Peer Review Comments for the Ecological Risk Screening Summary Process

Responses to Comments by:
Fish and Aquatic Conservation's Branch of Aquatic Invasive Species (USFWS)
and Region 3 Aquatic Invasive Species Coordinator (USFWS)

This report corresponds to the peer review plan "Rapid Screening of Species Risk Assessment and Impact in the United States" posted on the U.S. Fish and Wildlife Service's Science website on December 19, 2012 (http://www.fws.gov/science/pdf/ERSS-Process-Peer-Review-Agenda-12-19-12.pdf)

The U.S. Fish and Wildlife Service (Service) selected these five peer reviewers for their expertise in one or more disciplines: aquatic zoology, invasive species, risk assessments, aquaculture; and, laws, policy, and regulations of organisms in trade.

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Peer Reviewer comments were compiled by:
Donald R. MacLean, Fish and Wildlife Biologist
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Peer reviewers provided their comments directly to Mr. MacLean, who then compiled them without attributions. The comments were provided to several Service employees for response via a "blind" review (with the exception of Mr. MacLean); peer reviewers also could not see each other's comments. The comments of each reviewer are independent and do not necessarily reflect the views of their associated organizations or employers. This document contains all of the comments received from the Ecological Risk Screening Summary **(**ERSS) peer review, except for those editorial comments that were done within track changes in Microsoft Word. They have been placed in one of three categories – 1) General Comments; 2) Answers to the Six Questions Posed to the Reviewers; and 3) Specific Comments – and given a number for easy reference.

General Comments

Comment 1 – *This document provides a standard operating procedure for undertaking a rapid risk assessment of potential aquatic invasive species based on history of invasiveness and climate match. Rapid risk assessment is a useful tool in providing timely [information] to risk managers if suitable data are available. A major challenge for developing such a tool for multiple users is minimizing user bias. Clear and explicit guidance on the steps used in the tool is essential to minimize such bias. This document generally does a good job of clearly explaining the steps required to conduct and document the risk assessment. However, I do think that some additional thought needs to be put into the climate match section.*

> **FWS Response:** Comment only, no response required here. Responses to "additional thoughts" on the climate match section are provided elsewhere in this response document.

Comment 2 – *Having been involved in the development of the National Invasive Species Management Plan (circa 2000) that called for a screening process for first time introductions as well as involved in numerous false starts to develop a screening process under ISAC and/or ANSTF, I am pleased to compliment the Service, and especially Michael Hoff, for creating a long overdue rapid screening process. While the ERSS process needs some refinements/additions, it is more transparent, informative and objective than several other models being touted, such as a modified FISK model*

> **FWS Response:** Comment only, no response required. Refinements/additions are detailed in other comments in this document.

Comment 3 – *In general, the ERSS process is clearly described, and each step is explained in detail as it takes one through a logical progression to recommended "low," "uncertain" or "high" risk status. As explained herein, there are certain areas where some "warnings" or "notations" may need to be repeated to ensure that assessors/reviewers clearly document not only resources relied upon, but also steps taken to ensure accuracy, objectivity and thoroughness.*

> **FWS Response:** Comment only, no response required. Comments on "warnings" or "notations" that may need to be repeated can be found elsewhere in this document

Comment 4 – *That being said, the absence of a Quality Assurance/Quality Control mechanism at both the assessors and the reviewers levels is of serious concern. Such QA/QC checklists are essential to ensure that (a) the best available science has been reviewed/relied upon and properly referenced/documented, (b) an adequate selection of resource databases have been reviewed, (c) there is inclusion of a well-documented administrative record, and (d) transparency is strictly adhered to at each stage of the process. I recommend inclusion of a Checklist for each stage of the process to ensure that the assessor/reviewer has in fact performed the requested task(s). The Checklist should include a comment area wherein the person indicates any anomalies identified or deviations from the prescribed steps. This would allow the final reviewer(s) the ability to ascertain objectivity of the process. Inclusion of a rigorous QA/QC mechanism would enhance the ERSS process' usage of the best available science and strengthen its scientific foundation.*

> **FWS Response**: As an ERSS goes through its development stages (from author to technical reviewer, to policy reviewer)*****, it is subjected to a level of QA/QC that we feel is equivalent or better than anything achieved via a checklist (this includes an administrative record and list of appropriate databases). However, we believe a check list will be beneficial, particularly for outside agencies and others that may use this SOP. A checklist will be added to the SOP as either a new section or an appendix.
>
> ***** While this description of the stages of the ERSS development process is our preference for how they will be developed, we can't unequivocally commit to this approach in this responsiveness summary, binding the agency's hands in the future. Rather, we will balance the fiscal and staffing realities of the agency in delivering its conservation mission with the benefit of keeping these roles differentiated.

Comment 5 – *While it may be inferred that basic tenets of the National Academy of Sciences' recommendations for risk assessments are incorporated in the process, I recommend that the "Introduction" specifically notes that ERSS assessors and reviewers are independent and not the ultimate regulators responsible for evaluating the ERRS results for the purposes of rule-making, legislation or developing mitigation measures. This is important for both transparency as well as for scientific credibility and objectivity.*

FWS Response: We agree with this comment. The Original Author (ERSS assessors), ERSS reviewers, and regulators will not be the same individuals. The Original Author will compile data from literature and database searches, cite, and record all references incorporated into the administrative record, complete the Climate Match analysis, and produce an ERSS incorporating all this information. The Reviewer will assess the accuracy and completeness of the ERSS and its accompanying administrative record. If the ERSS says the species is high risk, the regulatory office will decide whether to pursue an injurious wildlife listing under the Lacey Act (18 U.S.C. 42)*****. If the ERSS classifies the species as uncertain risk, species will then be assessed using a separate decision support tool, such as the Bayesian network model on invasiveness. The ERSS and its accompanying administrative record will be used in the injurious wildlife listing, Bayesian network model, or other processes used. We intend to add language to the SOP clarifying this issue.

***** While this description of the stages of the ERSS development process is our preference for how they will be developed, we can't unequivocally commit to this approach in this responsiveness summary, binding the agency's hands in the future. Rather, we will balance the fiscal and staffing realities of the agency in delivering its conservation mission with the benefit of keeping these roles differentiated.

Comment 6 – *Stakeholder participation in the process is also an important factor that should not be ignored. Recognizing the importance of stakeholder inclusion is unfortunately problematic within a Federal setting, such interaction should be required when the ERSS is utilized by non-Federal entities, especially non-governmental organizations. Such inclusion hopefully mitigates assertions of bias.*

FWS Response: We recognized stakeholders as important from the beginning of the risk assessment process, and their input has been reflected at all stages. Stakeholder involvement was an important part of the development and peer review of the model ERSS approach (under the aegis of the Mississippi River Basin Panel), and as a part of a second peer review (under the aegis of ANSTF/ISAC and Nonnative Wildlife Screening Working Group). The model ERSS approach was developed within the context of a rapid risk analysis process (even more comprehensive than the ERSS). The model process has been available for review at the MRBP and other websites since it was developed, reviewed, and approved by the MRBP. The model process remains on the internet at http://anstaskforce.gov/Meetings/2008_October/MRBP_Working_Version_Model_Risk_Assess._&_Management_Process_10-20-08.pdf. We are also making the ERSS results publically available (http://www.fws.gov/injuriouswildlife/Injurious_prevention.html) and have provided an e-mail address for the public and stakeholders to submit information on the ERSS reports, such as new, substantive information or to point out inaccuracies that might change our assessment.

The role of stakeholders will occur during the risk management phase and not necessarily in the risk assessment phase (of collecting data on species and initially

running it through the model). We recognized the value of stakeholders in the process and thus included a representative in the peer review process. One benefit of using the ERSS SOP is that the assessment scores can be saved and can be made available to the public and subject matter experts for review, thus allowing for transparency. What is important to understand is that an ERSS' result is not the final answer for whether a species should be listed as injurious. Rather, when the ERSS process results in "uncertain" risk, the Bayesian network model will be used. Once a species is run through the Bayesian network model using scientific information, and depending on the resulting score, the Service may then decide whether to pursue listing the species as injurious and would have to justify the listing in the rule, at which time there would be an opportunity for stakeholder input through the public comment process.

Finally, regarding the "requirement" of stakeholder inclusion when the ERSS process is used by non-Federal entities, the Service has no authority to force that requirement. Using the ERSS process in a manner other than that described in this SOP is not endorsed or recommended without further testing, but is not something that the Service can enforce.

Comment 7 – *Being a rapid screen, it is likely that the assessments will be conducted by a single individual, hopefully, with subject matter expertise. The ERSS process is not clear as to whether or not individual assessments would be merged into a single assessment when input from multiple assessors or would multiple assessors participate in a group session to work through the template. The ERSS protocol should be abundantly clear as to how multiple assessments are merged into the final report. Personally, and based on recent experience with a faulty process utilized by a sister Department, "group think" or "group therapy" sessions are undesirable since the knowledge level of the participants varies significantly and undue influence could result from a particularly vocal member who may or may not possess the requisite expertise. To avoid bias or lack of objectivity, I strongly recommend, whenever possible, that an ERSS analysis be conducted by one or more people individually with their analysis combined for or by the reviewer. Group dynamics should be avoided whenever possible.*

FWS Response: We agree with this comment and will add language to the SOP to clarify this point. It is not anticipated that an "input team" will be used to develop Ecological Risk Screening Summaries. Although multiple people do work on an ERSS, it is never done in a group setting; we do not intend to have a roundtable group discussion to reach a consensus for any species. The development process is one that moves through a series of stages as follows:

AUTHOR → TECHNICAL REVIEWER → EDITORIAL/POLICY REVIEWER → INJURIOUS WILDLIFE LISTING ASSESSOR*****.

ERSSs are not completed by or in group settings; we may at some point, however, have several people assess the same species individually and then compare results for QA/QC purposes. That said, we are very much aware of the potential problems associated with use of teams or expert panels; in a separate project, one of the team members on the

Bayesian network model development team, the second stage of risk assessment, developed, implemented, and published a strict protocol for avoiding such problems (Marcot et al. 2012).

***** While this description of the stages of the ERSS development process is our preference for how they will be developed, we can't unequivocally commit to this approach in this responsiveness summary binding the agency's hands in the future. Rather, we will balance the fiscal and staffing realities of the agency in delivering its conservation mission with the benefit of keeping these roles differentiated.

Comment 8 – *As indicated below, one area that could enhance the results of the ERSS is the inclusion of some form of review of water temperatures when ascertaining invasiveness of aquatic organisms. While air/water temperatures are often closely aligned at the water's surface, the actual water temperatures may vary from a variety of factors, including water column depth, water source, flow rates, thermal springs, etc. **

** Footnote from Reviewer: Air/Temperature correlation issues:*
[A)] Pilgrim, J. M., Fang, X., and Stefan, H. G. 1998. Stream Temperature Correlations with Air Temperatures in Minnesota: Implications for Climate Warming, Journal of the American Water Resources Association, 34 JAWR:1109-1121;
[B)] Eaton, J. E. and Scheller, R. M. 1996. Effects of climate warming on fish thermal habitat in streams of the United States. Limnology and Oceanography 41:1109-1115;
[C)] Sinokrot, B. A. and Stefan, H. G. 1993. Stream temperature dynamics: Measurement and Modeling. Water Resources. Res., 29(7): 2299-2312. See also: http://waterwatch.usgs.gov/new/.

FWS Response: Although adding water temperature data to the ERSS assessments could certainly be useful, we cannot do so at this time because:

1) Although the U.S. does maintain a large database of water temperature data (http://www.epa.gov/storet/), we are not aware of any such database for the remainder of the world that provides temperature minimums in the coldest months and maximums in the warmest months that would allow us to conduct the recommended analyses; and
2) Even if the water data existed, data are often not available for the upper and lower lethal temperature limits of many of the non-native species being assessed.

Despite the lack of water and lethal temperature data, we believe the ERSS process to be a valid method to rapidly identify species that should be given a more thorough examination. Derived from two of the best predictors of potential invasiveness – climate match and history of invasiveness (Bomford 2008; Hayes and Barry 2008) – the Service's risk screening approach uses scientific literature to help develop risk analyses that are then reviewed by others.

In addition to the seminal references listed above, there is a substantial body of literature that indicates that climate match is one of the best predictors of potential

invasiveness. In 2001, researchers studying birds in Australia (Duncan et al. 2001) found that "*climate suitability significantly predicts introduction success and the subsequent geographical range size of introduced birds.*" This was corroborated by a 2003 study on birds and mammals (Bomford 2003) that found that the risk of establishment was greater for species with better climate matches. In 2004, further support for climate as a predictor of invasiveness was reported from a study of introduced mammals (Forsyth et al. 2004) which found that the 23 species that had become established all had a greater area of climatically suitable habitat in Australia than those that did not become established. Finally, climate matching has also proven useful as a predictor for invasiveness in the ecological niche modeling work on snakehead fish (Channidae) (Herborg et al. 2007) and Asian carp (Cyprinidae)(Chen et al. 2007) as well.

To our knowledge, the largest effort in North America to develop and test risk assessment tools is nearing completion. That effort was led by researchers from six universities, The Nature Conservancy, U.S. Geological Survey, and the Fisheries and Oceans – Canada. That research was advised by management input from eight States, Fisheries and Oceans – Canada, and managers from U.S. Departments of Agriculture, Commerce, and Interior. The research team independently analyzed climate match scores provided by the Service and concluded that a model based only on climate match performs very well for explaining which species have and have not become established. The justification for climate matching in the peer-reviewed publication (Hayes and Barry 2008) served as the scientific foundation for the rapid risk analysis (page 2 in http://anstaskforce.gov/Meetings/2008_October/MRBP_Working_Version_Model_Risk_Assess._&_Management_Process_10-20-08.pdf) and the ERSS approach.

Comment 9 – *As a rapid screen, the ERSS process is by far the best tool developed to date. It provides tools to generate the best available information in a usable format that clearly indicates the elements of the rapid screening process and the findings supporting the risk classification.*

FWS Response: Comment only, no response required.

Comment 10 – *Recognizing that modifications to the ERSS protocol would likely have to undergo a tedious and time-consuming bureaucratic approval process, I recommend that some form of instruction or caveat be included in the final ERSS protocol whereby new, relevant databases of other source material could be added to the "search list," such as an Addendum and updated as appropriate to include new resources. For example, useful information may surface under the recently created Global Invasive Alien Species Information Partnership (GIASI Partnership) under the Convention on Biodiversity. One of the initial activities involves IUCN's compiling a comprehensive "list of lists" of invasive species resources, including databases. Jamie Reaser, PhD, is leading this initiative and it could provide the Service with more complete*

information on GIASIP.
See http://www.cbd.int/doc/meetings/cop/cop-11/information/cop-11-inf-34-en.pdf.

> **FWS Response:** We agree with this comment. Section 1, #5 already instructs the ERSS author to "use whatever resources you can," but we will try and make it clearer that both the use of other data sources and the inclusion of new data sources when they become available are acceptable and should be used to the maximum extent practicable. We may also explore the idea of moving all the listed databases to an appendix, which may be more easily updatable than the main body of the SOP.

Comment 11 – *When asked to review the Ecological Risk Screening Summary process, which was described (in an email from Don MacLean) as "a rapid risk screening process to determine a high, low, or uncertain level of risk for imported non-native species", I expected to receive a document along the lines of Pheloung et al. (1999). Pheloung et al. (1999) presented an assessment tool (the Weed Risk Assessment for Australia), gave some scientific justification for its construction, evaluated its performance, and compared scores against expert opinion. Instead, what was received was an SOP providing instructions for those using a rapid screening tool developed by FWS. Reviewing the SOP for <u>using</u> the process is much different than reviewing the process itself (i.e., developing the template for the ERSS). Significant justification and scientific basis for how the process was developed is lacking and inadequately justified and should be provided. (E.g., why use history of invasiveness and climate match as the factors to predict risk? Why only these factors? How do we know this tool is valid for all climates and taxa? Why is this particular method of determining climate match appropriate? How much information is 'enough' to make accurate characterization of risk?) Perhaps [this] has been done in a previously-written and peer-reviewed document. If this is the case, then that document should be referenced in the SOP.*

> **FWS Response:** We agree with this comment and we intend to provide a background and justification for the ERSS process, which will provide answers to some of these questions and make it publically available through our website as either part of or complementary to the SOP.

Comment 12 – *The Food and Agriculture Organization of the United Nations provides the following discussion of SOPs at (http://www.fao.org/docrep/W7295E/w7295e04.htm): "A Standard Operating Procedure is a document which describes the regularly recurring operations relevant to the quality of the investigation. The purpose of a SOP is to carry out the operations correctly and always in the same manner…A SOP is a compulsory instruction. If deviations from this instruction are allowed, the conditions for these should be documented including who can give permission for this and what exactly the complete procedure will be. The original should rest at a secure place while working copies should be authenticated with stamps and/or signatures of authorized persons." Key goals of this SOP, then, should be to standardize data collection, interpretation, and risk assessment and within stringent guidelines to assure*

credibility of resulting reports, for transparency, and repeatability. Clearly delineating these reasons seems like an important addition to the introductory material of the SOP.

> **FWS Response:** We agree with this comment. These key goals will be added to the introduction to make clear the purpose of the SOP.

Comment 13 – *There are a number of places in the SOP that a course of action appears suggested whereas a course of action should be prescribed. For example, must one search each and every [one] of the six databases listed in Section 1 for plants to determine if the species in question is established in the U.S? Could the first suffice if it contained a wealth of information? A major benefit of instituting a screening process such as the one supported by this SOP is to provide a 'stopping point' for data collection, i.e., by following steps in the SOP, it becomes clear when 'enough' data have been obtained to support decisions. As written, however, it seems that this benefit is not fully realized because insufficient criteria are provided to limit the search for additional data. If the listed resources provide 'insufficient' data, then some criteria could be provided to search for more information, with clear guidelines for stopping the search. Perhaps an expectation for the depth and completeness of data necessary to 'stop' could be included in each field? I was surprised, for instance, that one sentence from FishBase sufficed for description of 'Native Range' in the completed ERSS provided. The SOP should clearly lay out definitions, data thresholds, and limits for each field for which data is being collected (including appropriate justification for each).*

> **FWS Response:** One of the main difficulties in developing the ERSSs is that, for many of these species, the information we are seeking is typically broad or general (because that is typically all the information that is available), which makes it very difficult to set data thresholds and limits. The ERSS authors are expected to review multiple sources for each section, select the most thorough for entry, and add new information from other sources if it exists. The approach is intended to mine data and information from the key websites listed in the SOP. If all websites recommended in the ERSS SOP are visited (including googlescholar.com), and little information has been found, then due diligence has been taken, the lack of data should be noted, and searching can stop. We intend to expand this section of the SOP, including both primary and secondary data sources and clarification on when the ERSS author can stop searching.
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> The data search performed for an ERSS must be part of the clear, detailed administrative record that should accompany each ERSS. This record should include a list of correctly cited references, list of all databases accessed, and a saved (PDF) copy of all cited information (article, electronic database entry, report) made at the time the information was accessed. We will develop a checklist as suggested by the commenter.

Comment 14 – *Throughout the document and as each data field is encountered, each data field should be defined, and the type of information that is being sought should be described. E.g., in the Native Range under Section 1, a text description rather than a map is sought; this is not*

intuitive. Similarly, definitions and data requirements for 'Environment', 'Short description', 'Biology', and 'Threat to humans', all within the Biology and Ecology Section, are not intuitive. Each data field must be defined and data thresholds and limits be provided.

> **FWS Response:** We agree with this comment and will add a short description of what we are looking for in the data fields in this section. However, the difficulty in developing the ERSSs is that, for many of these species, the information we are seeking is typically broad or general (because that is typically all the information that is available), which makes it very difficult to set data thresholds and limits. We will also clearly emphasize that what we want in each section is the best information available that can be derived from the information sources recommended in the ERSS SOP (which can include maps when available).

Comment 15 – *There are numerous places throughout the SOP that provide too much detail, given that SOPs contain compulsory instructions (as in the FAO discussion of SOPs). Therefore, amendments would need to be written to the SOP if CLIMATCH or FishBase or other web resources described in the SOP update their methods or tools. For that level of detail, perhaps an instruction SOP is needed. At the level of this SOP (seemingly how to obtain and procure the data and information necessary to complete and then to complete the risk assessment), frequent updates for software changes would be undesirable.*

> **FWS Response:** We recognize that some of the compulsory instructions may require updates if the associated web resources update their methods or tools. However, we do not feel that a separate instructional SOP is needed as that would just render the ERSS process more confusing – especially in light of other peer review comments calling for a separate justification document. We will review the compulsory instructions within the SOP and explore the options of leaving them within the SOP, simplifying them, or perhaps moving them to one or more appendices.

Comment 16 – *There should be a clear distinction in the SOP between data collection and risk assessment phases. All data collection should occur in Sections 1-6. All data interpretation and risk assessment should occur in Sections 7 and 8. As a matter of procedure, expertise required for personnel gathering and interpreting data and the process by which templates will be reviewed should be included in the SOP (perhaps in the introductory material). For instance, are there minimum qualifications of personnel collecting data from websites? Could the same person interpret data and conduct the risk assessment? If not (and it seems advisable to reduce bias that the risk assessor be different than the data-gatherer), then what are the minimum qualifications of the assessor? Will the completed assessment be reviewed before being considered final? If so (and it seems advisable that they should be reviewed), what process would be used?*

FWS Response: In general, we agree with this comment and we intend to address these issues within the SOP. The primary "interpretation" in an ERSS occurs at the "Certainty of Assessment" section that is necessarily subjective and must be completed by the data gatherer (there is however also some degree of interpretation in the assessment of impacts and in the selection of weather stations when performing a climate match). Section 8 is not at all an interpretation, but is a summary of the data and ranking based on standardized scoring. However, this is the very reason that we have the "Original Author ---> Technical Reviewer ---> HQ Reviewer ---> I.J. Listing Assessor" process*****. Finally, although we can certainly prescribe the qualifications of Service ERSS assessors/authors, we do not have the authority to prescribe the qualifications of others who may choose to conduct risk assessments using the ERSS process. Consequently, we will also explore the idea of including some information on the credentials of ERSS assessors/authors within the ERSS SOP.

***** While this description of the stages of the ERSS development process is our preference for how they will be developed, we can't unequivocally commit to this approach in this responsiveness summary, binding the agency's hands in the future. Rather, we will balance the fiscal and staffing realities of the agency in delivering its conservation mission with the benefit of keeping these roles differentiated.

Comment 17 – *Part of the reason for having the SOP, it seems, is to ensure proper content and documentation of a high quality Administrative Record upon completion of the assessment. This fact could be stated in the introductory material, the components of the Administrative Record listed, and then throughout the document, places at which a required document for the Record is produced could be indicated. Alternatively, at the end of the SOP, procedures for creating the Record could be described.*

FWS Response: We agree with the suggestion and will add instructions for creating the Administrative Record.

Comment 18 – *Discussion of data quality standards should be included in the SOP, perhaps in the introductory discussion. Can data in white papers be included as references? When is it appropriate to use personal communications as references? If looking at a website, is it appropriate to cite primary literature when it was not consulted? Are there guidelines to assess the validity of a website? Could it be a newspaper article with claims of species impacts, for instance?*

FWS Response: Some of these issues have been addressed (citing when not consulted, personal communications), but perhaps need more specificity in the SOP. We will clarify and expand upon this information within the SOP. ERSS author's primary source of information will be from expert-validated native and invasive species information systems (GBIF, NAS Database, BISON, etc.). Information from websites, newspapers, or

other non-scientific literature can be used and noted, but should not be used as the sole basis for risk in an ERSS. In addition:

- The assessors (authors) need to clearly indicate whether primary sources were accessed or whether the information was retrieved from a secondary source. Citations from secondary source should correctly cite the primary source.
- Data cited from "white papers" and "gray literature" may be included as references. However, assessors do need to understand the differences between actual data, opinions, and recommendations in white papers.
- A newspaper article that has documented evidence of species' presence and impacts may be used.

Ultimately, the ERSS should be a compilation of facts, data, and actual occurrences of species effects and not hypothetical circumstances.

Comment 19 – *Grammatical suggestions: Use command form sentence structure throughout; eliminate pronouns; use the same phrase throughout the document to describe the species for which the assessment is being conducted: e.g., 'the species in question' or 'species being assessed', etc. For suggestions that occur throughout the document, usually only the first instance of the suggestion is indicated in the document.*

FWS Response: We agree with these suggestions. In addition, many of the suggested changes provided in track changes will also be considered.

Comment 20 – *Suggest adding a section where a variety of terms, including data collection fields, are defined. Another term to define might be: United States—does the process for which this SOP was developed apply to the 48 contiguous or all 50 states, or include U.S. territories as well? Or can the assessor choose one of these definitions depending on the species in question? This distinction seems important because of the higher prevalence of tropical climate found in Hawaii and much of the U.S. territories. Also, the fact that islands seem more vulnerable to invasion seems relevant to providing this distinction.*

FWS Response: We agree with this comment and will add a short description of exactly what we are looking for in the data fields in the ERSS. However, the difficulty in developing the ERSSs is that for many of these species the information we are seeking is typically broad or general (because that is typically all the information that is available), which makes it very difficult to set data thresholds and limits. We will also clearly emphasize that what we want in each section is the best information available.

The SOP will also be altered to clearly indicate that the contiguous U.S. is the default setting for ERSSs but that an ERSS can also easily be done for all of the U.S., or just the continental U.S. (including AK), or for a specific part of the U.S. if desired (by States or for specific regions, for example).

Finally, we will create a location on the ERSS web site where ERSS developers can download ".clm" files for CLIMATCH for both the contiguous and continental U.S., or just Hawaii, or Alaska, or the U.S. as a whole. Individual files may also be uploaded for each state.

Answers to the 6 Questions Posed to the Peer Reviewers

Peer Review Question 1: Are the steps in the ERSS process clearly stated and logical? If not, please identify the specific methods and assumptions that are unclear or illogical.

Comment 21 – *While the steps as outlined in the ERSS process make sense to me, the evaluation procedure is somewhat technical in nature and for a person unfamiliar with the project, it may take some time for them to completely appreciate all the details.*

FWS Response: Comment only, no response required.

Comment 22 – *In general, the steps are clearly stated and logical.*

FWS Response: Comment only, no response required. Two exceptions were provided as part of this comment – they are under specific comments.

Comment 23 – *Places in the SOP that might be more clearly stated are noted on the Word document provided via track changes.*

FWS Response: We intend to review and address all the recommended changes that were provided via track changes in Microsoft Word.

Peer Review Question 2: Is the ERSS process based on the best available science? If not, please provide the specifics of each situation.

Comment 24 – *I would agree that the process as outlined does make use of the best available science, with the exception of climate change. If the process is updated in the future, it may be beneficial to consider including a climate change component along with the climate matching section (6). I do appreciate the challenges in doing this, as we are grappling with this issue in our state assessment process as well.*

FWS Response: We agree with this comment and, in fact, do have a separate tool that incorporates IPCC Climate change scenarios (two scenarios--A1b, B2a; and three

generations--2020, 2050, 2080). Thus, we can account for climate change in our mapping and scoring of a nonnative species climate niche. We did not include the climate change tool in the ERSS peer review, because that tool is still in development and will undergo a separate peer review. See Comment 57 for more details on the Risk Assessment Mapping Program (RAMP).

Comment 25 – *The sources of information and data that are recommended to complete species-specific risk assessments represent the best available sources. Appropriately, the SOP urges the user to be on the lookout for spurious or illogical data, which is a hazard even with traditionally published sources, and a particular hazard when one must rely on websites, as is the case for many data in this SOP. This SOP relies appropriately on the most scientifically rigorous and best documented web sources.*

FWS Response: Comment only, no response required.

Comment 26 – *As written, there is no way to know if this SOP is based on science; the peer-reviewed literature is rarely cited. How the template was developed, e.g., the appropriateness of using history of invasiveness and climate match as predictors of potential invasiveness, and only those factors instead of others, as well as the appropriateness of using CLIMATCH as a potential range predictor, in particular, do require justification—but not in this SOP. An SOP is about USING the tool—not justifying its development.*

FWS Response: We have clearly stated that the climate matching portion of the ERSS process utilizes the Australian CLIMATCH model (Australian Bureau of Rural Sciences 2013; http://adl.brs.gov.au:8080/Climatch/) which has been peer reviewed (See SOP Appendix C – CLIMATCH User's Manual). We will develop a background and justification for the ERSS process to address these issues and make it publically available through our website as either part of or complimentary to the SOP.

Peer Review Question 3: Are there any significant peer-reviewed scientific papers that the ERSS process omits from consideration that would enhance the scientific quality of the document?

Comment 27 – *Several related publications, which staff are likely familiar with, are as follows:*

- *Aquatic Nuisance Species Task Force, Risk Assessment and Management Committee, October 1996, "Generic Nonindigenous Aquatic Organisms Risk Analysis Review Process".*
- *Commission for Environmental Cooperation, 2009, "Trinational Risk Assessment Guidelines for Aquatic Alien Invasive Species".*
- *USDA, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, October 2000, Version 5.02, "Guidelines for Pathway-Initiated Pest Risk Assessments".*

- *Cowie, R H, et. al., 2009. "Alien non-marine snails and slugs or priority quarantine importance in the United States: A Preliminary Risk Assessment", Amer. Malac. Bull. 27:113-132.*
- *Molnar J.L. et. al., 2008, "Assessing the global threat of invasive species to marine biodiversity", Frontiers in Ecology and the Environment", doi:10.1890/070064*
- *Zanden M.J. and J.D. Olden. 2008. "A Management Framework for Preventing the Secondary Spread of Aquatic Invasive Species", Can. J. Fish. Aquat. Sci. 65:1512-1522.*

FWS Response: We thank the reviewers for these additional references. We will review them and determine whether they can be added to the SOP.

Comment 28 – *Because only two sources are cited (Bomford 2008, and the CLIMATCH document), it is impossible to know which potential sources of information guided the overall structure of the SOP. However, the components and overall logic of the tool are consistent with the rich scientific literature on biological invasions. I provide a citation above for one specific component of the SOP that needs further thought (lag times).**

***Costello, C., J.M. Drake, and D.M. Lodge. 2007. Evaluating an Invasive Species Policy: Ballast Water Exchange in the Great Lakes. Ecological Applications, 17(3), 2007, pp. 655–662.*

FWS Response: We will review this citation and consider adding a component on lag times to the SOP if we can determine how to do so without altering the rapid nature of the ERSS process. Bomford (2008), and CLIMATCH were the primary sources that guided the development of the ERSS process; however, we are adding a background and justification document in support of the SOP to shed more light on the sources of information that guided the overall structure of the SOP. Please also see the second paragraph of our response to Comment 8.

Comment 29 – Unless methods or analyses are being borrowed from the peer-reviewed literature, SOPs do not typically cite much peer-reviewed literature. SOPs should provide directions to carry out a standard task that is carried out repeatedly.

FWS Response: Since the SOP relies on the use of CLIMATCH, which was developed and peer-reviewed by the Australians, we feel it is necessary to include references in the SOP. While it may be true that SOPs do not typically cite much peer reviewed literature, we have decided to include references because there will be some readers who will desire to see the references. In addition, we intend to provide a background and justification for the ERSS process, which will provide a more detailed history on the development of the ERSS process as well as a justification for the use of climate matching and the use of history of invasiveness as predictors of invasive risk. This document will be publically available through our website

(http://www.fws.gov/injuriouswildlife/Injurious_prevention.html) as either part of or complementary to the SOP.

Comment 30 – Reference: Pheloung, P.C., P.A. Williams, and S.R. Halloy. 1999. A weed risk assessment model for use as a biosecurity tool evaluating plant introductions. Journal of Environmental Management 57:239-251. [This reference was provided by one reviewer without explanation as to how it might be useful]

FWS Response: We thank the reviewer for this additional reference. We will review it and determine whether it can be added to the SOP or background/justification document.

Peer Review Question 4: Is the scientific foundation of the ERSS process reasonable and how can it be strengthened?

Comment 31 – *I would agree that the scientific foundation of the ERSS process is sound.*

FWS Response: Comment only, no response required.

Comment 32 – *The scientific justification is strong to use this approach for a rapid risk assessment. A large literature attests that climate match is one of the best predictors of whether an introduced species will become established, and whether an established species will become invasive. There are many ways to conduct climate matching analyses. CLIMATCH is a defensible and time-tested algorithm that is quick. We are not aware of any risk assessment tool being used for policy purposes in any country that does not include a climate matching component. If only two, easily ascertained pieces of information are going to be considered in a risk assessment, they should be climate suitability and history of invasiveness. Obviously, a serious limitation of the latter is that it can only be available for species that have previously been introduced.*

FWS Response: Comment only, no response required. We would like to point out, however, that the Bayesian network model mentioned earlier in this document (see the responses to comments 4 and 5) could be useful for species that have not been previously introduced.

Comment 33 – *The justification for this overall approach—relying on climate matching and history of invasiveness—could be strengthened by a study that as directly as possible tests the accuracy of using climate matching and history of invasiveness for taxonomic groups of interest to the USFWS. The accuracy of risk assessment tools can only be measured in postdiction, i.e., measuring how well a tool can discriminate species known to have been invasive from those known not to have been invasive. The assumption must then be made that tools that are*

accurate in describing the past will be the most accurate tools in describing the future. An exercise in postdiction would improve the already strong foundation of the approach chosen by the USFWS.

FWS Response:
The development of the ERSS process started with the development of a rapid risk analysis process (even more comprehensive than the ERSS) under the aegis of the Mississippi River Basin Panel (MRBP) of the Aquatic Nuisance Species Task Force. The model process has been available for review at the MRBP and other websites since it was developed, reviewed, and approved by the MRBP. The model process remains on the WWW at http://anstaskforce.gov/Meetings/2008_October/MRBP_Working_Version_Model_Risk_Assess._&_Management_Process_10-20-08.pdf. During this development period, the approach was tested and found to provide useful classification of species that became established and then impacted the U.S. The approach was measured in postdiction on a number of species including (but not limited to) bighead carp, grass carp, silver carp, green swordtail, and several species of snakehead fish. Although the postdiction testing was never compiled into a final report, the positive results ultimately led to the development of the ERSS SOP. Later, an independent evaluation of the approach resulted in support of the process. The results of that independent analysis are presumably under development for publication, and will be submitted in the form of a manuscript for peer review. In addition, we will develop a background and justification for the ERSS process and make it publically available through our website as either part of or complimentary to the SOP.

Comment 34 – *Places in the text where clarity, transparency, and repeatability might be increased have been noted on the document.*

FWS Response: All edits provided via handwritten comments and track changes will be considered.

Peer Review Question 5) Are there any significant oversights, omissions, or inconsistencies in the formulation of the risk assessment tool?

Comment 35 – *The only suggestion I would have is to incorporate climate change into the formula at some time in the future.*

FWS Response: We agree with this comment and in fact, do have a tool that incorporates IPCC Climate change scenarios (two scenarios--A1b, B2a; and three generations--2020, 2050, 2080). Thus, we can account for climate change in our mapping and scoring of a nonnative species climate niche. We did not include the climate change tool in the ERSS peer review, because that tool is undergoing a separate peer review.

Comment 36 – *No, other than the issues identified under other questions above.*

FWS Response: Comment only, no response required.

Comment 37 – *The SOP does not present, justify, or describe how the risk assessment tool was formulated.*

FWS Response: We agree with this comment and we intend to provide a description of how the ERSS process was created and a justification for the ERSS process. In addition, we will develop a background and justification for the ERSS process and make it publically available through our website as either part of or complimentary to the SOP.

Peer Review Question 6) Will the proposed assessment provide adequate information to governments and industry to be used as a rapid screening tool?

Comment 38 – *I would agree that the proposed process will provide sufficient information to interested stakeholders.*

FWS Response: Comment only, no response required.

Comment 39 – *Yes, with some additional explanation and justification behind some of the components of the SOP, as noted above.*

FWS Response: Comment only, no response required.

Comment 40 – *Places in the text that could increase the utility of the SOP as a rapid screening tool are indicated on the document.*

FWS Response: We appreciate the reviewer's comments and intend to review and address all the recommended changes that were provided via track changes in Microsoft Word.

Specific Comments

Comment 41 – [Page 2, 1st paragraph, last sentence] **–** *"risk analysis assessments" should read "risk assessments." In the scientific literature, "risk analysis" generally refers to a combination of risk assessment and risk management. This SOP is about only risk assessment.*

FWS Response: We agree with this comment; this edit has been completed.

Comment 42 – [Page2, 2nd paragraph, penultimate sentence] **–** *I believe that "survives" should be replaced by "is established . . ." The title of the SOP and P 9 makes it clear that establishment, not survival, is the state of invasion that is of concern.*

FWS Response: We agree with this comment; this edit has been completed.

Comment 43 – [P 2, 5th para, first sentence] **–** *The meaning of the last phrase "and as a risk analysis tool" is unclear and could be deleted.*

FWS Response: We agree with this comment; this edit has been completed.

Comment 44 – [Page 2, 5th paragraph, last sentence] **–** *At the end of the sentence, I believe that "importation" should be inserted between "the" and "of live animals."*

FWS Response: We agree with this comment; this edit has been completed.

Comment 45 – [Page 2] **–** *INTRODUCTION: By just using 'escape' in the first sentence, it implies that organisms willfully leave captivity or domestication and assumes that the reader is familiar with various vectors of species spread. Suggest at least adding the phrase 'from intended uses' to clarify meaning as indicated on the document.*

FWS Response: We agree with this comment; this edit has been completed.

Comment 46 – [Page 2] **–** *USING THE TOOLS: Even though it seems the Service's interest in developing this SOP lies in regulation, there are many other potential uses for the process described in this SOP. For example, developing watch lists and monitoring programs, targeting control efforts, etc. Perhaps some of these uses could be listed and described? Alternatively, if inappropriate for those uses, spell out the intended and appropriate uses of the SOP.*

FWS Response: The sole purpose for the SOP is to guide a reviewer in completing the ERSS process. The completed ERSSs, however, are intended to provide two functions: 1) to inform the injurious wildlife listing process and 2) to inform interested parties of the risk of imported or transporting certain species. For the injurious wildlife listing process, species deemed as high risk or uncertain risk through the ERSS will be reviewed for possible injurious wildlife listings. For informing interested parties (such as importers of live animals), the ERSSs will be posted on the Service website to let the public know the high and uncertain risk species they may choose to voluntarily avoid importing or transporting and the low risk species to consider as more responsible alternatives for importing or transporting. Ultimately, the completed ERSSs could also lead to State regulatory actions banning certain species and other measures to prevent the introduction of these species into the U.S. We intend to add language to clarify the purpose of the SOP.

Comment 47 – [Page 3, General Notes] **–** *Third bullet: Page 3, under "Development of ERRS reports…" reads "Brackets can be used…" I recommend that "must" be substituted for "can" to make it abundantly clear that a quotation is incomplete/ altered.*

FWS Response: We agree with this comment; this edit has been completed.

Comment 48 – [Page 3, General Notes] **–** *Need to insert language stressing the importance of creating a detailed, inclusive and clear administrative record of materials/sources investigated whether or not relied upon. If a database was checked but not useful or used, the reference should be so noted in the administrative record.*

FWS Response: We agree with the suggestion and will add instructions for creating the Administrative Record.

Comment 49 – [Page 3, General Notes] **–** *Should include reference to QA/QC Checklist (to be developed) as means of ensuring that an assessors/reviewers assessment is thorough and complete. Human nature being what it is, one can easily skip through checking databases if they believe they have found sufficient information in a couple of databases*. One should not ignore Jim Quinn's (UC Davis) admonition on simply relying upon database summaries rather than underlying references due to "garbage in – gospel out." A checklist would reduce the likelihood of human nature (error) resorting to relying on summaries in lieu of thoroughly checking references. In the event the Service incorporates a QA/QC mechanism as a safety net, the instructions should specifically explain the importance of and the need to utilize and comply with the QA/QC checklist(s).*

***** *Footnote from Reviewer: From personal experience when I conducted an assessment to test the system I skipped over several databases after relying upon several well-known databases*

indicating "high risk." Upon further research, I discovered that the species status was not so clear and realized the importance of reviewing, albeit quickly, each of the relevant databases listed under ERSS Standard Operating Procedures Sections 1, 2, and 3. As a result, my ultimate assessment showed "uncertain" not "high" risk.

> **FWS Response**: As an ERSS goes through its development stages (from author to technical reviewer, to policy reviewer)***** it is subjected to a level of QA/QC equivalent or better than anything achieved via a checklist (this includes an administrative record and list of appropriate databases). However, we understand that for outside agencies or the general public who would be new to the process, the creation of a QA/QC checklist to enable them to successfully complete ERSS's would be beneficial to add to the SOP; the checklist would also be useful for the administrative record. We agree with this comment and we will add a QA/QC process or checklist to the SOP.
>
> ***** While this description of the stages of the ERSS development process is our preference for how they will be developed, we can't unequivocally commit to this approach in this responsiveness summary, binding the agency's hands in the future. Rather, we will balance the fiscal and staffing realities of the agency in delivering its conservation mission with the benefit of keeping these roles differentiated.

Comment 50 – [Page 3, General Notes] **–** *Recently unveiled, the USGS "BISON" database should be evaluated for inclusion in the ERSS protocol as an additional resource. This database would supplement, not supplant, GBIF and other databases set forth in the ERSS protocol. See: (http://bison.usgs.ornl.gov/).*

> **FWS Response:** We agree with this comment and will consider adding BISON (Biodiversity Information Serving Our Nation) as an additional resource. We also agree that BISON should be portrayed as a supplemental resource for use in the development of ERSSs and not a replacement for GBIF. According to Annie Simpson (biologist & information scientist in the Eco-Science Synthesis, Core Science Systems Division of USGS) : "*you really shouldn't approach this as a "which database should I use" question. Without NAS and other biodiversity data resources, BISON couldn't exist. They collect the data and we help disseminate it. If you have used them in the past you should continue to use them to fulfill your needs. BISON's 'value added' offering is providing a place which allows the user to select and display search results from multiple datasets, displayed on a large variety of backgrounds/GIS layers. We also allow direct access to the data via Web services and encourage developers to create tools that enable innovative and/or specialized (taxonomic or geographic) views of the data*."

Comments 51 and 52– Two similar comments

- **Comment 51 –** [page 4] – *FishBase will contain AFS common names only for fishes already found in North America. In that case, the 2013 AFS Names book (Page et al. 2013) should be used instead as it will be more up to date than FishBase. Guidance needs to be provided*

on which common name to choose when multiple names are given in FishBase for species not already in North America and for which AFS has not assigned a name.

- **Comment 52 –** [Page 4] **–** *Catalog of Fishes not Fish Base is the authority for scientific names and should be used when there is no ITIS entry for a fish species. Not sure what "taxonomic references that often occur after the scientific names" means - do you mean "taxonomic authority"? If so, use that term instead. [Note from D. MacLean: Yes, I meant "taxonomic authority"]*

  FWS Response: We agree with these comments and we intend to revise the SOP to reflect both of these changes. After communication with Bill Eschmeyer (California Academy of Sciences – Catalog of Fishes) the language will be revised to show that for acquiring the current scientific name for fish species, the order of preference should be:
  - Catalog of Fishes; then
  - The AFS Name Book (if the species occurs in North America and if the book is available to ERSS authors); then
  - FishBase; and then finally,
  - ITIS

  Guidance for common names will also be added to the SOP and ITIS will still be recommended for non-fish species as well as other appropriate information sources.

Comment 53 – [Page 7] **–** *ERSS Section 3: Impacts of Introductions - Would insert note or caveat that identified "databases" are not the only databases to be relied upon; encourage checking other databases in addition to the ERSS listed databases. Moreover, clear instruction should be repeated in this section to identify in the template and in the administrative record all databases reviewed whether or not relied upon.*

FWS Response: We agree with this comment. Section 1, #5 of the SOP already instructs the ERSS author to "use whatever resources you can," but we intend to make it clearer that both the use of other data sources and the inclusion of new data sources when they become available are acceptable. We may also explore the idea of moving all the listed databases to an appendix, which can be more easily updated than the main body of the SOP.

Comment 54 – [Page 8] **–** *Google Scholar – I would add "introduced" to search.*

FWS Response: We agree with this comment; this edit has been completed.

Comment 55 – [Page 9] **–** *Add Web of Science as well for primary literature search?*

FWS Response: Web of Science is an online subscription-based scientific citation indexing service maintained by Thomson Reuters that provides a comprehensive

citation search. The subscription is for institutions only and is fairly expensive. Because the SOP is supposed to be a process that can be completed by anyone, we are reluctant to require or even suggest the use of Web of Science. We will list it as an alternate database for those who have subscriptions.

Comment 56 – [Page 9] **–** *I do not think it is sufficient to search only GBIF to determine the global distribution of a species. This will lead to an underestimation of its actual range that, in turn, will lead to an underestimate in the climate match. Other sites should be included as well such as WorMs, VertNet, AquaMap, and species-specific searches for distribution data or maps in Google.*

FWS Response: While we agree with this comment, we will only use range locations that have been geographically verified (i.e., coordinates provided for specimens), to avoid range "estimates". We are aware that we may underestimate actual range, and thus, our approach is conservative. We prefer to underestimate rather than overestimate global range. GBIF is our default, but we use other sources of information at times. Based on the review of information by the risk assessor and each and all reviewers, if data and information in GBIF is considered to be overly conservative or omitting information that should be considered, we will modify the ERSS to include other possibilities.

Comment 57 – [Page 11, Section 5, #2] **–** *Delete "the" between "document" and "any."*

FWS Response: We agree with this comment; this edit has been completed.

Comment 58 – [Page 11, ERSS Section 6: Climate Matching] **–** *Hopefully, a more user-friendly software package than CLIMATCH is on the horizon. Apart from the fact that the site is often down or extremely slow, I find navigating/mapping somewhat tedious and of questionable accuracy.*

FWS Response: We agree with this comment. Although still a valuable tool, the reviewer correctly describes only a subset of the issues with CLIMATCH. For those reasons, and several other, important reasons, we have developed the Risk Assessment Mapping Program, (RAMP), our own climate matching system. Based on the CLIMATCH algorithm, RAMP is more user friendly, faster, and addresses some of the shortcomings of CLIMATCH. RAMP will be peer reviewed under a separate process. If results of that peer review process are supportive, then we will dramatically improve the user interface over what CLIMATCH currently offers, with enhancements in site navigation and mapping. We will also streamline the species station selection, using the species name for matching pre-selection and we will also improve the resolution of the target stations across North America as compared to CLIMATCH. The majority of this work will

be conducted during 2014 and 2015. Once the web application is complete, the new version of RAMP will be served online by the Service*.

***** While this this is our preference for how RAMP will be delivered, we can't unequivocally commit to this approach in this responsiveness summary, binding the agency's hands in the future. Although it is out plan to serve RAMP online, we must balance this goal with the fiscal and staffing realities of the agency in delivering its conservation mission.

Comment 59 – [Page 11] **–** *ERSS Section 6: Climate Matching - However, based on current state of the art, CLIMATCH is useful for identifying extralimital destinations that could be a host for a potential invasive species due to climate similarities between native range states and projected destination ranges. CLIMATCH, however, is air temperature dependent. Recognizing that water temperature tolerances (high/low) are limiting factors for most aquatic species' ability to establish self-sustaining populations, I recommend that in addition to relying on CLIMATCH, the assessors/reviewers should take an additional step to analyze water temperature data. Air temperature alone may not be the most accurate determinant for aquatic species survival in destination areas where water flow rates, solar radiation, relative humidity, water sources (e.g., glacial versus thermal), artificial heat inputs, and temperatures at various column depths dramatically differ from surface air temperatures, etc. exist. A rapid review of applicable water temperature data is needed to ascertain if any anomalies surface that could supplement the knowledge base of a potential species' invasiveness.*

FWS Response: Although adding water temperature data to the ERSS assessments could certainly be useful, we cannot do so at this time because:

1) Although the U.S. does maintain a large database of water temperature data (http://www.epa.gov/storet/), we are not aware of any such database for the remainder of the world that provides temperature minimums in the coldest months and maximums in the warmest months that would allow us to conduct the recommended analyses; and
2) Even if the water data existed, data are often not available for the upper and lower lethal temperature limits of many of the non-native species being assessed.

Please see the response to Comment Number 8 for a brief description of the foundation of the ERSS process. We also plan to develop a more detailed background/justification for the ERSS process which will provide a history of the ERSS process and justification for the use of climate matching and history of invasiveness as sufficient indicators of invasiveness from which to make informed management decisions.

Comment 60 – [Page 11] **–** *ERSS Section 6: Climate Matching - Dealing with outliers: In instances where CLIMATCH indicates an outlier, such as in Southern California compared to an East Coast cluster (See Amazon Sailfin Catfish (Pterygoplichthys pardalis) http://www.fws.gov/injuriouswildlife/pdf_files/Pterygoplichthys_pardalis*

_WEB_8-29-12.pdf), I recommend that the protocol instruct assessor/reviewer to conduct further research on the outlier for such variants as water temperature, thermal springs, etc. to determine if the species presence is an anomaly.*

****** Footnote from Reviewer: Similar issue arose regarding recent reports of Water Hyacinth wintering over in the upper Mississippi River's Pool 5. Was survival an anomaly resulting from thermal springs or some other unique factor limited to Pool 5 that not otherwise found in the upper Mississippi?*

FWS Response: We agree with this comment and will expand the SOP to include either a new section or an appendix to explain how to recognize outlier data points and what to do with them.

Comment 61 – [Page 11] - *ERSS Section 6: Climate Matching – The posting of the two Plecos species on the ERSS website raises an interesting anomaly. While there does not appear to be an indication that either species is currently "in trade" (i.e., commercially imported into the U.S.), a review of the USGS database indicates that these species are established in Puerto Rico and have been spotted (possibly introduced) in the Carolinas and Florida. I recommend two ways to remedy any confusion that may surface from similar situations:*

[61a.] *The ERSS protocol should specifically instruct the assessor(s)/ reviewer(s) to indicate in the write-up that the species have been/are introduced/established in U.S. and if the aquarium industry is suspected source that these species was in-trade though no clear evidence exists that the species is currently in trade.*

[61b.] *The ERSS website should be amended to include a separate category for species that clearly are in the United States though nor evidence exists that the species remain in-trade. The website should also invite public comment seeking information to determine if the species, while it appears that the species is no longer being commercially imported, are being raised in the United States by hobbyists or being occasionally imported by specialty importers.*

FWS Response:

61a – We agree with this comment and intend to add a data field or some other instruction to indicate whether a species has been historically or is currently in trade. However, in our experience, this is not an easy question to answer. While it can be fairly easy to tell if a species is currently in trade, not finding a species does not necessarily mean it is not in trade somewhere or that it has not been in trade in the past.

61b – We intend to add more categories to the web site (or a companion site) as we add more ERSSs and the distinctions become necessary. As for the website inviting comments, we have had such a request already posted since the site was created; it says 'In addition, due to the large number of species in trade, some species may be in trade in this country that we do not know are in trade. Thus, we are seeking information from the public as to what species are in trade or are otherwise present in

the United States.' This should cover hobbyists and minor importation.

Comment 62 – [Page 12] **–** *You should provide the U.S. *.clm file to make sure that everyone uses exactly the same target map.*

FWS Response: We agree with this comment and plan to provide ".clm" files for download on the ERSS web site for both the contiguous and continental U.S., as well as more specific ".clm" files such as Hawaii, Alaska, and the whole U.S.

Comment 63 – [Page 12] **–** *Be explicit about what are the default settings.*

FWS Response: Due to the page number reference in this comment, we assume the reviewer is referencing default settings of CLIMATCH. If that is the case, we agree with this comment. The only time "default" appears in the SOP is describing the contiguous U.S. as the "default" target location. This will always be true unless we are doing a geographic specific risk assessment. Otherwise there are no settings to change using the CLIMATCH website. We will ensure that the ERSS SOP makes this clear.

Comment 64 – [Page 13] **–** *It would be useful to show a CLIMATCH examination using screen captures of every step.*

FWS Response: Although we do agree with this comment, depicting an example CLIMATCH examination with screen captures for every step would substantially increase the size (both pages and megabytes) of the document. We intend to explore the concept of creating an example CLIMATCH examination and of either including it as an appendix or perhaps as a separate document; but we are not yet sure whether we will include this as part of the SOP. A separate document that walks the reader through an entire CLIMATCH exercise would keep the main SOP shorter, but would be more difficult to keep track of.

Comment 65 – Two similar comments –

● [Page 14] **–** *I do not understand how the climate match categories in Figure 2 (BTW, it is a table not figure) were determined. The data are in Bomford 2008, but I could not find the threshold analysis. In Appendix D, it is not clear where PESTAB comes from, what 95% and 80% rejected mean, and how these thresholds were determined. Bomford et al. 2010 (Biol Inv 12: 2559-2571) show the lowest average climate match score for the same dataset as ~20% +/- SE (Australia).*

● [Page 14] **–** *One exception is the background and justification of Figure 2 (p 14), which categorizes the Climate 6 score in terms of Low, Medium or High climate match. The reader is referred to Appendix D, which is too brief and cryptic to be understood or evaluated. For*

example, it is unclear from the figure legend what is the source of the PESTAB data (the vertical axis, which I assume stands for the probability of establishment); do these data come from Bomford or the USFWS? And what exactly do the vertical lines labeled "X % Rejected" represent? The ultimate source cited for this is a 200 p technical report (Bomford 2008), but I cannot find such a figure in that document. For transparency's sake and in order to make any assumptions and decisions clear, this important component of the process requires a longer Appendix to explain and justify the recommended categorizations of climate match scoring.

FWS Response: No database is available that contains all the variables we need to develop a better categorical system for our Climate 6 scores. Such a database would need to include factors, such as propagules introduced, timing of introductions, life stages introduced, exact locations and habitat where introduced, weather and other abiotic factors, fate of introductions, and other factors that can be modeled, tested, and validated. We used the best and most comprehensive dataset available (Bomford 2008) on Climate match scores and fate of establishment, which was coupled with an a priori statistical approach, to develop our climate categories. Those categories can be easily modified, based on risk assessor and/or managers tolerance for risk. A more detailed description about our approach follows below and will be included into a background/justification document to better explain and justify our recommended categorizations of climate match scoring.

The categories (Low, Med., High) were based on an analysis of data for 255 species established in 10 countries (Bomford 2008). The Climate 6 scores showed that even species with near 0 Climate 6 scores became established. The Service approach was to use those scores to graph Climate 6 scores in relation to Bomford's probability of establishment (PESTAB) (Figure 1), and then develop categorical climate categories based on statistical categories. The statistical categories were developed (a priori) before the graph was developed. Statistical categories presently used by the Service are: 1) rejection of 95 percent of the established populations or scores, and 2) rejection of 80% of the established populations or scores (Table 1). Thus, the statistical approach is based on rejection of percentages of species established in 10 countries. That statistical approach can be modified, based on the tolerance of risk assessors and risk managers. However, our approach was objective and statistical (and documented below in Table 1).

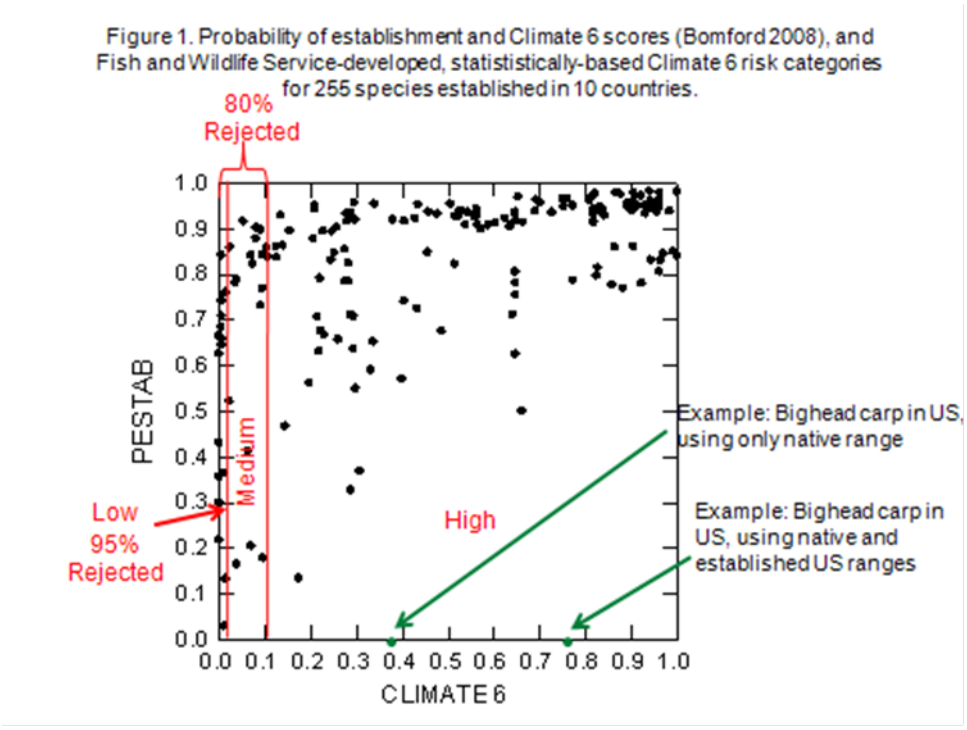

Table 1: Climate 6 Score and its relationship with Climate Match Category. These relationships were based on analysis of data for 255 species established in 10 countries (Bomford 2008).

Climate 6: Proportion of (Sum of Climate Scores 6-10) / (Sum of total Climate Scores)	Climate Match Category
0.000≤X≤0.005	Low
0.005<X<0.103	Medium
≥0.103	High

The statistical approach was applied after entering (in EXCEL) and sorting Bomford's Climate 6 data in tabular form. Data in that table, along with our statistical categories, determined the Climate 6 scores that are in our categorical system. Figure 1 (above) was not used to develop our categories. Instead, that graph was developed to illustrate (for the peer review process, and for potential review and modification by risk assessors and risk managers) our Climate 6 categories developed using our statistical approach. In that graph, we used PESTAB (which was not used in developing our categories) because it was the only other factor published by Bomford that could be graphed to view the Climate 6 scores. The graph simply illustrates statistical categories presently used by the Service, and an example for the climate match scores of bighead carp in the U.S. Note the example for the climate match score of bighead carp in the U.S. is based on only the native range. That example illustrates that bighead carp, which has become established widely in the United States, was scored at < 0.4.

We also note that Climate 6 scores are only a portion of the climate analysis, but scores are needed to provide a scoring index of climate niche that matches with the target region (typically the contiguous U.S.). In addition to the scores, each species' climate match is illustrated on a map of the target region. Climate matches of 6 and above are shown on that map in the ERSS, so risk assessors and risk managers can evaluate the spatial extent of high climate match in the contiguous U.S. That spatial information will be helpful, along with the scores, in supporting decisions on which, if any, risk management approaches are proposed for implementation.

Finally, regarding the comment on a longer appendix, the purpose of the SOP is to describe standard operating procedures for users, not describe detailed background on development of any part of that procedure. We intend to address the two comments above and the information in this response by including a more detailed explanation within Appendix D (Derivation of Climate Match Categories). In addition, We intend to provide a background and justification for the ERSS process, which will provide answers to some of these questions and make it publically available through our website as either part of or complementary to the SOP. Regardless, the Service website (http://www.fws.gov/injuriouswildlife/Injurious_prevention.html) also provides contact information, so anyone wishing to inquire about the background of our Climate 6 categories, or any of the other steps in our SOP process, can always do so.

Comment 66 – [Page 14] – *A shortcoming of using the entire continental U.S. as the target region is that matches for species with relatively narrow distributions will get lower climate matches with the broad range of climates in the U.S. although some areas of the U.S. will be highly suitable.*

FWS Response: Our Federal responsibility requires us to view risk nationally, so as part of our standardized approach to assess risk of establishment (using Climate 6 score) we calculate our climate match score for the contiguous U.S. Our ERSS approach is intended for ecological risk screening (risk assessment that can be completed in several hours), so we will not calculate many climate match scores. The reviewer recommended climate matching for other, smaller regions of the U.S., but did not recommend a standardized approach. The reviewer also recommended selection of a subjectively determined region, where climate match is all or mostly high, and then calculating the score for that region. The results of such an analysis will certainly result in a high score. Although we may, at the request of any entity, conduct an ERSS that includes climate match scoring for an ecosystem (e.g., Great Lakes basin), state, or any other region, we do not do that in our standard Ecological Risk Screening Summaries.

The reviewer is also considering that our only analysis and documentation of match is to provide the statistically-based climate match category. That is not correct. Instead we provide the map that clearly shows Climate 6 scores for the contiguous U.S., so risk

assessors and risk managers can evaluate the climate match for any geographic construct in the contiguous U.S.

Additionally, we interpret what parts of the U.S. have high climate matches (see online ERSS examples - http://www.fws.gov/injuriouswildlife/Injurious_prevention.html). The analysis, interpretation, and synthesis results in understanding whether high climate match is restricted to only limited areas (i.e., only within a single state), or much greater areas (locations that include at least parts of several states, or among states). Thus, we account for climate match on all scales. As a final summary – the score is, by default, demonstrating the climate match to most of the U.S. – we need a default scoring system that addresses climate match on a national scale. When necessary, climate matches can be run at various scales for a particular area of interest such as an individual state or region of the U.S., or the entire U.S. (including territories). Sometimes, when providing ERSS materials to our continental neighbors, we match climate with all of North America. Regardless of the geographic level, the spatial information is helpful, along with the scores depicted, in supporting decisions on which, if any, risk management approaches are proposed for implementation in any region of the U.S.

Comment 67 – Two similar comments –

● [Page 14] - *A second exception is a component of the scoring for History of Invasiveness (p 14, bottom of page). The meaning of the brackets around ". . .[10 or more] years . . ." is unclear. Furthermore the choice of 10 or any other number requires explanation and justification. Apparent lag times between introduction and establishment (or between the first introduction and establishment), and lag times between establishment and spread or impact have often been much longer than 10 years for a variety of taxa, including fishes (e.g., Costello et al. 2007 and citations therein)*. The same issue recurs under Overall Risk Assessment Category (p 15). No citations for these decisions are provided, and they are very important decisions.*

**Costello, C., J.M. Drake, and D.M. Lodge. 2007. Evaluating an Invasive Species Policy: Ballast Water Exchange in the Great Lakes. Ecological Applications, 17(3), 2007, pp. 655–662.*

● [Page 15] - *"(e.g., a million specimens) for substantial time [10 or more years] – this seems way too subjective. At the very least, you should exclude trade provision because it is related to introduction not impact.*

FWS Response: Regarding the frames of reference (10 years, a million species), if a mathematical model was developed (tested and validated), using 10 years of data and a million specimens, we would consider that a tenable tool. Concordantly, we consider a qualitative review of data, by a trained risk assessor, that includes evaluation during a decade or more, and a million specimens, as tenable.

The bracketed materials provide our frame of reference, not a specified period. Risk screenings are conducted, by trained risk assessors, using a combination of data, models (including climate matching), qualitative information, and risk assessor structured,

expert judgment. We standardized our approach as much as possible, but, in the end, our screenings are not completely quantitative and formulaic (although we will continue to strive for quantifying the SOP as much as tenable science allows). Trained risk assessors use guidance provided in the SOP, including the bracketed frames of reference, and decide on Overall Risk Assessment categories using History of Invasiveness, Climate Match, and the quantity and quality of the information available. One point that may not be clearly apparent is that we include our Certainty of Assessment as part of the Risk Assessment section in the ERSS. Thus any reviewer of our ERSSs can view the Overall Risk Assessment categorization along with the Certainty of Assessment—those categories are important to be viewed together, which is why they are included together in the Risk Assessment section of the ERSS.

Risk assessments conducted in the past, by other countries, states, and the U.S. Fish and Wildlife Service have used, in part, some form of structured, expert judgment. Our review of literature, and monitoring of scientific risk assessment tools being developed and tested, demonstrates that screening will need to include all the information we have (data, models, qualitative information). That information will need to continue to be judged, in a structured, standardized approach, by a trained risk assessor. If, at some time in the future, scientific advancement provides us with a totally quantitative approach (and does not require expert judgment) that is tested, validated, and accurate, then we will use that approach. Until that time, structured, expert judgment will remain a tenant in our screening process.

Regarding the exclusion of a trade provision, we are conducting rapid screening. We do not have access to trade data, and acquiring that data typically has taken years. Therefore, we continue to request from industries information on the volumes of organisms in trade that we can use to develop and update our draft ERSSs. But because acquiring that data is taking years, we will continue to use the data available to conduct risk screening. In the rare cases that we are provided with trade data, we intend to use it in our ERSS.

Once the ERSS's are complete, the Service will post them online (http://www.fws.gov/injuriouswildlife/Injurious_prevention.html) where industry and others can provide trade data and other comments through our public comment process. The agency has also recently entered into an invasive species "voluntary risk management" MOU with the Association of Fish and Wildlife Agencies, Pet Industry Joint Advisory Committee, and others where the agency's role is providing the results of risk screening to the parties. The MOU acknowledges and welcomes parties bringing forward the results of their risk screening and risk assessment approaches as well.

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