-causing agents, extra precautions may be necessary.

The Containment Plan should use a combination of physical, biological, environmental, and/or chemical barriers to contain or confine all life stages of the organism possibly present during the research. **The development and inclusion of the HACCP approach tailored to natural resource pathways is recommended** (see <http://www.haccp-nrm.org/>).

Appendix I provides sources of information related to containment.

Considerations when developing a Containment Plan for research:

- Know and follow all federal, state, local and institutional regulations pertaining to the species you intend to obtain, especially the need for specific permits for collection or possession of those species; obtain required permits prior to proposing the research, if possible. (See Appendix II for a partial list of laws and regulations. However, the researcher is responsible for ascertaining all applicable local, state, and federal regulations that apply to his/her research).
- Understand the biology and behavior of the organisms relative to potential escape or unintentional release. Are the organisms prone to escape from captivity? Are there highly resistant or physiologically tolerant life stages (e.g., eggs resistant to desiccation)? Are there life stages with high dispersal potential?
- Understand the distribution and physiological tolerances of the organisms. What is the previous invasion/introduction history? Can they survive within the research area(s) if escape or release occurs? Would escape or release likely result in sustainable new populations?
- Learn and maintain good management practices, such as: clean and disinfect systems (and if appropriate, personnel) between activities; do not leave water or organisms in systems after work is complete (unless maintaining as research stock); isolate systems (e.g., have separate nets and cleaning equipment for each system).

- Establish a written standard operating procedure (SOP) for proper handling, housing, husbandry and disposal of specimens. These may be simple or complex as dictated by the organism, the types of activities involving the organism, the housing facility and applicable regulations. For example, maintenance of nonindigenous species in outdoor facilities will require more containment safeguards than the use of an indoor laboratory facility. Protocols should incorporate redundant safeguards to contain organisms if one level of containment is breached. Practicality is also an important characteristic of effective protocols.
- Unnecessarily stringent and ridged SOPs may make research impossible to conduct and thus ignored or by-passed by research staff. The written SOPs should be rigorous, but allow flexibility and application of judgment where appropriate.
- Train colleagues, staff, and students in proper handling, housing, husbandry, and disposal of specimens. Do not allow unsupervised access to facilities holding live or viable specimens by untrained personnel or the public. Do not allow untrained personnel to perform procedures where escape would be possible.
- Take precautions when moving field gear (e.g., boats, trailers, nets, waders, scuba, snorkeling and similar personal gear, etc.) between locations if transport of nonindigenous species is possible. Field personnel should also be checked if the situation dictates. For example, someone snorkeling in a body of water infested with a species like *Cercopagis pengoi*, the fishhook waterflea, could easily carry a significant number of those organisms caught up in their hair and clothing. Even though adults of that species would quickly die out of water, they could be carrying eggs that can remain viable after such exposure. Procedures such as visual inspection, washing, removal of plant material or sediments, drying, and disinfection can reduce the probability of moving organisms between field sites.

For containment of diseases, parasites, small species, or the early life stages of larger species, the procedures outlined in the NIH guidelines (FR 51 No. 88, May 7, 1986, pg. 16959) or guidelines developed by the U.S. Department of Health and Human Services (see references) are the most comprehensive.

For containment or confinement of larger forms, the guidelines developed for whole plants or animals by the Office of Agricultural Biotechnology, USDA, are the most appropriate, especially if the research is to be conducted outside the laboratory (see Appendix I).

The Principal Investigator and the Research Institution are responsible for ensuring that research activities do not violate laws or regulations and do not result in spread of nonindigenous species.

Reporting

Escape or release of a nonindigenous aquatic species must be reported in compliance with applicable local, state, and federal laws, as well as to the federal agency funding the research. Violation of any conditions attached to funding by a federal agency may have consequences that will be determined and administered by the funding agency.

APPENDICES

Warning: The information presented in Appendices I and II was last updated in April 2009 and is believed to be accurate as of that date, but is subject to change. In addition, there may be other sources of information not included here. The reader is advised to check for additional and/or more recent content and guidelines, as needed.

APPENDIX I

Existing Guidelines and Protocols

Guidelines for Recombinant DNA Molecular Research:

The following is a list of guidelines and protocols used to confine or contain nonindigenous species or organisms involved in recombinant DNA research. These can also be applied to nonindigenous aquatic species proposals. Consulting one or more of these will help investigators to identify physical, biological, chemical, and/or environmental preventative measures that may be used to confine or contain the nonindigenous aquatic species during research, transportation and storage.

Federal Register 51, No. 8, pg. 16958;

Federal Register 51, No. 123, pg. 23367

Federal Register 52, No. 154, pg. 29800

Federal Register 56, No. 22, pg. 4134

Federal Register 51, No. 88, pg. 16959

For the most updated information visit <http://oba.od.nih.gov/oba/index.html>

Guidelines for Microorganisms

National Institutes of Health (NIH). 1968. Guidelines for Research Involving Recombinant DNA Molecules. Published in Federal Register May 7, 1986 (51FR 16958-16961) with additional major actions August 24, 1987 (52F 31838); July 29, 1988 (53FR 28819); October 26, 1988 (53FR 43410); March 13, 1989 (54FR 10508); March 1, 1990 (55FR 7438); and August 11, 1987 (52FR 29800) with appendix P for plants and Q for animals; and May 28, 2002 (NOT-OD-02-052). For the most updated information visit <http://oba.od.nih.gov/oba/index.html>

Guidelines for Whole Plants and Animals

ICES Code of Practice on the Introductions and Transfers of Marine Organisms 2004. <http://www.ices.dk/reports/general/2004/ICESOP2004.pdf>

U.S. Department of Agriculture (USDA). 1984. Coordinated Framework for Regulation of Biotechnology. Federal Register December 31, 1984 (49FR 50856) and June 26, 1986 (51FR 23302).

USDA. 1986. Advance Notice of Proposed USDA Guidelines for Biotechnology Research. Federal Register June 26, 1986 (51FR 23367-23393) and February 1, 1991 (56FR 4134-4149).

USDA. 1986. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or for Which There is Reason to Believe are Plant Pests. Federal Register June 26, 1986 (51FR 23352-23366) and June 16, 1987 (52FR 22892-22915) and Code of Federal Regulations January 1, 2008 (7CFR340.0).

Coulson, J. R. & R. S. Soper. 1989. Protocols for the introduction of biological agents in the United States, pp. 1-35. *In*: R. P. Kahn (ed.), Plant Protection & Quarantine, Vol. 3, Special Topics. CRC Press, Inc., Boca Raton, FL. 215 pages.

USDA, Office of Agricultural Biotechnology. 1988. USDA Guidelines for Research Outside the Laboratory Involving Biotechnology, also Federal Register June 26, 1986 (51FR 23367-23313) and February 1, 1991 (56FR 4134-4149). <http://www.aphis.usda.gov/brs/pdf/abrac%201991.pdf>

International Guidelines and Protocols:

Daszak P, Cunningham AA, Hyatt AD. Draft guidelines for international translocation of amphibians with respect to infectious diseases. Attachment 6. In: Speare R and Steering Committee of Getting the Jump on Amphibian Disease. Developing management strategies to control amphibian diseases: Decreasing the risks due to communicable diseases. School of Public Health and Tropical Medicine, James Cook University: Townsville. 2001: 150-156.

European Inland Fisheries Advisory Commission. 1988. Code of Practice and Manual of Procedures for Consideration of Introductions and Transfers of Marine and Freshwater Organisms. FAO. EIFAC. Occasional paper No. 23. 52 pages.

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Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Microbial Pathogens (Fungi, Bacteria, Rickettsia Viruses, Protozoa) into the United States for Biological Control of Arthropod Pests of Plants, Man, and Domestic Animals, and Vectors of Plant, Human, and Animal Pathogens, and for the Export of Foreign and Native Arthropod Pathogens for Research.

Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Arthropods and Nematodes into the United States for Biological Control of Weeds, and for the Interstate Movement and Export of Foreign and Native Arthropod and Nematode Natural Enemies of Weeds.

Guidelines for the Importation, Interstate Movement, and Field Release in the United States of Foreign Microbial Pathogens for Biological Control of Weeds, and for the Interstate Movement and Export of Foreign and Native Pathogens of Weeds for Research.

Guidelines for the Importation, Interstate Movement, and Field Release of Foreign Beneficial Organisms (Microbial Pathogens and Antagonists) into the United States for Biological Control of Plant Nematodes and Plant Pathogens, and for the Export of Such Organisms (Foreign and Native) for Research.

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APPENDIX II

Other Relevant Legislation and Executive Orders

Applicable State Laws, Regulations, Permit and Notification Requirements - Must be determined on an individual basis by Principal Investigators and Research Institutions.

Lacey Act of 1900 - 16 USC 3371-3378 and 18 USC 42 Item 2,58 amended with the 2008 Farm Bill http://www.aphis.usda.gov/plant_health/lacey_act/index.shtml

Endangered Species Conservation Act of 1973-16 USC 1531-1543 plus Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)-16 USC 1531-1543.

Executive Order #11987 dated March 1977 - Exotic Organisms

Plant Quarantine Act of 1912 (7 USC 151 et seq.)

Terminal Inspection Act of 1915

Federal Plant Pest Act of 1957 (7 USC 150aa et seq.)

Federal Noxious Weed Act of 1974 (Public Law 93-629-Jan. 3, 1975) (7 USC 2801 et seq. + 21 USC 111 et seq.)

National Environmental Policy Act of 1969 (NEPA)

Occupational Safety and Health Act of 1970 - Federal Register April 12, 1984 (50FR 14468) (29 USC et seq.)

Animal Welfare Act. 7 USC 2131-2155; 80 STAT.350, 84 STAT.1560, 90 STAT.417, 99 STAT.1645.

The Plant Protection Act of 2000 – replaced the Plant Quarantine Act, the Federal Pest Act and the Federal Noxious Weed Act and seven other statutes.

APPENDIX III

Definitions

Aquatic Nuisance Species (NANPCA, 1990, as amended): an aquatic nonindigenous species that threatens the diversity or abundance of native species or the ecological stability of infested waters, or commercial, agricultural, aquacultural or recreational activities dependent on such waters.

Established Population: when used in reference to a species, means the species is reproducing and self-sustaining in an open ecosystem, i.e. in waters where the organisms are able to migrate or be transported to other waters.

Nonindigenous Species: any species or other viable biological material that enters an ecosystem beyond its historic range, including any such organisms transferred from one country to another. Nonindigenous species include both exotics and transplants. [Note: Historic range is interpreted to mean the territory occupied by a species at the time of European colonization of North America.]

Pathogen: as defined in USDA guidelines, is a virus or microorganism (including its viruses and plasmids, if any) that has the ability to cause disease in another living organism.

Surrounding Waters: any free flowing or standing waters in the immediate vicinity of the research facility that are connected with public waters either directly or indirectly.

Survive: when used in reference to biological species, means the species is able to live in an ecosystem during its normal life span, but not necessarily that it is able to reproduce itself.

Unintentional Introduction: an introduction of nonindigenous species that occurs as a result of activities other than the purposeful or intentional introduction of the species, usually involving the release, often unknowingly, of nonindigenous organisms without any specific intent.

Waters of the United States: the navigable waters and the territorial sea of the United States. Since aquatic species can move or be transported by currents into navigable waters, all internal waters of the United States, including its territories and possessions, are included. The Territorial Sea of the United States is that established by Presidential Proclamation Number 5928 of December 27, 1988.

APPENDIX IV

Suggested Content for Containment Plans

Identification of Principal Investigator and Research Institution

Description of research

Description and location(s) of research facility(ies) and sampling sites

Source of specimens if not from sampling sites (e.g., provided by another researcher or research institution)

Nonindigenous species to be collected or used in the research

Summary of

- Biology, including Diseases and Parasites
- Life History
- Ecology
- Environmental Factors
- Prior Invasion History
- Present Distribution and
- Status of the Species in the Study Area(s).

Permits required (if any)

Containment procedures specified by regulations, if any

HACCP analysis

Containment procedures to be used for physical, biological, chemical, and environmental containment, in addition to any required by regulation

- Shipping and transportation precautions

Training and qualifications of personnel

Security at facilities where live specimens will be maintained

- Plan for extreme events (hurricanes, floods, etc.)
- Plan for securing facility and limiting access

Emergency Plans in case of escape or release

Procedures for terminating research

- Fate of Surviving Specimens – Close-Out Procedures

Administrative controls, roles, responsibilities

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