

Ecological Risk Assessment Final Peer Review Report and Lead Agency Response

Report Content and Charge:

This report describes the peer review process used for the Ecological Risk Assessment (ERA) and presents the lead agencies' response to the peer review. Also included are the names of the peer reviewers and their organizational affiliations, a compilation of all the peer review comments on the (ERA), and the principal investigators' responses to the peer review comments.

The ERA was developed as a supporting document for the Programmatic Environmental Impact Statement (EIS) for Oyster Restoration in Chesapeake Bay, Including the Use of a Native and/or Non-Native Oyster. The process followed for the ERA peer review is consistent with the peer review plan that was developed by the Lead Agencies for the EIS project. This peer review plan was specifically designed to comply with the December 16, 2005 Office of Management and Budget's Peer Review Guidelines and was accepted by the US Army Corps of Engineers for this purpose.

The peer review plan designated the Ecological Risk Assessment Advisory Group (ERAAG) as the principal group for the peer review of the ERA. The ERAAG was made up of risk assessment specialists from each of the lead and cooperating Federal agencies.

Study Objective: The objective of the ERA is to evaluate the potential ecological risks and benefits associated with the proposed action and alternative actions specified in the EIS in a manner that is consistent with the ecological risk assessment guidelines of the Environmental Protection Agency. The results of the ERA provide the basis for the Environmental Consequences section of the EIS.

The Lead Agencies Review and Response Process:

The chronology of the peer review process is presented as follows:

- 2004–2008 -- ERAAG participated in occasional technical discussions with the ERA Principal Investigators and others to provide technical input on issues germane to scoping the risk assessment.
- December 2007 and January 2008 -- ERAAG prepared and distributed brief comments on preliminary drafts of sections of the ERA.
- February 2008 -- ERAAG performed a line-by-line technical review of the ERA.
- March 2008 -- ERA Principal Investigators provided the ERAAG with a revised ERA and a document summarizing the Principal Investigator's responses to the ERAAG's comments made on the previous draft.
- April 2008 -- ERAAG provided consensus peer review comments on the revised ERA.
- May 2008 -- Principal Investigators responded to the April peer review comments and provided a revised ERA to the ERAAG.
- June 2008 -- ERAAG prepared a consensus peer review report on the latest version of the ERA. The ERAAG was in agreement that the revised ERA was sufficiently developed to be a source of information to the Programmatic EIS.

- August 2008 -- Principal Investigators prepared a final response to the consensus peer review report on August 8, 2008.

The Lead Agencies are satisfied that the key concerns raised by the ERAAG during review of the ERA have been addressed.

The remainder of this report presents the ERAAG consensus review comments and the Principle Investigator's responses, beginning with the April 2008 phase of the peer review.

Deposition of Peer Review:

Dr. Todd Bridges

US Army Corps of Engineers
Vicksburg, Mississippi

Mr. Chris Guy

US Fish & Wildlife Service

Mr. Simeon Hahn

National Oceanographic and Atmospheric Administration

Ms. Barbara Okorn

U.S. Environmental Protection Agency
Region 3, Philadelphia, Pennsylvania

ERAAG - Fourth Phase Review: Consensus Peer Review Statement (April 15, 2008)

BACKGROUND AND PROCESS

This document represents the consensus findings of a peer review performed by the Ecological Risk Assessment Advisory Group (ERAAG) at the request of the Non-native Oyster EIS Project Delivery Team (PDT).

The members of the ERAAG are:

Dr. Todd S. Bridges, U.S. Army Engineer Research and Development Center
Mr. Chris Guy, U.S. Fish and Wildlife Service
Mr. Simeon Hahn, National Oceanic and Atmospheric Administration
Ms. Barbara Okorn, U.S. Environmental Protection Agency

Dr. Todd Bridges chaired this peer-review effort at the request of the PDT.

The peer review was conducted in four phases. During the first phase, the ERAAG participated, at the request of the PDT, in occasional technical discussions (over a period of about 5 years) with the team conducting the ecological risk assessment (ERA). The purpose of these discussions was to provide opportunity for the ERA team to seek technical input from the ERAAG on issues germane to scoping the risk assessment. The second phase occurred during the latter half of December 2007 and early January 2008, when the ERAAG was asked to provide brief comments on preliminary drafts of sections of the ERA. The third phase of the peer review was completed during February 2008. In this third phase of review the ERAAG was asked to perform a line-by-line technical review of the following materials:

- Final Draft Ecological Risk Assessment for Oyster Restoration Alternatives, dated 13 February 2008
- Attachment A: Modeled Relationships Between Oyster Biomass, Water Quality, And Ecological Responses
- Attachment B: Review of Temporal Trends in Abundance For Select Biota In Chesapeake Bay
- Attachment C: Draft Escapement Table

The ERAAG provided a consensus peer review of these documents in a report entitled “Consensus Peer Review Statement for the Ecological Risk Assessment for Oyster Restoration Alternatives.” This report was delivered to the PDT on 21 February, 2008. The Fourth phase of the peer review was initiated on 21 March, 2008, when the ERAAG was provided with a revised ERA along with a document summarizing the ERA team’s responses to the ERAAG’s comments made on the previous draft of the ERA. The ERAAG reviewed the response to comments document and categorized the ERA teams’ responses using the following descriptions:

- A) Comment appears to be adequately addressed based on information provided
- B) More information is required to determine if the comment has been adequately addressed
- C) Comment appears to have NOT been adequately addressed based on information provided

This information was sent by the ERAAG to the PDT on 27 March, 2008. The intent of this effort was to provide an opportunity for the ERA team to provide additional information to the ERAAG about the how the ERAAG's comments were addressed in the revised ERA. On 3 April, 2008 the PDT provided the ERAAG with supplementary response information prepared by the ERA team.

As a part of this fourth phase of the peer review, the ERAAG has developed responses to each of the 6 questions comprising the peer review charge to the ERAAG. This fourth phase of review primarily considers the ERAAG's line-by-line review of the February draft ERA as well as the information contained in the two response-to-comments documents that were prepared by the ERA team and provided to the ERAAG by the PDT. In conducting this fourth phase of review, the ERAAG did consult portions of the 21 March version of the ERA; however the ERAAG did not perform a line-by-line review of the 21 March draft. The ERAAG reached one of three conclusions regarding each response to its 86 comments:

- A) Response satisfies the ERAAG's concern
- B) Insufficient information was provided for the ERAAG to determine whether the source of concern was addressed or corrected
- C) Response does not satisfy the ERAAG's concern

A summary of these scores is provided in the accompanying spreadsheet (named "ERAAG response to 2nd response integrated").

The PDT provided a peer-review charge to the ERAAG in the form of the following 6 questions:

1. Are the conclusions adequately supported by evidence, analysis and argument?
2. Are uncertainties or incompleteness in the evidence explicitly recognized?
3. If any conclusions are based on value judgments, is this acknowledged and are adequate reasons given for reaching these judgments?
4. Are the data and analyses adequately described and well-suited to address the questions being investigated?
5. Are statistical methods applied appropriately?
6. Is the report fair and impartial in tone?

Below, the ERAAG provides responses for each of these questions. The following responses do not repeat comments that are still germane.

THE SUBJECT OF THE PEER REVIEW

An Ecological Risk Assessment (ERA) was commissioned by the PDT in order to evaluate potential ecological risks associated with implementing the proposed action, or any of the alternative actions, specified in the Programmatic Environmental Impact Statement (PEIS) for Oyster Restoration in Chesapeake Bay. The proposed action is to establish a naturalized, reproducing, and self-sustaining population of an Asian species, *Crassostrea ariakensis*, in the tidal waters of Maryland and Virginia through introductions beginning after the PEIS is completed while continuing efforts to increase the numbers of the native oyster, *Crassostrea virginica*, using best available restoration strategies and stock assessment techniques.

The ERA will be used to inform the development of a Programmatic Environmental Impact Statement (PEIS).

The alternatives being considered are:

Alternative 1 – No Action--Not taking the proposed action: Continue Maryland's present Oyster Restoration and Repletion Programs, and Virginia's Oyster Restoration Program under current program and resource management policies and available funding using the best available restoration strategies and stock assessment techniques.

Alternative 2 – Expand Native Oyster Restoration Program: Expand, improve, and accelerate Maryland's Oyster Restoration and Repletion Programs, and Virginia's Oyster Restoration Program in collaboration with Federal and private partners. This work would include but would not be limited to an assessment of cultch limitations and long-term solutions for this problem, and the development, production, and deployment of large quantities of disease resistant strain(s) of *C. virginica* (Eastern oyster) for broodstock enhancement.

Alternative 3 – Harvest Moratorium: Implement a temporary harvest moratorium on native oysters and an oyster industry compensation (buy-out) program in Maryland and Virginia or a program that offers displaced oystermen on-water work in a restoration program.

Alternative 4 – Aquaculture: Establish and/or expand State-assisted, managed, or regulated aquaculture operations in Maryland and Virginia using the native oyster species.

Alternative 5 – Aquaculture: Establish State-assisted, managed, or regulated aquaculture operations in Maryland and Virginia using suitable triploid, non-native oyster species.

Alternative 6 – Introduce and Propagate an Alternative Oyster Species (Other than *C. ariakensis*) or an Alternative Strain of *C. ariakensis*: Introduce and propagate in the State-sponsored, managed, or regulated oyster restoration programs in Maryland and Virginia, a disease resistant oyster species other than *C. ariakensis*, or an alternative strain of *C. ariakensis* from waters outside the U.S. in accordance with the ICES 2003 Code of Practices on the Introductions and Transfers of Marine Organisms.

Alternative 7 – Establish a naturalized, reproducing, and self-sustaining population of *C. ariakensis* in the tidal waters of Maryland and Virginia through introductions beginning in 2005 (or when the EIS is completed) but discontinue efforts to restore *C. virginica*.

Alternative 8 – Combination of Alternatives

The context for the ERA includes the potential that alternatives will meet certain goals. The primary goal is the restoration of oysters to a specified level. Additional ecological goals or expectations associated with restoring oysters include an improvement in overall water quality (e.g., increased dissolved oxygen) and the enhancement of overall ecological services. An implied goal that relates to the consideration of risks is that these positive outcomes would not result in unacceptable risks.

The ERA considers two primary risk questions:

1. How will the proposed action or alternatives affect an oyster population (native introduced, or both) in Chesapeake Bay?
2. How will the proposed action or alternatives affect the ecology of Chesapeake Bay and areas outside the Bay including the broader mid-Atlantic region? The latter portion of this question was addressed only for alternatives involving a non-native species of oyster.

The ERA also addresses five risk-related questions related to successfully naturalizing *C. ariakensis* in Chesapeake Bay:

1. What is the potential for introduction and spread of diseases to other species in the Bay? This does not include human health considerations, which are addressed elsewhere in the EIS.
2. Will *C. ariakensis* compete with *C. virginica* and other resident species, possibly leading to reduced populations or local extinction of these species?
3. Will *C. ariakensis* provide ecosystem services similar to those afforded by *C. virginica*?

4. Will *C. ariakensis* become an invasive or nuisance species?
5. Will *C. ariakensis* disperse to areas outside of Chesapeake Bay (NRC 2004) and pose the kinds of risks identified above?

PEER REVIEW COMMENTS

Overall Assessment: The ERAAG submitted 86 comments on the February draft of the ERA. Significant improvements have been made in the ERA in the March draft. Of the 86 comments made by the ERAAG on the February draft of the ERA, 33 have been addressed in a manner that satisfies the ERAAG's motivating concern, in 9 cases insufficient information was provided to determine whether the ERAAG's comments have been addressed, and for 44 of the comments the response provided did not satisfy the ERAAG's concern. It is the judgment of the ERAAG that further modifications to the ERA will be required to address the technical issues identified in ERAAG comments in order to support use of the ERA as an aid to decision-making. A repetition of all 53 ERAAG comments that have yet to be resolved was not made in the responses presented below. Therefore, the ERAAG considers its complete response to the peer review charge to include both the previous (phase 3) and current report (phase 4).

Charge Questions

1. Are the conclusions adequately supported by evidence, analysis and argument?

Response: The documents provided to the ERAAG for peer review included a large amount of information germane to assessing the potential impacts associated with the decision alternatives. However, the ERA lacks sufficient transparency, specificity and resolution regarding the presentation of evidence, specific choices made by the assessment team in developing that evidence, and the conclusions reached by the assessment. Therefore, our judgment is that the presentation of evidence does not adequately support the conclusions reached by the assessment. Given the fact that a decision to implement the proposed alternative is irrevocable, the evidence supporting the decision must be strongly established.

- *In order for the ERA to serve the decision-making process, the information contained in the ERA must be presented in a transparent fashion, i.e., that the assumptions, logic, approaches used to develop inputs for assembling evidence, and the conclusions reached by the assessment, are discussed in sufficient detail that they can be subjected to challenge. The ERA falls short of providing sufficient transparency.*
- *The ERA should provide an integration of the all the evidence on risks and benefits and present this evidence as a comparison and ranking of alternatives in terms of cumulative risks and benefits.*

- *Additional clarity and transparency is needed regarding the description and application of the Relative Risk Model, including the development and assignment of association factors. A listing of key assumptions relevant to the application of the RRM should be made, including a discussion of the implications of those assumptions as sources of uncertainty in the assessment.*
- *The ERA's focus on risks within a 10-yr time horizon limits the use of the assessment to support decision-making. This constraint on the assessment has not been adequately explained or justified, nor have the implications of this constraint been adequately discussed in relation to the conclusions reached by the assessment.*
- *The conclusion that there is a low probability that *C. ariakensis* would colonize substrates other than hard bottom is not sufficiently supported by the evidence presented in the ERA.*
- *The distinction between such terms as influence, effect, impact, change, and risk that the ERA attempts to make is unclear and confusing. The relationships among these overlapping concepts and how the evidence provided can be used to reach conclusions about relative differences in the magnitude or risks among decision alternatives (which the ERA must establish in order to support informed decision-making) is not sufficiently established.*

2. Are uncertainties or incompleteness in the evidence explicitly recognized?

Response: The assessment does recognize uncertainties and incompleteness in regards to the evidence presented. The ERA discusses sources of uncertainty and provides estimates for uncertainty associated with conclusions. However, the current narrative does not adequately present or describe the implications of key uncertainties for decision-making.

- *Uncertainties resulting from the 10-yr timeframe considered in the ERA require additional consideration and description within the ERA.*
- *The information on uncertainty that is discussed in the assessment is not presented in a fashion that is conducive to it being considered and incorporated into a comparison of alternatives in support of decision-making.*

3. If any conclusions are based on value judgments, is this acknowledged and are adequate reasons given for reaching these judgments?

Response: The assessment is not consistent with how it deals with value judgments. Some consequences addressed within the assessment are clearly accepted as being adverse or beneficial; in other cases the assessment attempts to avoid categorizing

consequences as adverse or beneficial. This fact makes it difficult to develop or evaluate overall conclusions about risks and benefits to compare the decision alternatives.

4. Are the data and analyses adequately described and well-suited to address the questions being investigated?

Response: The ERA presents a large amount of information concerning methods, data and analysis in a relatively concise manner. However, in several cases the amount of information provided did not provide an adequate basis for developing a sufficient understanding of why specific methods were chosen and how the analyses were performed. This limits an informed reader's ability to make judgments about the soundness of the assessment.

- *Based on responses provided to the ERAAG, it seems that the intention is to defer some the key activities related to presentation, comparison, and discussion of risks related to the decision alternatives to the EIS, rather than to include these activities within the ERA. Therefore, these activities have been excluded from this peer review. The ERAAG recommends that, to the maximum extent practical, the ERA should present a comprehensive analysis and comparison of the decision alternatives in terms of ecological risks and benefits.*

5. Are statistical methods applied appropriately?

Response: The assessment does not substantively rely upon statistical methods in reaching its conclusions. In large part this is due to the lack of quantitative data germane to the specific questions/hypotheses being evaluated within the assessment.

- *The ERA should explore the implications of the uncertainty in data or estimates that are used as inputs for specific calculations or predictions in manner that reveals the implications of both under- and over-estimating the risks.*

6. Is the report fair and impartial in tone?

Response: The report contains no evidence of systematic bias in the presentation of results.

- *The absence of overall conclusions, based on a comparison and ranking of decision alternatives in terms of the cumulative ecological risks and benefits associated with those alternatives, limits a reader's ability to detect the presence*

of bias. Failure to present results as a comparison and ranking will introduce the potential for readers to reach uninformed conclusions.

- *It is not possible to evaluate the presence of bias in the selection of association factors because the discussion supporting the selection of each association factor lacks sufficient specificity.*
- *The text in section 4-2 does not support the conclusion that scientific consensus has been reached on the role of oyster in the ecosystem, as represented by the ERA authors.*

RECOMMENDATIONS REGARDING RECURRING COMMENTS

The ERA should provide a risk characterization that integrates the risks and benefits posed by each decision alternative in a manner that allows for comparing and ranking the alternatives in view of the full range of ecological consequences.

The uncertainties within the assessment should be evaluated in greater depth, including the implications of these uncertainties for decision-making.

Principal Investigators Response (May 30, 2008)

Roadmap for ERAAG Review of Second Revised ERA

In discussions during the ERAAG/MT/ERA Team meeting/call on May 12, Todd Bridges suggested that it would be useful to the reviewers if the Writing Team could direct them to revised text sections in which revisions were made in response to ERAAG comments. This document provides that guide. It is organized around the 85 ERAAG comments that were documented in the table entitled “Responses to the ERAAG’s Comments on the Final Draft ERA.” Comment numbers presented here correspond to the comment numbers in that table. In going through those comments, all agreed that many dealt with the same topic or issue. Thus, in preparing this guide, we have gone through the comments and grouped them according to topic to facilitate the review. In response to a suggestion by Todd (and addressing **Comments 38 and 69**), we made one major revision to the ERA. We reorganized all the text in all sections around eight clearly defined risk questions, five of which are the NRC questions relating to an introduction of *C. ariakensis*. Once we explored that idea, we found that it was a useful way of clarifying issues and outcomes, although it did require extensive text revisions to accomplish.

In the interest of time, we suggested to Todd at the May 12 meeting that he inform us (brichkus@versar.com, camenzie@exponent.com, cdelisle@versar.com) of any issues or concerns that arise as the ERAAG conducts their review. This may allow us to begin making revisions, corrections, etc. as the review is on-going rather than waiting until the ERAAG has completed its review. This procedure may be especially valuable in cases where the reviewers may not understand something and an explanation can be provided and text clarified.

General Summary Comments (1, 18, 33, 36, 51, 53) – These were general comments that summarized the ERAAG responses on the specific comments that followed each of them. We did not address them directly, assuming that if we were able to adequately address the detailed comments on which a general summary comment was based, that would, a priori, result in resolution of the general comment. If the ERAAG disagrees, let us know.

Comments on issues which the ERAAG concluded the ERA had addressed adequately (4, 5, 11, 13, 19, 21, 22, 24, 25, 27, 31, 32, 33, 37, 51, 52, 53, 56, 57, 59, 61, 62, 63a, 63b, 66, 73, 76, 77, 78, 80, 81, 83) – These were all comments for which the ERAAG concluded responses or revisions had addressed their concerns. We have not addressed those comments further, except to ensure that in the major text revision we did not inadvertently reverse or change something that was found to be already satisfactory.

Issues relating to the need to rank alternatives according to the degree of risk, whether this ERA is actually a comparative risk assessment, and whether the document should provide more guidance to decision makers (2, 34, 35, 60) – The

issues of whether the ERA is actually a risk assessment or simply an impact assessment, whether it should provide some type of ranking of the alternatives according to level of risk and whether it was a comparative risk assessment or simply a presentation of individual risk assessments of eight possible actions (or actually six) was discussed at length by the Management Team, Col. Anninos and the ERAAG at the May 12 meeting/call. Col. Anninos clarified that the intent was to have the ERA **not** provide a ranking of alternatives but only to provide information on risk/benefit outcomes of each of the actions reviewed. Those findings would be incorporated into the draft PEIS and be the basis for obtaining stakeholder input on the pros and cons of the different alternatives. Todd accepted that direction and indicated it should be stated at the beginning of the ERA so readers may not be misled on what to expect from the document. We inserted clarifying text in the Executive Summary (pg ES-2, second full paragraph) and in ERA Section 1 (pg. 1-3, second paragraph) intended to address these issues and explain that this is an atypical ERA and also not a comparative risk assessment.

Concerns regarding 10-year assessment period (8, 29, 41, 79) – A number of ERAAG comments related to limiting the assessment to a period of 10 years. That issue has been a source of confusion for a number of reviewers. We provided in the revision an explanation for why the ODM was limited to a 10 year projection of oyster abundance/biomass (Section 3, pg. 3-1, first full paragraph; Section 4.7.2, fourth paragraph). We also added some discussion of likely population trajectories after 10 years for each of the alternatives and the reasoning behind those trajectories (e.g., Section 4.1.1, next to last paragraph; Section 4.1.2, paragraphs 2, 4 and 6). We also made clear that the narratives addressing the five NRC questions had no specific time frame, since they a priori assumed that *C. ariakensis* was established and abundant in the Bay, which we considered a conservative assumption (i.e., a worst case since those questions specified outcomes considered undesirable) (Executive Summary, pg. ES-3; Section 3, page 3-2, second paragraph).

Issues relating to the RRM, association factors, RRM scores, etc. (6, 9, 10, 42, 43, 44, 45, 46, 47, 67, 71) - All of these comments related to the description and application of the RRM. In order to address them comprehensively, Charlie Menzie revised the RRM approach and provided that revision to Todd Bridges; Todd provided comments back to Charlie and additional revisions were made. The final revised RRM description is presented in Section 3.4; it would be advisable to read all of that section to see if all questions have been adequately addressed. A number of the questions related to use of the CBEMP in the RRM. Further explanation is presented in Section 3.4.2 and in the introductory text of Attachment A.

Comment 3 (range of outcomes) – We created the table in the Executive Summary (Table ES-1, pg ES-17) that provides a summary of risk and associated uncertainty for the proposed action and the alternatives for the eight risk questions to address this comment. While the table only provides the summary, the details supporting the summary are presented throughout Section 4 of the ERA.

Comments 7 and 40 (triploid to diploid model as a framework and approach) – In an earlier version, we had referred to the approach taken in addressing the risk of triploid aquaculture resulting in a diploid introduction as a “framework.” That language was subsequently deleted. In Section 3.3 (first three pages), we describe the approach taken to address that specific risk question and clarified that APHIS was a process used to develop the analysis approach. In Section 4.3 we present the analyses conducted to implement the approach. At the end of Section 4.3 (third and fourth from last paragraphs), we list the factors that could make the overall probability low and the factors that could make the overall probability high, and in the next to last paragraph acknowledge that some stakeholders believe it is a certainty, but point out that no one else has attempted to calculate a probability.

Comments 12, 72 and 82 (effects of oysters on the Bay ecosystem) – These comments were initially directed toward a discussion and appendix in which long term trends in various Bay species were evaluated relative to long term trends in oysters, and to some extent also directed at some aspects of the RRM. That section and the appendix were subsequently deleted, but a new section was included that presented findings of research relating oyster abundance to Bay water quality (old Section 4.2). There remained a concern that this discussion of effects on water quality suggested that oysters were of no significance. That discussion of research remains (now Section 4.5) because the intent is to show that the regression analyses of CBEMP data used in the RRM are reasonable, in that effects on the scale of the large state/salinity zones which have been used in the ERA and PEIS are likely to be small, but that effects on smaller scale, such as individual tributaries, might be much greater but were not analyzed. See the last two paragraphs of Section 4.5 for details.

Comment 14 (pathogens evolving ability to infect ariakensis) – We included this issue in the last paragraph of Section 4.2.3 and pointed out that such a phenomenon has never been reported in the literature. That appeared to us to be the best way of addressing it.

Comments 15, 30 and 55 (outline a range of outcomes of competition) – We understood this concern to relate to the fact that with regard to interactions between *C. ariakensis* and *C. virginica*, coexistence could range from local extinction of *virginica*, to mixed reefs, to dominance by one or the other species in various geographical locations. We added a description of that range of potential outcomes in the Executive Summary (pg. ES-9, first paragraph; Section 4.2.2, third to last paragraph) and indicated it was an indication of the uncertainty of outcomes.

Comments 16 and 68 (personal communications) - We have acknowledged this comment and have developed a means of addressing it but could not do it in the timeframe for this revision of the ERA. What we will do is to distinguish personal communications that represent researchers comments on their own work that has been published and personal communications that represent their view, interpretation or opinion on others’ work or some unpublished result. We will probably do this by using an asterisk or something like that. We also did not complete the peer review status of NOAA research table. While this will still be done, we have attempted to capture the

consequence of conclusions based on limited findings or professional opinions in describing the level of and basis for uncertainty associated with conclusions.

Comments 17 and 48(CBEMP and Appendix A) – The summary description of the CBEMP in Attachment A was expanded. A description of the peer review of the model was also added. The explanation for the “counter intuitive” results was presented in the text and how analyses were adjusted to account for data limitations is described (Sect. 3.4.2 and Attachment A introduction)

Comments 20 (trophic cascades) and 23 (sources of uncertainty and implications) – We edited Section 4.7 extensively to eliminate redundancy (Section 4.7). The discussion of uncertainty associated with the simplified approach to ecosystem analysis employed in the ERA was expanded. We also added some observations on implications (e.g., introduction of *ariakensis* would be irreversible).

Comment 26 (ODM uncertainty) – We expanded the discussion of the ODM and the OAP’s concerns about it in Section 3.1 (second and third paragraphs), which clarifies uncertainties. Also, in the first paragraph of Section 4, we explain how the OAP’s concerns about the model have been taken into account in the manner in which it is used in the ERA.

Comments 28, 49, 54, 84 and 85 (probability of diploids from triploids) – In response to the ERAAG comments, we revised the discussion of the probabilities substantially and clearly explained that the probabilities would continue to increase over time (Section 4.3, first paragraph and the last four paragraphs). We changed the characterization of the risk from low. However, we found ourselves unable to establish a risk category and simply listed factors that would make the risk high and those that would make it low, and indicated the uncertainty associated with that risk was high.

Comment 39 (why ODM results not used in CBEMP) – This is explained in Section 3.4.2, first paragraph.

Comment 50 (negligible) – We standardized and defined the terms for risk and uncertainty in the executive summary (pgs ES4-5) and in Section 1 (pg. 1-6); applicability of negligible is evident in the text where it is used (e.g., Table ES-1).

Comments 64 and 75 (map of salinity zones and oysters) – The map was added as Figure 3-1 in Section 3.

Comment 65 (citations) – Citations of sources have been added throughout, particularly in Section 2.

Comment 70 (was APHIS approach peer reviewed) – A sentence was added to the last paragraph of section 3.3.

Comment 74 (monitoring) – The list of studies and monitoring in Section 4.7.7 presented as means of reducing risk was expanded to include important studies of the native oyster.

ERAAG – Fifth Phase Review: Consensus Peer Review Statement for the Ecological Risk Assessment for Oyster Restoration Alternatives (June, 20 2008)

BACKGROUND AND PROCESS

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THE SUBJECT OF THE PEER REVIEW

An Ecological Risk Assessment (ERA) was commissioned by the PDT in order to evaluate potential ecological risks associated with implementing the proposed action, or any of the alternative actions, specified in the Programmatic Environmental Impact Statement (PEIS) for Oyster Restoration in Chesapeake Bay. The proposed action is to establish a naturalized, reproducing, and self-sustaining population of an Asian species, *Crassostrea ariakensis*, in the tidal waters of Maryland and Virginia through introductions beginning after the PEIS is completed while continuing efforts to increase the numbers of the native oyster, *Crassostrea virginica*, using best available restoration strategies and stock assessment techniques.

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ERAAG PEER REVIEW

The members of the ERAAG are:

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Ms. Barbara Okorn, U.S. Environmental Protection Agency

Dr. Todd Bridges chaired this peer-review effort at the request of the PDT.

The peer review was conducted in five phases. During the first phase, the ERAAG participated, at the request of the PDT, in occasional technical discussions (over a period of about 5 years) with the team conducting the ecological risk assessment (ERA). The purpose of these discussions was to provide opportunity for the ERA team to seek technical input from the ERAAG on issues germane to scoping the risk assessment. The second phase occurred during the latter half of December 2007 and early January 2008,

when the ERAAG was asked to provide brief comments on preliminary drafts of sections of the ERA.

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- A) Comment appears to be adequately addressed based on information provided
- B) More information is required to determine if the comment has been adequately addressed
- C) Comment appears to have NOT been adequately addressed based on information provided

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- A) Response satisfies the ERAAG's concern

- B) Insufficient information was provided for the ERAAG to determine whether the source of concern was addressed or corrected
- C) Response does not satisfy the ERAAG's concern

On 12 May, 2008 the ERAAG met with the ERA writing team and members of the PDT in Richmond, VA to discuss comments and to formulate a path forward for the next revision to the ERA report. A revised version of the ERA report was provided to the ERAAG on 30 May 2008. The ERAAG was asked by the PDT to review the revised sections of the report, using the guide prepared by the ERA team which identifies sections of the report that were modified in response to the ERAAG's comments. The PDT charged the ERAAG to provide a review in the form of responses to the following 6 questions:

1. Are the conclusions adequately supported by evidence, analysis and argument?
2. Are uncertainties or incompleteness in the evidence explicitly recognized?
3. If any conclusions are based on value judgments, is this acknowledged and are adequate reasons given for reaching these judgments?
4. Are the data and analyses adequately described and well-suited to address the questions being investigated?
5. Are statistical methods applied appropriately?
6. Is the report fair and impartial in tone?

ERAAG RESPONSES TO CHARGE QUESTIONS AND SPECIFIC COMMENTS

Overall Response: Over the last 6 months, the ERAAG has reviewed and commented on more than 4 drafts of the ERA, or portions of the ERA. Over this period, the ERA has undergone significant revision, resulting in substantial improvements. After the ERA team addresses the comments contained within this final phase of the peer review, the ERAAG is confident that the ERA will be sufficiently developed and described such that it will provide a necessary source of information to the PEIS.

Charge Questions

1. Are the conclusions adequately supported by evidence, analysis and argument?

Response: The ERA presents estimates of the ecological risks posed by each of the alternatives with respect to eight risk questions. The ERA stops short of comparing the alternatives by estimating the cumulative risk across all of the risk questions and pathways in order to rank the alternatives in terms of overall risk. The ERA presents conclusions only in terms of responses to individual risk questions and alternatives and presents no overall conclusions. The text of the ERA implies that the integration necessary to present overall conclusions will be performed within the PEIS. The ERA does not discuss how information and evidence will be integrated in order to compare and rank alternatives in terms of risk. However, we wish to emphasize how critical the

integration step, and the approaches used to accomplish it, will be to developing conclusions and understanding regarding overall ecological risks associated with the alternatives. This step must be accomplished before information about ecological risks can be used along side estimates of benefit to support decision-making that leads to the selection of an alternative, or combination of alternatives.

The documents provided to the ERAAG for peer review included a large amount of information germane to assessing the potential impacts associated with the decision alternatives. In order for the ERA to serve the decision-making process, the information contained in an ERA must be presented in a transparent fashion, i.e., that the assumptions, logic, approaches used to develop inputs for assembling evidence, and the conclusions reached by the assessment, are discussed in sufficient detail that they can be subjected to challenge. Improvements made through successive revisions of the ERA report will produce an analysis that is sufficiently transparent and specific in its presentation of evidence that readers of the report will be able to reach informed decisions about the soundness of the analysis and the conclusions that are reached, once this final round of peer review is completed and the document is finalized. The conclusions reached by the analysis are generally supported by presentation of the analysis when considered in combination with qualifications related to uncertainties associated with data and evidence (except where noted in this review).

2. Are uncertainties or incompleteness in the evidence explicitly recognized?

Response: The assessment does recognize uncertainties and incompleteness in regards to the evidence presented. The ERA discusses sources of uncertainty and provides estimates for uncertainty associated with conclusions.

We recommend that the risk definitions for low, moderate, and high risk be clarified. The current definitions of low and high include multiple conditions. For example, a risk is considered low if either one of two conditions is met: the likelihood that the condition is considered low or the magnitude of the impact is considered low. We recommend keeping the magnitude of the impact, its likelihood and the description of uncertainty as distinct variables. In this way, the ERA would present the best estimate of the condition as a low, moderate, or high probability of a low, moderate or high impact, giving 9 possible combinations. The level of uncertainty associated with the risk estimate would be classified as either low, moderate or high.

3. If any conclusions are based on value judgments, is this acknowledged and are adequate reasons given for reaching these judgments?

Response: The ERAAG recognizes that all risk assessments involve making decisions and developing conclusions that at some level involve the values of those contributing to the analysis. It is not possible to conduct a value-free risk assessment. The selection of assessment endpoints, formulating conclusions in the face of uncertainties, as well as other key elements of a risk assessment require judgments that involve the values of the

analysts. This being said, the ERA contains sufficient transparency related to the rationale for the judgments made within the assessment.

4. Are the data and analyses adequately described and well-suited to address the questions being investigated?

Response: The ERA presents a large amount of information concerning methods, data and analysis in a relatively concise manner. The scope of the risk assessment is large and varied, as reflected in the range of issues contained within the risk questions posed by the analysis. The scope of the assessment required the use of a range of approaches for developing lines of evidence to support conclusions about risks and benefits. Overall, the methods and analyses used in performing this assessment are germane to the questions posed and these approaches have been described in sufficient detail for readers to understand how the assessment was conducted and what the limitations of the assessment are. If the recommendations made within the assessment regarding ways for reducing uncertainties associated with the conclusions are acted upon, the availability of new information would likely lead to opportunities for drawing upon other methods and means of analysis that would serve to strengthen the overall assessment and its conclusions. It would be appropriate and expedient to incorporate such follow-on activities as a part of an overall adaptive management strategy, the goal of which would be to provide a practical mechanism for managing both the risks and uncertainties associated with the management actions taken. Structured monitoring activities that track the consequences associated with implementing alternative(s) will be an essential component of such risk management.

The presentation of RRM scores as stacked bar graphs will likely lead to misinterpretation and erroneous conclusions about influences and risks, i.e., that the sum of individual RRM values for the separate assessment endpoints could be viewed as a cumulative risk score. It was explained to the ERAAG by the ERA team that the summation of individual RRM scores has no meaning, which is the reason why the negative RRM scores are not subtracted from the total positive scores to present an overall RRM score. However, the text does not appear to contain a caution against interpreting the plots as cumulative scores. We recommend that the ERA present the RRM results in a clearer and more neutral fashion by plotting the RRM scale from -5 to +5 on the y-axis and the risk score for each assessment endpoint as a separate bar on the x-axis. Alternatively, presentation of RRM results in tabular form, as in Tables 4.4 to 4.7, represents a clear and neutral presentation.

5. Are statistical methods applied appropriately?

Response: The assessment does not substantively rely upon statistical methods in reaching its conclusions. In large part this is due to the lack of quantitative data germane to the specific questions/hypotheses being evaluated within the assessment. The ERA does present statistical results of modeling using the ODM and CBEMP; however, the ERAAG did not review these modeling efforts as these models have been subjected to other review activities.

*However, the presentation and use of the demographic modeling poses a problem that should be addressed prior to finalizing the ERA report. The results of the demographic modeling that are emphasized, and presented graphically, in section 4.1.1 are the abundances associated with the 50th and 95th percentiles, i.e., the upper portion of the results distribution. While reference is made within the text to results associated with the 5th percentile, which has a probability of occurring that is equal to the 95th percentile values, these results are not presented graphically. We also note that only results associated with the 50th and 95th percentile are considered when calculating the scores using the relative risk model. Evaluating risks with the RRM using only the upper portion of the predicted abundance distribution will result in over-estimating the occurrence and magnitude of negative and positive influences. Given that the RRM results include a greater number of small positive influences than small negative influences, using only the upper portion of the abundance distribution leads to overestimating the potential for an overall positive influence of introducing *C. ariakensis*.*

This issue could be addressed by giving greater emphasis to the lower portion of the predicted abundance distribution within the risk assessment and qualifying the interpretation of the RRM results based on the 50th and 95th percentile results.

6. Is the report fair and impartial in tone?

Response: The report is generally fair and impartial in tone. Addressing the issues raised within this review will serve the important goal of eliminating opportunities for data to be misinterpreted by readers and decision makers. The ERAAG believes that the recommendations offered within this review will also help readers of the report, including decision-makers, give appropriate consideration to the uncertainties associated with the conclusions reached within the ERA.

Other specific comments related to the peer-review charge questions:

1. Page 4-12 states that *C. ariakensis* are naturally found on soft bottoms with high sediment loads, less likely to grow in high densities compared to the native oyster, and do not produce as much vertical relief as the native. It also states that biomass will decrease in both species when competing for space. These facts don't seem to be carried through the assessment to the degree that facts such as faster growth rates and greater disease resistance in *C. ariakensis* are. For example, it would seem that if they can grow on soft bottoms (with some scattered debris) and they don't grow in high densities (and are therefore more difficult to manage through harvesting) that they may become "invasive".
2. Page 4-27 concludes that the two oyster species can coexist. The ERA should include some discussion of the implications of inter-specific competition on the results of the ODM and future projections about oyster abundance and biomass.
3. The ERA contains some contradictory statements of evidence that should be clarified. Specifically, page 4-16 states that infected *C. ariakensis* can transmit *P. marinus* to *C. virginica* in aquaculture settings. Most of the other discussion about disease states that there is a low probability of spreading disease. Page 4-27 states

- that *C. ariakensis*' movement into polyhaline waters might be limited because of its susceptibility to *Bonamia*. Page 4-31 states that Guo noted "...given this broad range, diseases might not be a permanent obstacle to long distance dispersal."
4. One of the risks considered by the ERA is that *C. ariakensis* would not provide ecosystem services similar to those afforded by *C. virginica*. The assessment concludes that this risk is low. Low is defined as "either the chance that the outcome will occur is very small, or the magnitude of the outcome is expected to be small and perhaps undetectable." A more supportable conclusion, based on the evidence provided, is that this risk is moderate, i.e., "an outcome is possible". Ecological services considered in this ERA are those associated with provision of reef habitat for other Bay species, provision of food for other Bay species, and filtration capacity. Although the reef building nature of *C. ariakensis* is discussed, there is uncertainty and differences in regard to the reef building nature of *C. virginica*. It also appears that there are differences in colonization preferences (subtidal for *C. ariakensis*) that could influence availability as a food resource for some receptors versus *C. virginica* which can colonize intertidal habitats. Furthermore, there is limited discussion and/or research on the palatability of *C. ariakensis* to ecological receptors that may feed on them, though it is stated that the shell is thin and should not present problems as was found with *C. gigas*. The uncertainty estimate for the risk conclusion included in the current draft is moderate, defined as "We are reasonably sure of the conclusion, but some aspects of the mechanism of action or consequences are not well understood, and its magnitude may be uncertain." A more supportable conclusion about uncertainty associated with this risk conclusion is that the uncertainty is high, defined as "Available information (e.g. data from laboratory studies) provides some insight into mechanisms of action, but we are not sure about how interactions would be manifested in the environment (i.e., regarding either likelihood or magnitude)." This is particularly related to the ecosystem service of being a food resource for other species and reef building provision.
 5. Although several aspects of *C. ariakensis* biology were investigated to evaluate ecological services, there appear to be minimal studies and data collection efforts directed at inter-specific interactions related to representative assessment endpoints, particularly ecosystem services as a food source and to a lesser extent reef building services. We recommend that the ERA acknowledge and discuss the uncertainty associated with this aspect of the ERA, including the RRM, given the ERA's dependency on oyster biomass as the dominant variable through which influences on assessment endpoints are related.
 6. In evaluating the risk of meeting the goals of the EIS, the authors state the risk of failure is high for all alternatives except the proposed alternative and alternative 7, in which it is judged moderate. This risk estimate for alternative 1, 2, 3, 4, and 5 is based on the population projections of the Oyster Demographic Model (ODM). Under no scenario outlined will any of these alternatives meet the population objectives as defined in the problem formulation. Using the ODM, the authors demonstrate that the proposed alternative and alternative 7 can meet the objectives established in the problem formulation using upper bound estimates of

ODM results (i.e., somewhere between the 50th and 95th percentile population estimates). We believe the most supportable risk conclusion for the proposed alternative and alternative 7 is moderate to high risk of failure because only the 95th percentile population model shows that the objective can be met.

7. In the assessment of risks concerned with triploid aquaculture resulting in a diploid introduction, the ERA argues that the uncertainty is too great to estimate risk. However, the risk analysis provides a fairly elaborate evaluation of risks associated with triploid aquaculture. The evaluations clearly demonstrate that the risk of triploid aquaculture, in a given year, is low; however, this risk is cumulative with time. Under the scenario provided, the cumulative risk increases linearly without plateau. If the authors of the ERA accept that the risk analysis is appropriate for this alternative, they should accept the risk conclusions it produces. The uncertainty surrounding assumptions that goes into the modeling effort and the fact that there are multiple pathways in which an unintentional introduction may occur, make the uncertainty surrounding the estimates of free living diploids and the slope of the risk line highly uncertain. It is important to state this clearly, so the risk managers can consider this when making decisions about the merits of this alternative.
8. The ERA states that the risk assessment is not intended to be a comparative analysis. However, in Table ES-1, alternatives 2 and 3 are discussed in terms of comparative risk (e.g., risk of alternative 3 is low, “ but lower than for alternative 2”). Having comparative assessment in some parts of the document but not others makes forming conclusions extremely difficult. Likewise, section 4.4.8 is a relative risk comparison across alternatives. This is the only place in section 4 where this is done. While we feel this is an appropriate comparison, it is inconsistent with the statements and rationale about not wanting to use comparative evaluations among alternatives.
9. The evidence developed and described in the ERA led the ERAAG to different conclusions about risks and uncertainty presented in the report, including Table ES-1. For Risk Question 8C, potential for benefits to fish and wildlife species that depend on oysters for habitat and food, the conclusion is that the potential is high. High is defined as “the chance that an outcome will occur is large, or the magnitude of the out-come is expected to be large.” As previously stated, separate risk characterizations should be presented for likelihood and magnitude. The evidence presented in the ERA for Risk Question 8c is more consistent with a conclusion of moderate, i.e., an outcome is possible. Further, it should be clarified in the table, as is done for alternative 2 and to some extent alternative 3, that the expected benefit is expected to be proportional to increases in living oyster hard bottom. In addition, for alternative 1 it should be clarified that it is dependent on the similarity of reef structure compared to *C. virginica*. Similarly, the evidence supporting the conclusion for 8B, potential for improvement in extent and viability of living oyster hard-bottom, is more consistent with a characterization of moderate (versus moderate to high). For risk question #5, potential for *C. ariakensis* to become invasive, available evidence supports a conclusion of moderate.

Principal Investigators Response to the consensus peer review report (August 8, 2008)

(Revisions made in the Final ERA in response to ERAAG's fifth review comments are described in inserts entered in **Bold** below)

Fifth Phase Review: Consensus Peer Review Statement for the Ecological Risk Assessment for Oyster Restoration Alternatives

20 June 2008

BACKGROUND AND PROCESS

This document represents the consensus findings of a peer review performed by the Ecological Risk Assessment Advisory Group (ERAAG) at the request of the Non-native Oyster EIS Project Delivery Team (PDT).

THE SUBJECT OF THE PEER REVIEW

An Ecological Risk Assessment (ERA) was commissioned by the PDT in order to evaluate potential ecological risks associated with implementing the proposed action, or any of the alternative actions, specified in the Programmatic Environmental Impact Statement (PEIS) for Oyster Restoration in Chesapeake Bay. The proposed action is to establish a naturalized, reproducing, and self-sustaining population of an Asian species, *Crassostrea ariakensis*, in the tidal waters of Maryland and Virginia through introductions beginning after the PEIS is completed while continuing efforts to increase the numbers of the native oyster, *Crassostrea virginica*, using best available restoration strategies and stock assessment techniques.

The ERA will be used to inform the development of a Programmatic Environmental Impact Statement (PEIS).

The alternatives being considered are:

Alternative 1 – No Action--Not taking the proposed action: Continue Maryland's present Oyster Restoration and Repletion Programs, and Virginia's Oyster Restoration Program under current program and resource management policies and available funding using the best available restoration strategies and stock assessment techniques.

Alternative 2 – Expand Native Oyster Restoration Program: Expand, improve, and accelerate Maryland's Oyster Restoration and Repletion Programs, and Virginia's Oyster Restoration Program in collaboration with Federal and private partners. This work would

include but would not be limited to an assessment of cultch limitations and long-term solutions for this problem, and the development, production, and deployment of large quantities of disease resistant strain(s) of *C. virginica* (Eastern oyster) for broodstock enhancement.

Alternative 3 – Harvest Moratorium: Implement a temporary harvest moratorium on native oysters and an oyster industry compensation (buy-out) program in Maryland and Virginia or a program that offers displaced oystermen on-water work in a restoration program.

Alternative 4 – Aquaculture: Establish and/or expand State-assisted, managed, or regulated aquaculture operations in Maryland and Virginia using the native oyster species.

Alternative 5 – Aquaculture: Establish State-assisted, managed, or regulated aquaculture operations in Maryland and Virginia using suitable triploid, non-native oyster species.

Alternative 6 – Introduce and Propagate an Alternative Oyster Species (Other than *C. ariakensis*) or an Alternative Strain of *C. ariakensis*: Introduce and propagate in the State-sponsored, managed, or regulated oyster restoration programs in Maryland and Virginia, a disease resistant oyster species other than *C. ariakensis*, or an alternative strain of *C. ariakensis* from waters outside the U.S. in accordance with the ICES 2003 Code of Practices on the Introductions and Transfers of Marine Organisms.

Alternative 7 – Establish a naturalized, reproducing, and self-sustaining population of *C. ariakensis* in the tidal waters of Maryland and Virginia through introductions beginning in 2005 (or when the EIS is completed) but discontinue efforts to restore *C. virginica*.

Alternative 8 – Combination of Alternatives

The context for the ERA includes the potential that alternatives will meet certain goals. The primary goal is the restoration of oysters to a specified level. Additional ecological goals or expectations associated with restoring oysters include an improvement in overall water quality (e.g., increased dissolved oxygen) and the enhancement of overall ecological services. An implied goal that relates to the consideration of risks is that these positive outcomes would not result in unacceptable risks.

ERAAG PEER REVIEW

The members of the ERAAG are:

Dr. Todd S. Bridges, U.S. Army Engineer Research and Development Center
Mr. Chris Guy, U.S. Fish and Wildlife Service
Mr. Simeon Hahn, National Oceanic and Atmospheric Administration
Ms. Barbara Okorn, U.S. Environmental Protection Agency

Dr. Todd Bridges chaired this peer-review effort at the request of the PDT.

The peer review was conducted in five phases. During the first phase, the ERAAG participated, at the request of the PDT, in occasional technical discussions (over a period of about 5 years) with the team conducting the ecological risk assessment (ERA). The purpose of these discussions was to provide opportunity for the ERA team to seek technical input from the ERAAG on issues germane to scoping the risk assessment. The second phase occurred during the latter half of December 2007 and early January 2008, when the ERAAG was asked to provide brief comments on preliminary drafts of sections of the ERA.

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contained in the two response-to-comments documents that were prepared by the ERA team and provided to the ERAAG by the PDT. In conducting the fourth phase of review, the ERAAG did consult portions of the 21 March version of the ERA; however the ERAAG did not perform a line-by-line review of the 21 March draft. The ERAAG also provided a listing of its conclusions regarding each response to its 86 comments:

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The PDT charged the ERAAG to provide a review in the form of responses to the following 6 questions:

1. Are the conclusions adequately supported by evidence, analysis and argument?
2. Are uncertainties or incompleteness in the evidence explicitly recognized?
3. If any conclusions are based on value judgments, is this acknowledged and are adequate reasons given for reaching these judgments?
4. Are the data and analyses adequately described and well-suited to address the questions being investigated?
5. Are statistical methods applied appropriately?
6. Is the report fair and impartial in tone?

ERAAG RESPONSES TO CHARGE QUESTIONS AND SPECIFIC COMMENTS

Overall Response: Over the last 6 months, the ERAAG has reviewed and commented on more than 4 drafts of the ERA, or portions of the ERA. Over this period, the ERA has undergone significant revision, resulting in substantial improvements. After the ERA team addresses the comments contained within this final phase of the peer review, the ERAAG is confident that the ERA will be sufficiently developed and described such that it will provide a necessary source of information to the PEIS.

Response to Charge Questions

1. Are the conclusions adequately supported by evidence, analysis and argument?

Response: The ERA presents estimates of the ecological risks posed by each of the alternatives with respect to eight risk questions. The ERA stops short of comparing the

alternatives by estimating the cumulative risk across all of the risk questions and pathways in order to rank the alternatives in terms of overall risk. The ERA presents conclusions only in terms of responses to individual risk questions and alternatives and presents no overall conclusions. The text of the ERA implies that the integration necessary to present overall conclusions will be performed within the PEIS. The ERA does not discuss how information and evidence will be integrated in order to compare and rank alternatives in terms of risk. However, we wish to emphasize how critical the integration step, and the approaches used to accomplish it, will be to developing conclusions and understanding regarding overall ecological risks associated with the alternatives. This step must be accomplished before information about ecological risks can be used along side estimates of benefit to support decision-making that leads to the selection of an alternative, or combination of alternatives.

The documents provided to the ERAAG for peer review included a large amount of information germane to assessing the potential impacts associated with the decision alternatives. In order for the ERA to serve the decision-making process, the information contained in an ERA must be presented in a transparent fashion, i.e., that the assumptions, logic, approaches used to develop inputs for assembling evidence, and the conclusions reached by the assessment, are discussed in sufficient detail that they can be subjected to challenge. Improvements made through successive revisions of the ERA report will produce an analysis that is sufficiently transparent and specific in its presentation of evidence that readers of the report will be able to reach informed decisions about the soundness of the analysis and the conclusions that are reached, once this final round of peer review is completed and the document is finalized. The conclusions reached by the analysis are generally supported by presentation of the analysis when considered in combination with qualifications related to uncertainties associated with data and evidence (except where noted in this review).

No revisions of the ERA were required in response to the major portion of this comment. The ERAAG does qualify their agreement with this charge question by stating that conclusions reached in the ERA are generally supported except where noted in their later comments. Revisions to the ERA have been made or further explanations are presented in this response to respond to those later comments

2. Are uncertainties or incompleteness in the evidence explicitly recognized?

Response: The assessment does recognize uncertainties and incompleteness in regards to the evidence presented. The ERA discusses sources of uncertainty and provides estimates for uncertainty associated with conclusions.

We recommend that the risk definitions for low, moderate, and high risk be clarified. The current definitions of low and high include multiple conditions. For example, a risk is considered low if either one of two conditions is met: the likelihood that the condition is considered low or the magnitude of the impact is considered low. We recommend keeping the magnitude of the impact, its likelihood and the description of uncertainty as

distinct variables. In this way, the ERA would present the best estimate of the condition as a low, moderate, or high probability of a low, moderate or high impact, giving 9 possible combinations. The level of uncertainty associated with the risk estimate would be classified as either low, moderate or high.

The risk definitions were revised to clarify their meaning, as suggested by the ERAAG. The revised definitions eliminate reference to magnitude of effect and are as follows (Section 1.0):

- **Negligible - If assumptions are met, there is no chance or virtually no chance that this outcome will occur.**
- **Low - The chance that the outcome will occur is very small.**
- **Moderate - An outcome is possible.**
- **High - The chance that an outcome will occur is large.**

3. If any conclusions are based on value judgments, is this acknowledged and are adequate reasons given for reaching these judgments?

Response: The ERAAG recognizes that all risk assessments involve making decisions and developing conclusions that at some level involve the values of those contributing to the analysis. It is not possible to conduct a value-free risk assessment. The selection of assessment endpoints, formulating conclusions in the face of uncertainties, as well as other key elements of a risk assessment require judgments that involve the values of the analysts. This being said, the ERA contains sufficient transparency related to the rationale for the judgments made within the assessment.

No revisions were necessary to finalize the ERA in response to this comment.

4. Are the data and analyses adequately described and well-suited to address the questions being investigated?

Response: The ERA presents a large amount of information concerning methods, data and analysis in a relatively concise manner. The scope of the risk assessment is large and varied, as reflected in the range of issues contained within the risk questions posed by the analysis. The scope of the assessment required the use of a range of approaches for developing lines of evidence to support conclusions about risks and benefits. Overall, the methods and analyses used in performing this assessment are germane to the questions posed and these approaches have been described in sufficient detail for readers to understand how the assessment was conducted and what the limitations of the assessment are. If the recommendations made within the assessment regarding ways for reducing uncertainties associated with the conclusions are acted upon, the availability of new information would likely lead to opportunities for drawing upon other methods and

means of analysis that would serve to strengthen the overall assessment and its conclusions. It would be appropriate and expedient to incorporate such follow-on activities as a part of an overall adaptive management strategy, the goal of which would be to provide a practical mechanism for managing both the risks and uncertainties associated with the management actions taken. Structured monitoring activities that track the consequences associated with implementing alternative(s) will be an essential component of such risk management.

This recommendation from the ERAAG applies to the overall oyster restoration program and is thus related to management decisions that cannot be determined by the writing team. No revisions to the ERA were made in response to this comment.

The presentation of RRM scores as stacked bar graphs will likely lead to misinterpretation and erroneous conclusions about influences and risks, i.e., that the sum of individual RRM values for the separate assessment endpoints could be viewed as a cumulative risk score. It was explained to the ERAAG by the ERA team that the summation of individual RRM scores has no meaning, which is the reason why the negative RRM scores are not subtracted from the total positive scores to present an overall RRM score. However, the text does not appear to contain a caution against interpreting the plots as cumulative scores. We recommend that the ERA present the RRM results in a clearer and more neutral fashion by plotting the RRM scale from -5 to +5 on the y-axis and the risk score for each assessment endpoint as a separate bar on the x-axis. Alternatively, presentation of RRM results in tabular form, as in Tables 4.4 to 4.7, represents a clear and neutral presentation.

The stacked bar approach is a standard presentation format for RRM results and the writing team believes that the presentation in the ERA should be consistent with standard practice. The text indicates that these do not represent a cumulative total score but rather a visual depiction of overall negative and positive influences on groups of receptors (Section 4.4). Thus, the figures were not revised. The writing team agreed with the comment on use of a table and have moved the tabular information (the same information in the graphs) close to the graphical presentations to complete the presentation related to provision of ecosystem services (see Section 4.4.9, Tables 4-3, 4-4, 4-5, and 4-6). Both visual (graphical) and tabular information are now provided in close proximity in the final ERA.

5. Are statistical methods applied appropriately?

Response: The assessment does not substantively rely upon statistical methods in reaching its conclusions. In large part this is due to the lack of quantitative data germane to the specific questions/hypotheses being evaluated within the assessment. The ERA does present statistical results of modeling using the ODM and CBEMP; however, the ERAAG did not review these modeling efforts as these models have been subjected to other review activities.

*However, the presentation and use of the demographic modeling poses a problem that should be addressed prior to finalizing the ERA report. The results of the demographic modeling that are emphasized, and presented graphically, in section 4.1.1 are the abundances associated with the 50th and 95th percentiles, i.e., the upper portion of the results distribution. While reference is made within the text to results associated with the 5th percentile, which has a probability of occurring that is equal to the 95th percentile values, these results are not presented graphically. We also note that only results associated with the 50th and 95th percentile are considered when calculating the scores using the relative risk model. Evaluating risks with the RRM using only the upper portion of the predicted abundance distribution will result in over-estimating the occurrence and magnitude of negative and positive influences. Given that the RRM results include a greater number of small positive influences than small negative influences, using only the upper portion of the abundance distribution leads to overestimating the potential for an overall positive influence of introducing *C. ariakensis*. This issue could be addressed by giving greater emphasis to the lower portion of the predicted abundance distribution within the risk assessment and qualifying the interpretation of the RRM results based on the 50th and 95th percentile results.*

Additional discussion of the 5th percentile outcomes was added to the discussion of each alternative in Section 4.4 of the report. However, a figure depicting 5th percentile outcomes was not added. A figure was not warranted because the very small responses would be difficult to discern when plotted on the same scale as the 50th and 95th percentile data. The following is an example of text that was typically added, “Even greater declines would occur if the 5th percentile value were used for estimating future oyster abundance and biomass.”

6. Is the report fair and impartial in tone?

Response: The report is generally fair and impartial in tone. Addressing the issues raised within this review will serve the important goal of eliminating opportunities for data to be misinterpreted by readers and decision makers. The ERAAG believes that the recommendations offered within this review will also help readers of the report, including decision-makers, give appropriate consideration to the uncertainties associated with the conclusions reached within the ERA.

No revisions were necessary to finalize the ERA in response to this comment.

Other specific comments related to the peer-review charge questions:

1. Page 4-12 states that *C. ariakensis* are naturally found on soft bottoms with high sediment loads, less likely to grow in high densities compared to the native oyster, and do not produce as much vertical relief as the native. It also states that biomass will decrease in both species when competing for space. These facts don't seem to be carried through the assessment to the degree that facts such as faster growth rates and greater disease resistance in *C. ariakensis* are. For example, it would seem that if they can grow on soft bottoms (with some scattered debris) and they don't grow in high densities (and are therefore more difficult to manage through harvesting) that they may become "invasive".

The discussion of this specific topic was expanded in several places (e.g., Executive Summary and Section 4.4.2). The following excerpts are taken from the Executive Summary and indicate the key points made there and throughout the report:

Because C. ariakensis can tolerate high loads of suspended sediment and exist in muddy systems (albeit on shell), reefs of the species could provide localized benefits for SAV by buffering the action of waves and currents and by filtering suspended solids from the water. Both oyster species are expected to filter the same kinds of algae and suspended matter from the water. Reefs of C. ariakensis would provide habitat for other species; however, no studies have investigated if the small-scale structure of reefs of C. ariakensis or mixed-species reefs would attract and support the same biological community that reefs of C. virginica do.

In its native environment, C. ariakensis forms the base of reefs that support smaller species of oysters.

The following sentence has been added to Section 4.2.1 to clarify the anticipated reef-forming characteristics of *C. ariakensis*:

While there might be some differences in reef formation between the two species, C. ariakensis is a reef former and would support other communities.

The following sentence helps clarify the degree to which *C. ariakensis* could utilize soft sediments:

The ability of C. ariakensis to settle on scattered shell provides some evidence that the species could form a local colony in a region dominated by soft sediment. Guo (pers. comm. 2008) further noted that C. ariakensis can survive in systems with high sediment loads by growing upward, and that it is very common for C. ariakensis to be partially buried in mud. Although Guo's observations suggest that C. ariakensis can occupy soft sediments, the availability of at least some fragments of shell upon which to settle appears to

be a prerequisite. Overall, research suggests that the probability that C. ariakensis would colonize substrates other than hard bottom is low.

The additional text notes that if a *C. ariakensis* introduction were successful, an increase in Bay-wide reef habitat would be expected and result in an increase in ecosystem benefits related to the presence of reefs. The text excerpt provided above indicates that *C. ariakensis* can grow in muddy areas but only if there is shell or hard substrate on which to settle, a requirement also applicable to *C. virginica*. The reference to biomass as mentioned in the ERAAG’s response (Section 4.2.2.2) is discussed in the context of the potential for competition between the two species and is not directly relevant to reef forming capability.

2. Page 4-27 concludes that the two oyster species can coexist. The ERA should include some discussion of the implications of inter-specific competition on the results of the ODM and future projections about oyster abundance and biomass.

The ODM is not structured to account for the mechanism of competition. A narrative discussion for the potential for competitive interactions between *C. ariakensis* and *C. virginica* is provided in Section 4.2.2. The ODM is not used to make population projections for *C. ariakensis*.

3. The ERA contains some contradictory statements of evidence that should be clarified. Specifically, page 4-16 states that infected *C. ariakensis* can transmit *P. marinus* to *C. virginica* in aquaculture settings. Most of the other discussion about disease states that there is a low probability of spreading disease. Page 4-27 states that *C. ariakensis*’ movement into polyhaline waters might be limited because of its susceptibility to *Bonamia*. Page 4-31 states that Guo noted “.....given this broad range, diseases might not be a permanent obstacle to long distance dispersal.”

Some clarifications were added to indicate that diseases can be transmitted from *C. ariakensis* to *C. virginica*, as they can among individual *C. virginica* (Section 4.2.3). The low probability relating to disease described in the text relates to the introduction of new diseases. The discussion on in Section 4.2.3 presents information that is available and contributes to the high uncertainty associated with this alternative.

4. One of the risks considered by the ERA is that *C. ariakensis* would not provide ecosystem services similar to those afforded by *C. virginica*. The assessment concludes that this risk is low. Low is defined as “either the chance that the outcome will occur is very small, or the magnitude of the outcome is expected to be small and perhaps undetectable.” A more supportable conclusion, based on the evidence provided, is that this risk is moderate, i.e., “an outcome is possible”. Ecological services considered in this ERA are those associated with provision of reef habitat for other Bay species, provision of food for other Bay species, and filtration capacity.

Although the reef building nature of *C. ariakensis* is discussed, there is uncertainty and differences in regard to the reef building nature of *C. virginica*. It also appears that there are differences in colonization preferences (subtidal for *C. ariakensis*) that could influence availability as a food resource for some receptors versus *C. virginica* which can colonize intertidal habitats. Furthermore, there is limited discussion and/or research on the palatability of *C. ariakensis* to ecological receptors that may feed on them, though it is stated that the shell is thin and should not present problems as was found with *C. gigas*. The uncertainty estimate for the risk conclusion included in the current draft is moderate, defined as “We are reasonably sure of the conclusion, but some aspects of the mechanism of action or consequences are not well understood, and its magnitude may be uncertain.” A more supportable conclusion about uncertainty associated with this risk conclusion is that the uncertainty is high, defined as “Available information (e.g. data from laboratory studies) provides some insight into mechanisms of action, but we are not sure about how interactions would be manifested in the environment (i.e., regarding either likelihood or magnitude).” This is particularly related to the ecosystem service of being a food resource for other species and reef building provision.

The text in the Executive Summary provides the key conclusions with respect to ecological services:

*The risk that *C. ariakensis* would not provide ecosystem services similar to those afforded by *C. virginica* is low. Ecological services considered in this ERA are those associated with provision of reef habitat for other Bay species, provision of food for other Bay species, and filtration capacity. *C. ariakensis*, if successful, is expected to populate historical oyster habitat and other hard substrates in the subtidal zone. Because *C. ariakensis* can tolerate high loads of suspended sediment and exist in muddy systems (albeit on shell), reefs of the species could provide localized benefits for SAV by buffering the action of waves and currents and by filtering suspended solids from the water. Both oyster species are expected to filter the same kinds of algae and suspended matter from the water. Reefs of *C. ariakensis* would provide habitat for other species; however, no studies have investigated if the small-scale structure of reefs of *C. ariakensis* or mixed-species reefs would attract and support the same biological community that reefs of *C. virginica* do.*

Both species would form reefs, provide buffers, and filter water; these are the three main features that contribute to ecological benefits, and both species share these. In accordance with the revision to the risk definitions made described above, the characterization of this risk as low was retained.

5. Although several aspects of *C. ariakensis* biology were investigated to evaluate ecological services, there appear to be minimal studies and data collection efforts directed

at inter-specific interactions related to representative assessment endpoints, particularly ecosystem services as a food source and to a lesser extent reef building services. We recommend that the ERA acknowledge and discuss the uncertainty associated with this aspect of the ERA, including the RRM, given the ERA's dependency on oyster biomass as the dominant variable through which influences on assessment endpoints are related.

This point is explicitly stated and is recognized as a source of uncertainty in Section 4.6 of the ERA. This section includes sub-sections related to uncertainties in understanding the overall ecosystem as well as uncertainties about interactions between the two oyster species.

6. In evaluating the risk of meeting the goals of the EIS, the authors state the risk of failure is high for all alternatives except the proposed alternative and alternative 7, in which it is judged moderate. This risk estimate for alternative 1, 2, 3, 4, and 5 is based on the population projections of the Oyster Demographic Model (ODM). Under no scenario outlined will any of these alternatives meet the population objectives as defined in the problem formulation. Using the ODM, the authors demonstrate that the proposed alternative and alternative 7 can meet the objectives established in the problem formulation using upper bound estimates of ODM results (i.e., somewhere between the 50th and 95th percentile population estimates). We believe the most supportable risk conclusion for the proposed alternative and alternative 7 is moderate to high risk of failure because only the 95th percentile population model shows that the objective can be met.

In response to comments from the OAP, the ODM is no longer used to make population projections for the alternatives involving *C. ariakensis* (including the Proposed Action and Alternative 7). The reviewer's comment is no longer applicable.

7. In the assessment of risks concerned with triploid aquaculture resulting in a diploid introduction, the ERA argues that the uncertainty is too great to estimate risk. However, the risk analysis provides a fairly elaborate evaluation of risks associated with triploid aquaculture. The evaluations clearly demonstrate that the risk of triploid aquaculture, in a given year, is low; however, this risk is cumulative with time. Under the scenario provided, the cumulative risk increases linearly without plateau. If the authors of the ERA accept that the risk analysis is appropriate for this alternative, they should accept the risk conclusions it produces. The uncertainty surrounding assumptions that goes into the modeling effort and the fact that there are multiple pathways in which an unintentional introduction may occur, make the uncertainty surrounding the estimates of free living diploids and the slope of the risk line highly uncertain. It is important to state this clearly, so the risk managers can consider this when making decisions about the merits of this alternative.

This specific point is acknowledged early in Section 4.3 where the alternative is evaluated:

The analysis is based on a large number of assumptions; consequently, much uncertainty accompanies the estimates. All of the assumptions were made conservatively, such that the likelihood of producing a reproductive population would be overestimated rather than underestimated.

*Many assumptions are made in estimating the probabilities at each step in the chain of events because of the paucity of information available about the basic biological processes of *C. ariakensis*. Because of this, the level of uncertainty associated with these estimates is high.*

In addition to the above, Section 4.6.6 specifically discusses this topic. No text revisions were made.

8. The ERA states that the risk assessment is not intended to be a comparative analysis. However, in Table ES-1, alternatives 2 and 3 are discussed in terms of comparative risk (e.g., risk of alternative 3 is low, “but lower than for alternative 2”). Having comparative assessment in some parts of the document but not others makes forming conclusions extremely difficult. Likewise, section 4.4.8 is a relative risk comparison across alternatives. This is the only place in section 4 where this is done. While we feel this is an appropriate comparison, it is inconsistent with the statements and rationale about not wanting to use comparative evaluations among alternatives.

While the writing team was instructed not to present a comprehensive comparison of the alternatives, limited comparisons among several alternatives appeared to contribute to clearly characterizing outcomes. No text revision was made.

9. The evidence developed and described in the ERA led the ERAAG to different conclusions about risks and uncertainty presented in the report, including Table ES-1. For Risk Question 8C, potential for benefits to fish and wildlife species that depend on oysters for habitat and food, the conclusion is that the potential is high. High is defined as “the chance that an outcome will occur is large, or the magnitude of the out-come is expected to be large.” As previously stated, separate risk characterizations should be presented for likelihood and magnitude. The evidence presented in the ERA for Risk Question 8c is more consistent with a conclusion of moderate, i.e., an outcome is possible. Further, it should be clarified in the table, as is done for alternative 2 and to some extent alternative 3, that the expected benefit is expected to be proportional to increases in living oyster hard bottom. In addition, for alternative 1 it should be clarified that it is dependent on the similarity of reef structure compared to *C. virginica*. Similarly, the evidence supporting the conclusion for 8B, potential for improvement in extent and viability of living oyster hard-bottom, is more consistent with a characterization of

moderate (versus moderate to high). For risk question #5, potential for *C. ariakensis* to become invasive, available evidence supports a conclusion of moderate.

The risk definitions were revised, as described earlier. The benefits presume that *C. ariakensis* is successful. This initial assumption was made in order to evaluate the potential risks. Under this assumption we believe that a successful establishment of *C. ariakensis* would involve successful reef formation and the associated ecological services that are associated with those reefs.

Other changes in addition to those in response to ERAAG

- 1. For the alternative involving triploid aquaculture, the number of diploid adults produced in an operation was recalculated as a result of several new probability figures being derived; the new number is 271 over a 10-year period. The cumulative probability of giving rise to a reproductive pair from all aquaculture operations with triploids was estimated to be 8% after 10 years. See Section 4.3.2.**
- 2. Based on comments from the OAP, a decision was made not to use ODM model projections for the proposed action. Therefore, the question related to whether the proposed action would achieve the goal is not addressed in the ERA (Section 4.1.1). In addition, the RRM is not applied to the outputs of ODM for the proposed action, as these were not considered reliable. Ecological services are described qualitatively (Section 4.4.1.1).**
- 3. We have included a more extensive discussion of effects of oysters on water quality at the local and regional levels; this is drawn from the modeling work of Cerco and is used to highlight the importance of local conditions (Section 4.4.1.1).**