

13 May 2009

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

Dear ANSTF,

The Research Committee was requested to review and update the "Protocol for Evaluating Research Proposals Concerning Nonindigenous Aquatic Species" (Research Protocol). I am attaching a draft revised version of the Protocol for ANSTF review and comment.

The draft revised Protocol is not being submitted for decision or adoption at this time. The Research Committee believes we have taken this as far as we should prior to receiving ANSTF comments and additional feedback, after which the Research Committee will make additional revisions as appropriate and prepare a final draft for Task Force action.

In addition the attached draft revised Protocol, I have appended below a set of notes that outline the major changes to the Protocol. This information also contains requests for comments and/or guidance from the ANSTF on specific issues.

At the Spring 2009 Meeting of the Task Force I will briefly highlight the changes and identify areas where the Research Committee has issues that remain open.

Finally, I will request a date certain (which I proposed to be August 3, 2009) for me to receive comments on the draft revised version from ANSTF members, but am open to alternate dates for the convenience of the ANSTF.

Respectfully,

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

Encl.



Notes and Committee Requests for the Draft Revised Federal Aquatic Nuisance Species (ANS) Research Risk Assessment Protocol

The original Protocol is 20 pages, the revised draft is 15 pages.

The original Protocol ("Protocol for Evaluating Research Proposals Concerning Aquatic Nonindigenous Species ") references a "Research Protocol Committee" and assigns it significant review and oversight responsibilities. As far as the Research Committee knows, no such Protocol Committee exists and references to it have been removed.

The descriptions of the responsibilities of the Principal Investigator, the Research Institution, and the Funding Agency have all been revised and shortened. In particular, following guidance provided at the ANSTF Fall 2008 Meeting, the responsibility for developing and implementing a Containment Plan now rests solely with the PI and his/her institution. There is no responsibility assigned to a Funding Agency to either review or approve such plans. <u>This remains a concern to several Research Committee members</u>.

Based on the language in NANPCA (1990 as revised) Section 1202(f)(3), the only responsibility assigned to a Funding Agency is to "condition" competitive research grants funded under authority of NANPCA on use of this Protocol. The Research Committee is conflicted about this section, as strict interpretation of the language in Section 1202(f)(3) would appear to narrow the <u>required use</u> of the Protocol only to research carried out under Subtitle C of the Act, and then only for competitive research grants funded by the National Sea Grant College Program and the Cooperative Fishery and Wildlife Research Units. This is of concern to the Research Committee.

The draft revised Protocol makes reference to and encourages use of a HACCP approach to containment plan development.

The main component of the draft revised Protocol is a simplified Risk Assessment (Part I), which consists of 8 questions leading to a determination of whether or not development of Containment Plans is required. <u>The Research Committee requests the ANSTF agencies</u> thoroughly review the logic flow of the Risk Assessment and advise the Committee of any gaps or lapses in the logic path that would reduce the effectiveness of the Risk Assessment.

Within the Risk Assessment, the language associated with potential for disease agents was changed to refer only to "known" disease-causing agents. The Committee members who took an active part in developing the revised Protocol felt the language in the existing Protocol required a level of knowledge and certainty not likely to be reasonably achievable.



Part II provides general guidance and considerations related to development of Containment Plans, but does require a specific format for them. Appendix IV provides an outline of suggested content for Containment Plans.

The "Reporting" Section of Part II of the draft revised Protocol is based on <u>only the final</u> <u>paragraph</u> of the "Compliance, Inspection, Reporting" section in the original Protocol. The original language directs specific actions by the Research Institution and the Funding Agency that is contrary to the guidance the Research Committee received at the ANSTF Fall 2008 Meeting. The Research Committee would like guidance as to the expectations, if any, of the ANSTF with regard to compliance and reporting by grantees.

The appendices have all been updated. Appendix IV of the original Protocol was moved to Appendix II since it is closely related to the content/intent of Appendix I. The Research Committee debated whether to retain the information in Appendices I and II, since it is subject to change and there is no clear mechanism for keeping it up to date. In particular, the present update was provided by Linda Beck (U.S. Fish and Wildlife Service), but no one else on the Research Committee felt knowledgeable enough to do so. Several options were discussed, including eliminating the content altogether, keeping it, but noting that it may be out of date and should be verified by the reader, or recommending that the ANSTF take responsibility for it and moving the material to the ANSTF web site. In the latter case the information would then be included by reference and web link in the Protocol document. The Research Committee decided to retain Appendices I and II, but to note this issue to the ANSTF for consideration.

Appendix III of the original Protocol was eliminated. It was a list of members of the nonexistent Research Protocol Committee (see above).

The new Appendix III is the "Definitions" section:

- Several definitions were removed: BSO, Confinement, Containment, IBC, PI, and "Research Institution", "Research Protocol Committee."
- Several definitions were modified: "Aquatic Nuisance Species", Established, "Unintentional Introduction."

Table 1 of the original Protocol was renamed Appendix IV for consistence and modified to be "suggested content" rather than required information, as well as some other minor modifications to simplify it and make it less prescriptive.

