

effects on minority and/or low income populations from this proposed rule. EPA believes, however, that this action affects the level of environmental protection equally for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. Any ozone depletion that results from this proposed rule will impact all affected populations equally because ozone depletion is a global environmental problem with environmental and human effects that

are, in general, equally distributed across geographical regions.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Imports, Methyl Chloroform, Ozone, Reporting and recordkeeping requirements.

Dated: December 7, 2009.
Lisa P. Jackson,
Administrator.

40 CFR part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.8 is amended by revising the table in paragraph (a) to read as follows:

§ 82.8 Grant of essential use allowances and critical use allowances.

(a) * * *

TABLE I—ESSENTIAL USE ALLOWANCES FOR CALENDAR YEAR 2010

| Company | Chemical | 2010 quantity (metric tons) |
|---|-----------------------------------|-----------------------------|
| (i) Metered Dose Inhalers (for oral inhalation) for Treatment of Asthma and Chronic Obstructive Pulmonary Disease | | |
| Armstrong | CFC–11 or CFC–12 or CFC–114 | 30.0 |

* * * * *

[FR Doc. E9–29556 Filed 12–10–09; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[Docket No. 0808041047–9114–02]

RIN 0648–AW62

Magnuson-Stevens Act Provisions; National Standard 2—Scientific Information

AGENCY: National Marine Fisheries Service (NMFS); National Oceanic and Atmospheric Administration (NOAA); Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes revisions to the guidelines for National Standard 2 (NS2) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) regarding scientific information. This action is necessary to provide guidance on the use of best scientific information available (BSIA) for the effective conservation and management of the nation’s marine living resources. NMFS proposes to modify the existing NS2 guidelines on BSIA and establish new guidelines for scientific peer review to ensure the reliability, credibility, and integrity of the scientific

information used in fishery conservation and management measures. Further, NMFS is proposing to add language to the guidelines regarding the role of the Scientific and Statistical Committees (SSCs) of the Regional Fishery Management Councils (Councils), and the relationship of SSCs to the peer review process. The proposed NS2 guidelines will also clarify the content and purpose of the Stock Assessment and Fishery Evaluation (SAFE) Report and related documents. These actions are necessary to ensure the use of BSIA in the development of fishery management plans and plan amendments, as required by NS2 of the MSA. The intended effect of these actions is to ensure that scientific information, including its collection and analysis, has been validated through formal peer review or other appropriate review, is transparent, and is used appropriately by SSCs, Councils, and NMFS in the conservation and management of marine fisheries. These guidelines are designed to provide quality standards for the collection and provision of biological, ecological, economic, and sociological information to fishery managers, Councils, and the public, while recognizing regional differences in fisheries and their management.

DATES: Written comments must be received by March 11, 2010.

ADDRESSES: You may submit comments, identified by 0648–AW62, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic comments via the Federal

eRulemaking Portal <http://www.regulations.gov>.

- *Fax:* Attn: William Michaels 301–713–1875.

- *Mail:* William Michaels, NOAA Fisheries Service, Office of Science and Technology, F/ST4, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All personal identifying information (for example, name address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: William Michaels, 301–713–2363 x136.

SUPPLEMENTARY INFORMATION:

I. Overview of Proposed Revisions to the Guidelines for National Standard 2

Section 301(a)(2) of the MSA specifies that fishery conservation and management measures shall be based upon the best scientific information available. Section 301(b) of the MSA states that “the Secretary (of Commerce) shall establish advisory guidelines

(which shall not have the force and effect of law), based on national standards, to assist in the development of fishery management plans.” The existing national standard guidelines appear at 50 CFR 600.310 through 600.355. The Magnuson-Stevens Fishery Conservation and Management Reauthorization Act (MSRA) of 2006 included provisions to improve the use of science in decisionmaking, provide a stronger role for Councils’ SSCs, and establish an optional peer review process for scientific information used to advise Councils about conservation and management of fisheries. Therefore, NMFS is proposing revisions to the NS2 guidelines to address these MSA provisions and provide guidance and recommendations on peer review processes. NMFS published an advanced notice of proposed rulemaking (ANPR) in the **Federal Register** on September 18, 2008 (73 FR 54132). NMFS has carefully considered the public comments received in developing this proposed rule.

II. Major Components of the Proposed Action

A. Best Scientific Information Available (BSIA)

In 2004, the National Research Council (NRC) of the National Academies examined the application of the BSIA standard in the development of fishery conservation and management measures. The NRC recommended approaches to more uniformly apply the BSIA standard for current and future fishery management actions. The NRC recommendations are available in the NRC (2004) publication entitled “Improving the Use of the ‘Best Scientific Information Available’ Standard in Fisheries Management” (2004, <http://books.nap.edu/openbook.php>).

NMFS proposes that the 2004 NRC recommendations regarding the use of BSIA for fishery management should be incorporated to the extent possible in this proposed revision to the NS2 guidance. The ANPR comments provided a nearly unanimous recommendation that the NS2 guidelines be revised to incorporate the NRC recommendations, and that an overly prescriptive definition of BSIA should be avoided due to the dynamic nature of science. Therefore, as recommended by the NRC, the proposed NS2 guideline revisions are based on the following widely accepted principles for evaluating BSIA: Relevance, inclusiveness, objectivity, transparency, timeliness, verification, validation, and peer review of fishery

management information as appropriate. NMFS also agrees with the comments that the NS2 guidelines should not prescribe a static definition of BSIA because of the dynamic developments inherent in making improvements in scientific information for fishery management.

The availability of scientific information to inform fisheries management varies. Ecosystems and human societies are complex, interacting, dynamic systems that are impacted by multiple factors, including those within the scope of fisheries management. Some fisheries are well studied and have much information from long-term annual research surveys and comprehensive biological, social, and economic fisheries data collection programs. Other fisheries do not have the same breadth of information available. In light of this variability, the proposed NS2 guideline revisions elevate the importance of evaluating the uncertainty and associated risk of the scientific information used to help inform fishery management decisions.

Similarly, the time available to review scientific information and the importance of that information to fishery management decisions are also variable. As a general rule, substantial management alternatives considered by a Council should be peer reviewed, but in some cases, formal peer review may not be possible due to time and resource constraints. For example, Councils may request that a NMFS Science Center provide calculations or analyses used in the development and assessment of fishery management alternatives for area-based or time-based harvest limits. It may be impractical to submit that scientific information to a formal peer review due to time and resource constraints. However, the development of such scientific information should be in accordance with the principles of transparency and openness set forth in this proposed action.

The proposed NS2 guidelines provide guidance that is fundamental for the reliability and integrity of scientific information to be used by NMFS and the Councils to effectively manage and conserve our nation’s living marine resources.

B. Peer Review Processes

Pursuant to its authority under the Information Quality Act (Pub. L. 106–554, Section 515), the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review (70 FR 2664, January 14, 2005) that establishes minimum peer review requirements for “influential scientific information” disseminated by

Federal agencies. As described in section II.C, a Council’s SSC is responsible for providing ongoing scientific advice to its Council for fishery management decisions. However, section 302(g)(1)(E) of the MSA provides for an optional peer review process: “(T)he Secretary and each Council may establish a peer review process for that Council for scientific information used to advise the Council about the conservation and management of the fishery.” If the Secretary and a Council establish such a process, it will be deemed to satisfy the requirements of the Information Quality Act, including the OMB Peer Review Bulletin guidelines. This proposed action provides guidance and national quality standards that are widely accepted, which should be followed in order to establish a peer review process per section 302(g)(1)(E). This action provides flexibility to maintain existing peer review processes established by the Secretary and Councils and also clarifies the role of the Councils’ SSCs in the scientific review process.

Section 302(g)(1)(E) peer review processes must be carefully designed to maximize the likelihood of an outcome that is objective, provides useful information, and meets the intent or scope of work of the particular process. This proposed action adopts many of the OMB peer review standards, including balance in the peer review process in terms of expertise, knowledge, and bias; lack of conflicts of interest; independence from the work being reviewed; and transparency of the process. A peer review may take many forms, including individual letter or written review or panel reviews. The amount of time and resources spent on any particular review may depend on the novelty and complexity of the scientific information being reviewed. Peer reviewers who are federal employees must comply with all applicable federal ethics requirements (available at: http://www.usoge.gov/federal_employees.aspx). Potential reviewers who are not federal employees must be screened for conflicts of interest in accordance with the procedures set forth in the NOAA Policy on Conflicts of Interest for Peer Review subject to OMB’s Peer Review Bulletin (available at: http://www.cio.noaa.gov/Policy_Programs/NOAA_PRB_COI_Policy_110606.html). The nature and scope of each peer review should be developed and defined prior to the selection of reviewers, to ensure reviewers with the

appropriate expertise and skills are selected.

Peer review processes established by the Secretary and a Council for that Council should not be duplicative and should focus on providing review for information that has not already undergone rigorous peer review. When the Secretary and a Council develop a peer review process per MSA section 302(g)(1)(E), the proposed NS2 guidelines provide that they must publish a notice and brief description of the process in the **Federal Register**, make a complete, detailed description of the process publicly available on the Council's Web site, and update it as necessary.

The proposed NS2 guidelines are not intended to replace or result in the duplication of effective peer review processes that have already been established by NMFS and the Councils, such as the Stock Assessment Review Committee (SARC), Southeast Data Assessment Review (SEDAR), Stock Assessment Review (STAR), and Western Pacific Stock Assessment Review (WPSAR). Section 302(g)(1)(E) provides that the peer review process established by the Secretary and a Council may include existing committees or panels. The aforementioned existing peer review processes (SARC, SEDAR, STAR and WPSAR) may qualify as 302(g)(1)(E) review processes, but the Secretary, in conjunction with the relevant Councils, has not yet made that determination. If such a determination is made, the Secretary will announce the decision in the **Federal Register**.

The impact of the proposed action on current Council peer review practices should be minimal since the proposed peer review standards are consistent with OMB's policy and presently incorporated in the existing peer review processes established by the Secretary and Councils. However, it may be necessary to refine those existing review processes in accordance with these proposed guidelines.

C. The Role of the SSC in the Review of Scientific Information

The proposed NS2 guidelines address several roles of the SSC and/or SSC members: the SSC as scientific advisor to its Council; the SSC as a peer review panel; and SSC members' participation on other peer review panels. With regard to the advisory role, the proposed NS2 guidelines provide that the SSCs are the scientific advisory bodies to the Councils.

Section 302(g)(1)(A) of the MSA mandates that "Each Council shall establish, maintain, and appoint the

members of a scientific and statistical committee to assist it in the development, collection, evaluation, and peer review of such statistical, biological, economic, social, and other scientific information as is relevant to such Council's development and amendment of any fishery management plan." As stated in MSA section 302(g)(1)(B), each SSC "shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch, preventing overfishing, maximum sustainable yield, and achieving rebuilding targets, and reports on stock status and health, bycatch, habitat status, social and economic impacts of management measures, and sustainability of fishing practices."

Questions have arisen with regard to the role of the SSC and peer review process under MSA section 302(h)(6). That section states that "each Council shall * * * develop annual catch limits for each of its managed fisheries that may not exceed the fishing level recommendations of its scientific and statistical committee or the peer review process established under subsection (g)." A possible interpretation of this section is that a Council could not exceed the fishing level recommendation of either the SSC or peer review process; the lower of the two levels would be the limit. However, NMFS believes that section 302(h)(6) should not be interpreted so as to displace the SSC's role in providing advice and recommendations to the Council. While MSA provides for establishment of peer review processes, such processes are optional, and as noted above, MSA section 302(g)(1)(A)–(B) mandates the types of advice the SSC provides for fishery management decisions. Further, as a practical matter, it is not clear how often an SSC or peer review panel would be generating different fishing level recommendations. The purpose of a peer review process is to ensure the quality and credibility of scientific information, rather than providing a specific result, such as a fishing level recommendation.

To address the above issues, as reflected in section (b)(1)(ii) of the proposed NS2 guidelines, a peer review process per section 302(g)(1)(E) should be conducted early in the scientific evaluation process, in order to provide the SSC with a reasonable opportunity to review the peer review report and make recommendations to the Council. The proposed NS2 guidelines also state that the SSC may provide a recommendation to its Council that is inconsistent with the findings of a peer

review, in whole or in part, but in such cases, the SSC should prepare a report outlining the areas of disagreement and the rationale and information supporting the SSC's determination. The proposed guidelines also state that the SSC should not repeat the peer review process by conducting a subsequent detailed technical review.

With regard to the SSC conducting a peer review of scientific information, the proposed action provides that the SSC's review should be complementary to, and not duplicative of, existing peer review processes established by the Secretary and each Council. Council and SSC members are encouraged to learn about the details in assessments and peer reviews by attending working group and peer review meetings that occur before any formal SSC evaluations of the scientific information are made.

With regard to SSC members, the proposed NS2 guidelines state that an SSC member may participate in the peer review of scientific information when beneficial due to the expertise and regional knowledge of the SSC member, as long as the SSC member meets the peer review quality standards as described in this proposed action. For an SSC member to participate in a peer review, the proposed action requires screening the SSC member as well as all other potential reviewers for conflicts of interest pursuant to NOAA's Policy on Conflicts of Interest for Peer Reviews Subject to OMB's Peer Review Bulletin. That policy limits review of one's own work. Furthermore, this proposed action provides that the review and evaluation of scientific information by the Councils' SSCs should be transparent, and include the recording of minority viewpoints.

Many ANPR comments focused on the evaluation and recommendations of the SSCs on the scientific information for catch-level specifications and pertinent measures of uncertainty; however, these issues were addressed in the recent revisions to the MSA National Standard 1 (NS1) guidelines (74 FR 3178, January 16, 2009).

D. SAFE Reports

The Secretary of Commerce (Secretary) has the responsibility for preparation and review of SAFE reports. The current NS2 guidelines state that the SAFE report is a document or set of documents that provides the Councils with a summary of scientific information, and contain specifications on the contents of SAFE reports. This proposed action would provide further clarification on the purpose and content of the SAFE report. Specifically, it provides guidance on the scientific

information that should be included in the SAFE to enable the SSC to fulfill its role in providing its Council with ongoing scientific advice for fishery management decisions.

ANPR comments suggested that a SAFE report should be a single report; however the proposed action maintains the existing NS2 guidelines language that describes the SAFE as a document or set of documents. This is necessary to provide the Secretary flexibility in the preparation of the SAFE report and accommodates differing regional practices with regard to the SAFE report. These proposed guidelines clarify that the SAFE report should include essential fish habitat (EFH) information, in accordance with the EFH provisions contained in § 600.815(a)(10), as a stand-alone chapter or clearly noted section.

The proposed NS2 guideline revisions contain provisions intended to facilitate the use of information in the SAFE reports and its availability to the Councils, NMFS, and public. For example, the proposed NS2 guideline revisions specify, as recommended by ANPR comments, that SAFE reports or similar documents must be made available by the Council or NMFS on a Web site accessible to the public, and that they include a summary of the information they contain and an index or table of contents of each component that comprises the SAFE report.

The proposed action would amend the existing NS2 guidelines by deleting the recommendation that the SAFE report contain information on safety for the fishery at issue. Safety of life at sea is now addressed in the National Standard 10 guidelines at § 600.355.

E. Fishery Management Plan (FMP) Development

This proposed action maintains the current NS2 guidelines language on FMP development, with only minor changes to the organization of the text.

III. References Cited

National Research Council of the National Academies (NRC). 2004. Improving the use of the "best scientific information available" standard in fisheries management. The National Academies Press, Washington, DC 105 pp.; <http://www.nap.edu/openbook.php>.

NOAA Office of the Chief Information Officer & High Performance Computing and Communications. 2006. National Oceanic and Atmospheric Administration Policy on Conflicts of Interest for Peer Review Subject to OMB Peer Review Bulletin. NOAA Memorandum, November 6, 2006; <http://www.cio.noaa.gov/>

Policy Programs/ NOAA_PRB_COI_Policy_110606.html.

Office of Management and Budget (OMB). 2004. Final Information Quality Bulletin for Peer Review. Executive Office of the President, Office of Management and Budget, memorandum M-05-03; December 16, 2004.

Classification

The NMFS Assistant Administrator has determined that this proposed action is consistent with the provisions of the MSA and other applicable law, subject to further consideration after public comment.

This proposed action has been determined to be not significant for purposes of Executive Order 12866.

NMFS has prepared a regulatory impact review of this action, which is available at: <http://www.nmfs.noaa.gov/msa2007/otherprovisions.html>. This analysis describes the economic impact this proposed action, if adopted, would have on small entities of the United States. NMFS invites the public to comment on this proposal and the supporting analysis.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that these proposed revisions to the NS2 guidelines, if adopted, would not have any significant economic impact on a substantial number of small entities, as follows:

I certify that the attached proposed action issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) will not have any significant economic impacts on a substantial number of small entities, as defined under the Regulatory Flexibility Act. The proposed action would revise the National Standard 2 (NS2) guidelines at 50 CFR 600.315.

The proposed revisions to the NS2 guidelines provide guidance on: use of "best scientific information available;" standards for discretionary peer review processes established by the regional Fishery Management Councils (Councils), in conjunction with the Secretary of Commerce; the role of the Councils' Scientific and Statistical Committees (SSCs) in the review and evaluation of scientific information; and requirements for Stock Assessment and Fishery Evaluation (SAFE) reports. Pursuant to section 301(b) of the MSA, the NS2 guidelines do not have the force and effect of law. Councils and the Secretary of Commerce would use the NS2 guidelines when developing or amending Fishery Management Plans (FMPs) and regulations to implement FMPs and FMP amendments. NMFS believes that revisions to the NS2 guidelines will assist the Councils and the Secretary in addressing new MSA requirements intended to strengthen the role of science in fishery management actions.

When NMFS takes fishery management actions, such actions typically could have impacts on vessel owners and operators and dealers. In this case, the proposed action would provide procedural guidance to the Secretary and Council regarding the development of fishery conservation and management measures. Because the NS2 guidelines are general guidance and focus on scientific information and review processes, they would not have any economic impacts on vessel owners, operators, dealers, or any other entities. The NS2 guidelines leave considerable discretion to the Councils and the Secretary to consider alternative ways to accomplish fishery conservation and management goals consistent with the NS, other provisions of the Magnuson-Stevens Act, and other applicable law. As the Councils and/or the Secretary develop FMPs, FMP amendments, or other regulatory actions, the actions will be accompanied by environmental, economic, and social analyses prepared pursuant to the Regulatory Flexibility Act, National Environmental Policy Act, and other statutes. Therefore, an IRFA has not been prepared for this action.

These proposed revisions to the NS2 guidelines do not contain any new recordkeeping or reporting requirements subject to the Paperwork Reduction Act. When the Councils and the Secretary develop FMPs, FMP amendments, or other regulatory actions per the Magnuson-Stevens Act and NS2 guidelines, such actions may include new proposed collection-of-information requirements. In the event that new collection-of-information requirements are proposed, a specific analysis regarding the public's reporting burden would accompany such action. NMFS is not aware of any other relevant Federal rules that may duplicate, overlap or conflict with the proposed action.

List of Subjects in 50 CFR Part 600

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: December 7, 2009.

Steve A. Murawski,

Director of Scientific Programs and Chief Science Advisor, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 600 is proposed to be amended as follows:

PART 600—MAGNUSON-STEVENS ACT PROVISIONS

1. The authority citation for part 600 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. Section 600.315 is revised to read as follows:

§ 600.315 National Standard 2—Scientific Information.

(a) *Standard 2.* Conservation and management measures shall be based upon the best scientific information available.

(1) Fishery conservation and management require high quality and

timely biological, ecological, economic, and sociological scientific information to effectively conserve and manage living marine resources. Successful fishery management depends, in part, on the thorough analysis of this information, and the extent to which the information is applied for evaluating the impact that conservation and management measures will have on living marine resources, essential fish habitat (EFH), marine ecosystems, fisheries participants, fishing communities, and the nation.

(2) Scientific information that is used to inform decision making should include an evaluation of its uncertainty and identify gaps in the information. Management decisions should recognize the biological (e.g., overfishing), ecological, sociological, and economic (e.g., loss of fishery benefits) risks associated with the sources of uncertainty and gaps in the scientific information. Limitations in scientific information may not be used as a justification for delaying fishery management actions.

(3) Information from data-poor fisheries may require use of simpler assessment methods and greater use of proxies for quantities that can not be directly estimated, as compared to data-rich fisheries.

(4) Scientific information includes, but is not limited to, factual input, data, models, analyses, technical information, or scientific assessments. Scientific information can be conveyed through data compiled directly from surveys or sampling programs, or through models that are mathematical representations of reality constructed with primary data. The complexity of the model should not be the defining characteristic of its value; the data requirements and assumptions associated with a model should be commensurate with the resolution and accuracy of the available primary data.

(5) Science is a dynamic process, and new scientific findings constantly advance the state of knowledge. Best scientific information is, therefore, not static and entails developing and following a research plan with the following elements: Clear statement of objectives; conceptual model that provides the framework for interpreting results, making predictions, or testing hypotheses; study design with an explicit and standardized method of collecting data; documentation of methods, results, and conclusions; peer review, as appropriate; and communication of findings.

(6) Principles for evaluating best scientific information must be based on relevance, inclusiveness, objectivity,

transparency and openness, timeliness, verification and validation, and peer review, as appropriate.

(i) *Relevance*. Scientific information should be pertinent to the current questions or issues under consideration and should be representative of the fishery being managed. In addition to the information collected directly about the fishery being managed, relevant information may be available about the same species in other areas, or about related species. For example, use of proxies may be necessary in data-poor situations. Analysis of related stocks or species is a powerful tool for inferring the likely traits of stocks for which stock-specific data are unavailable or are not sufficient to produce reliable estimates. Also, if management measures similar to those being considered have been introduced in other regions and resulted in particular behavioral responses from participants or business decisions from industry, such social and economic information may be relevant.

(ii) *Inclusiveness*. Three aspects of inclusiveness should be considered when developing and evaluating best scientific information:

(A) The relevant range of scientific disciplines should be consulted to encompass the scope of potential impacts of the management decision.

(B) Alternative points of view should be acknowledged and addressed openly when there is a diversity of scientific thought.

(C) Relevant local and traditional knowledge should be acknowledged (i.e., fishermen's empirical knowledge about the behavior and distribution of fish stocks). To the extent possible, an effort should be made to reconcile scientific information with local and traditional knowledge.

(iii) *Objectivity*. Scientific information should use standards for objectivity that prevent non-scientific considerations from impacting on its scientific integrity. The objectivity standards should ensure that information is accurate, reliable, and unbiased, and that information products are presented in an accurate, clear, complete, and balanced manner.

(iv) *Transparency and openness*.—(A) The Magnuson-Stevens Act provides broad public and stakeholder access to the fishery conservation and management process, including access to the scientific information upon which the process and management measures are based. Subject to the Magnuson-Stevens Act confidentiality requirements, the public should have access to each stage in the development of scientific information, from data

collection, to analytical modeling, to decision making. Public comment should be solicited at appropriate times during the development of scientific information. Communication with the public should be structured to foster understanding of the scientific process.

(B) Scientific information products should describe data collection methods, report sources of uncertainty or statistical error, and acknowledge other data limitations. Such products should explain any decisions to exclude data from analysis. Scientific products should identify major assumptions and uncertainties of analytical models. Finally, such products should openly acknowledge gaps in scientific information.

(v) *Timeliness*.—(A) Sufficient time should be allotted to analyze recently acquired data to ensure its reliability and that it has been audited and subjected to appropriate review before it is used to inform management decisions. For those data that require being updated on a regular basis, the temporal gap between information collection and management implementation should be as short as possible, subject to regulatory constraints, and should be explicitly considered when developing conservation and management measures. In particular, late submission of scientific information to the Council process should be avoided if the information has circumvented the review process.

(B) Timeliness may also mean that in some cases, results of important studies or monitoring programs must be brought forward before a study is complete. Uncertainties and risks that arise from an incomplete study should be acknowledged, but interim results may be better than no results to help inform a management decision. Management decisions should not be delayed due to data limitations or the promise of future data collection or analysis.

(C) Historical information should be evaluated for its relevance, to inform the current situation. For example, species' life history characteristics may not change over time, and so remain relevant. Other time-series data (e.g., abundance, catch statistics, market and trade trends) provide context for changes in fish populations, fishery participation, and effort, and therefore provide valuable information to inform current management decisions.

(vi) *Verification and validation*.—Methods used to produce scientific information should be verified and validated to the extent possible.

(A) *Verification* means that the data and procedures used to produce the

scientific information are documented in sufficient detail to allow reproduction of the analysis by others with an acceptable degree of precision. External reviewers of scientific information require this level of documentation to conduct a thorough review.

(B) *Validation* refers to the testing of analytical methods to ensure that they perform as intended. Validation should include whether the analytical method has been programmed correctly in the computer software, the precision of the estimates is adequate, model estimates are unbiased, and the estimates are robust to model assumptions. Models should be tested using simulated data from a population with known properties to evaluate how well the models estimate those characteristics. The concept of validation using simulation testing should be used, to the extent possible, to evaluate how well a management strategy meets management objectives.

(vii) *Peer review*. Peer review is a process used to ensure that the quality and credibility of scientific information and scientific methods meet the standards of the scientific and technical community. Peer review helps ensure objectivity, reliability, and integrity of scientific information. The peer review process is an organized method that uses peer scientists with appropriate and relevant expertise to evaluate scientific information.

(viii) To the extent practicable, substantial fishery management alternatives considered by a Council should be peer reviewed. Factors to consider when determining whether to conduct a peer review and if so, the appropriate level of review, include the novelty and complexity of the scientific information to be reviewed, the level of previous review and the importance of the information to be reviewed to the decision making process. If formal peer review is not practicable due to time or resource constraints, the development and analysis of scientific information used in or in support of fishery management actions should be as transparent as possible, in accordance with paragraph (a)(6)(iv) of this section.

(b) *Peer review process*. The Secretary and each Council may establish a peer review process for that Council for scientific information used to advise about the conservation and management of the fishery (Magnuson-Stevens Act section 302(g)(1)(E)). A peer review process is not a substitute for an SSC and should work in conjunction with the SSC (see § 600.310(b)(2)(v)(C)). This section provides guidance and standards that should be followed in

order to establish a peer review process per section 302(g)(1)(E).

(1) The objective or scope of the peer review, the nature of the scientific information to be reviewed, and timing of the review should be considered when selecting the type of peer review to be used. The process established by the Secretary and Council for each Council should focus on providing review for information that has not yet undergone rigorous peer review, but that must be peer reviewed in order to provide reliable, high quality scientific advice for fishery conservation and management. Duplication of previously conducted peer review should be avoided.

(i) *Form of process*. The peer review process may include or consist of existing Council committees or panels if they meet the standards identified herein. The Secretary and Council have discretion to determine the appropriate peer review process for a specific information product. A peer review can take many forms, including individual letter or written reviews, and panel reviews.

(ii) *Timing*. The peer review should be conducted early in the process of producing scientific information or a work product, to the extent practicable. The timing will depend in part on the scope of the review. For instance, the peer review of a new or novel method or model should be conducted before there is an investment of time and resources in implementing the model and interpreting the results. The results of this type of peer review may contribute to improvements in the model or assessment.

(iii) *Scope of work*. The scope of work or charge (sometimes called the terms of reference) of any peer review should be determined in advance of the selection of reviewers. The scope of work contains the objective of the specific advice being sought. The scope of work should be carefully designed, with specific technical questions to guide the peer review process; it should ask peer reviewers to ensure that scientific uncertainties are clearly identified and characterized, it should allow peer reviewers the opportunity to offer a broad evaluation of the overall scientific or technical product under review, and it must not change during the course of the peer review. The scope of work may not request reviewers to provide advice on scientific policy (e.g., amount of uncertainty that is acceptable or amount of precaution used in an analysis). Such policy considerations are in the purview of the Secretary and the Councils.

(2) *Peer reviewer selection*. The selection of participants in a peer

review must be based on expertise, independence, and a balance of viewpoints, and be free of conflicts of interest.

(i) *Expertise and balance*. Peer reviewers must be selected based on scientific expertise and experience relevant to the disciplines of subject matter to be reviewed, including a balance in perspectives. The group of reviewers that constitute the peer review should have sufficiently broad and diverse expertise to represent the range of relevant scientific and technical perspectives to complete the objectives of the peer review.

(ii) *Conflict of interest*. Peer reviewers who are federal employees must comply with all applicable federal ethics requirements. Peer reviewers who are not federal employees must comply with the following provisions. Peer reviewers must not have any real or perceived conflicts of interest with the scientific information, subject matter, or work product under review, or any aspect of the statement of work for the peer review. For purposes of this section, a conflict of interest is any financial or other interest which conflicts with the service of the individual on a review panel because it:

(A) Could significantly impair the reviewer's objectivity; or

(B) Could create an unfair competitive advantage for a person or organization.

(C) Except for those situations in which a conflict of interest is unavoidable, and the conflict is promptly and publicly disclosed, no individual can be appointed to a review panel if that individual has a conflict of interest that is relevant to the functions to be performed. Conflicts of interest include, but are not limited to, the personal financial interests and investments, employer affiliations, and consulting arrangements, grants, or contracts of the individual and of others with whom the individual has substantial common financial interests, if these interests are relevant to the functions to be performed. Potential reviewers must be screened for conflicts of interest in accordance with the procedures set forth in the NOAA Policy on Conflicts of Interest for Peer Review subject to OMB's Peer Review Bulletin.

(iii) *Independence*. Peer reviewers must not have participated in the development of the work product or scientific information under review. For peer review of some work products or scientific information, a greater degree of independence may be necessary to assure credibility of the peer review process; reviewers should not be employed by the Council or entity that produced or utilizes the product for

management decisions. Peer review responsibilities should rotate across the available pool of qualified reviewers or among the members on a standing peer review panel, recognizing that, in some cases, repeated service by the same reviewer may be needed because of essential expertise.

(3) *Transparency.* A transparent process is one that allows the public full and open access to peer review panel meetings, background documents, and reports, subject to Magnuson-Stevens Act confidentiality requirements. The evaluation and review of scientific information by the Councils and their advisory panels must also be publicly transparent in accordance with the Councils' requirements for notifying the public of meetings. The date, time, location, and terms of reference (scope and objectives) of the peer review should be publicly announced 14 days before the review to allow public comments during meetings. Background documents should be available for public review in a timely manner prior to meetings. Peer review reports describing the scope and objectives of the review, findings in accordance with each objective, and conclusions should be publicly available. Names and organizational affiliations of reviewers also should be publicly available prior to review.

(4) *Publication of the peer review process.* The Secretary will announce the establishment of a peer review process under Magnuson-Stevens Act section 302(g)(1)(E) in the **Federal Register** along with a brief description of the process. In addition, detailed information on such processes will be made publicly available on the Council's Web site, and updated as necessary.

(c) *SSC scientific advice to the Council.* Each scientific and statistical committee shall provide its Council ongoing scientific advice for fishery management decisions, including recommendations for acceptable biological catch, preventing overfishing, maximum sustainable yield, and achieving rebuilding targets, and reports on stock status and health, bycatch, habitat status, social and economic impacts of management measures, and sustainability of fishing practices (Magnuson-Stevens Act 302(g)(1)(B)).

(1) SSC scientific advice and recommendations to the Councils based on review and evaluation of scientific information must meet the guidelines of best scientific information available as described in paragraph (a) of this section. SSCs may conduct peer reviews, participate in peer reviews, or evaluate peer reviews to provide clear

scientific advice to the Council. Such scientific advice should attempt to resolve conflicting scientific information, so that the Council will not be forced to engage in debate on technical merits. Debate and evaluation of scientific information should be part of the role of the SSC.

(2) SSC members may participate in a peer review when such participation is beneficial to the peer review due to the expertise and institutional memory of that SSC member, or beneficial to the Council's advisory body by allowing that SSC member to make a more informed evaluation of the scientific information. Participation of a SSC member in a peer review should not impair the ability of that SSC member to accomplish the advisory responsibilities to the Council.

(3) If an SSC as a body, or individual members of an SSC, conducts or participates in a peer review, those SSC members must meet the peer reviewer selection criteria as described in paragraph (b)(2) of this section. These guidelines require separate consideration from those of § 600.235, Financial Disclosure for Councils and Council committees. Additionally, when the SSC as a body is conducting a peer review, it should strive for consensus and meet the transparency guidelines for best scientific information available and peer reviews as described in paragraphs (a)(6)(iv) and (b)(3) of this section. If consensus cannot be reached, minority viewpoints should be recorded.

(4) The SSC's evaluation of a peer review conducted by a body other than the SSC should be linked to the extent and quality of peer review that has already taken place. For Councils with extensive and detailed peer review processes (e.g., a process established pursuant to Magnuson-Stevens Act section 302(g)(1)(E)), the evaluation by the SSC of the peer reviewed information should not repeat the previously conducted and detailed technical peer review. However, SSCs must maintain their role as advisors to the Council about scientific information that comes from an external peer review process. Therefore, the peer review of scientific information used to advise the Council, including a peer review process established by the Secretary and the Council under Magnuson-Stevens Act section 302(g)(1)(E), should be conducted early in the scientific evaluation process in order to provide the SSC with reasonable opportunity to review the peer review report and make recommendations to the Council as required under Magnuson-Stevens Act section 302(g)(1)(B).

(5) If the evaluation of scientific information by the SSC is inconsistent with the findings or conclusions of a peer review, in whole or in part, the SSC should prepare a report outlining the areas of disagreement, and the rationale and information used by the SSC for making its determination.

(6) Annual catch limits (ACLs) may not exceed the SSC's recommendations for fishing levels (Magnuson-Stevens Act section 302(h)(6)). The SSC recommendation that is most relevant to ACLs is acceptable biological catch (ABC), as both ACL and ABC are levels of annual catch (see § 600.310(b)(2)(v)(D)). Any peer review related to such recommendations should be conducted early in the process as described in paragraph (c)(4) of this section. The SSC should resolve differences between its recommendations and any relevant peer review recommendations per paragraph (c)(5) of this section.

(d) *SAFE Report.* The term SAFE (Stock Assessment and Fishery Evaluation) report, as used in this section, refers to a public document or a set of related public documents, that provides Councils with a summary of scientific information concerning the most recent biological condition of stocks, stock complexes, and marine ecosystems in the fishery management unit (FMU), essential fish habitat (EFH), and the social and economic condition of the recreational and commercial fishing interests, fishing communities, and the fish processing industries. It summarizes, on a periodic basis, the best scientific information available concerning the past, present, and possible future condition of the stocks, EFH, marine ecosystems, and fisheries being managed under Federal regulation.

(1) The Secretary has the responsibility to assure that SAFE reports are prepared and updated or supplemented as necessary whenever new information is available that requires a revision to the status determination criteria (SDC) or is likely to affect the overfishing level (OFL), optimum yield, or ABC values (§ 600.310(c)). The SAFE report and any comments or reports from the SSC must be available to the Council for making its management decisions for each FMP to ensure that the best scientific information available is being used. The Secretary or Councils may utilize any combination of personnel from Council, state, Federal, university, or other sources to acquire and analyze data and produce the SAFE report.

(2) The SAFE report provides information to the Councils and the

Secretary for determining annual catch limits (§ 600.310(f)(5)) for each stock in the fishery; documenting significant trends or changes in the resource, marine ecosystems, and fishery over time; implementing required EFH provisions (§ 600.815(a)(10)); and assessing the relative success of existing state and Federal fishery management programs. In addition, the SAFE report may be used to update or expand previous environmental and regulatory impact documents and ecosystem descriptions.

(3) Each SAFE report should contain the following:

(i) A description of the SDC (e.g., maximum fishing mortality rate threshold and minimum stock size threshold for each stock or stock complex in the fishery) (§ 600.310(e)(2)), along with information to determine:

(A) Whether overfishing is occurring with respect to any stock or stock complex, whether any stock or stock complex is overfished, whether the rate or level of fishing mortality applied to any stock or stock complex is approaching the maximum fishing mortality threshold, and whether the size of any stock or stock complex is approaching the minimum stock size threshold; and

(B) Any management measures necessary to rebuild an overfished stock or stock complex (if any) in the fishery to a level consistent with producing the MSY in that fishery.

(ii) Information on which to base catch specifications, including the most recent stock assessment documents and associated peer review reports, and recommendations and reports from the Council's SSC on OFL and ABC, preventing overfishing, and achieving rebuilding targets. Documentation of the data collection, estimation methods, and consideration of uncertainty in

formulating catch specification recommendations should be included (see also § 600.310(f)(2)–(4)).

(iii) Information on sources of fishing mortality (both landed and discarded), including commercial and recreational catch and bycatch in other fisheries and description of data collection and estimation methods used to quantify total catch mortality, as required by National Standard 1 (§ 600.310(i)).

(iv) Information on bycatch of non-target species for each fishery.

(v) Review and evaluations of EFH information in accordance with the EFH provisions (§ 600.815(a)(10)), as a standalone chapter or in a clearly noted section.

(vi) Pertinent economic, social, community, and ecological information for assessing the success of management measures or the achievement of objectives of each FMP.

(4) To facilitate the use of the information in the SAFE report, and its availability to the Council, NMFS, and the public:

(i) The SAFE report should contain, or be supplemented by, a summary of the information and an index or table of contents to the components of the report.

(ii) The SAFE report or compilation of documents that comprise the SAFE report and index must be made available by the Council or NMFS on a readily accessible Web site.

(e) *FMP development.*—(1) FMPs must take into account the best scientific information available at the time of preparation. Between the initial drafting of an FMP and its submission for final review, new information often becomes available. This new information should be incorporated into the final FMP where practicable; but it is unnecessary to start the FMP process over again, unless the information

indicates that drastic changes have occurred in the fishery that might require revision of the management objectives or measures.

(2) The fact that scientific information concerning a fishery is incomplete does not prevent the preparation and implementation of an FMP (see related §§ 600.320(d)(2) and 600.340(b)).

(3) An FMP must specify whatever information fishermen and processors will be required or requested to submit to the Secretary. Information about harvest within state waters, as well as in the EEZ, may be collected if it is needed for proper implementation of the FMP and cannot be obtained otherwise. The FMP should explain the practical utility of the information specified in monitoring the fishery, in facilitating inseason management decisions, and in judging the performance of the management regime; it should also consider the effort, cost, or social impact of obtaining it.

(4) An FMP should identify scientific information needed from other sources to improve understanding and management of the resource, marine ecosystem, the fishery, and fishing communities.

(5) The information submitted by various data suppliers should be comparable and compatible, to the maximum extent possible.

(6) FMPs should be amended on a timely basis, as new information indicates the necessity for change in objectives or management measures consistent with the conditions described in paragraph (d) of this section (SAFE reports). Paragraphs (e)(1) through (e)(5) of this section apply equally to FMPs and FMP amendments.

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