



Regulatory Environment: APA, FOIA, IQA

I. Overview

This chapter explains the underlying statutory framework that regulations are written.

It begins with an overview of the legal system and an explanation of where regulatory agencies fit into that scheme. It then describes some basic parameters that apply to all agency rulemakings and information, specifically, APA, FOIA, and IQA.

The U.S. Constitution vests authority to make laws with the Legislative Branch, i.e., Congress. In many instances, Congress establishes a general set of requirements, and then delegates responsibility to a regulatory agency for fleshing out the details. Unlike Congress, regulatory agencies are not directly elected by the public, and thus there is a perception that agencies are less directly accountable than Congress. To address public concerns about this lack of accountability, in 1946, Congress enacted the Administrative Procedure Act (APA) which set forth specific requirements to enhance agency accountability to the public. The key components of the APA require agencies to utilize a notice and comment process, require a delay in the effectiveness of final rules, and require the final decision to be reasonable based on the facts in the record. Thus the administrative record, i.e., the body of information on which agency decision-makers base their decisions, is of fundamental importance.

Congress has also enacted laws ensuring public access to almost all agency information and requiring agencies to ensure the quality of the information they rely on. The Freedom of Information Act (FOIA), ensures public access to agency information, referred to broadly as “records.” Whether or not information is included in the “administrative record” before the decision maker, it is probably still a public record to which the public is entitled access under FOIA. The Data Quality Act (IQA) requires agencies to ensure that any information they disseminate is of appropriate quality, integrity, and utility.

This chapter discusses the more specific linkages of each of these underlying laws to the MSA fishery management process below.

II. APA links to MSA actions

The Administrative Procedure Act (APA) is the overarching law that applies to agency rulemakings. It includes both substantive and procedural requirements, and allows discretion within limits. Specifically, it requires that: (a) agency decisions must be reasonable in light of applicable requirements and facts in the record, (b) agencies must provide an opportunity for public comment, unless there is good cause to waive; and (c) it requires a 30-day delay in effectiveness of final rules unless there is good cause to waive.

A. Discretion within limits: The APA empowers judges to set aside agency actions and to issue injunctions. The law states that a “reviewing court shall”“hold unlawful and set aside” agency action, findings, and conclusions found to be:

- “Arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law;”
- “Contrary to constitutional right;”
- “In excess of statutory jurisdiction;” or
- “Without observance of procedure required by law...”¹

1. Arbitrary and Capricious (i.e., “Unreasonable”)

To determine whether an agency action is unreasonable, the APA requires the court to review the facts in the record. The APA specifically states that the court will “review the whole record or those parts of it cited by a party...”² Thus, the materials that we include in our “administrative records” are the most important element of judicial review of our regulations.

The Administrative Record contains all the information that the decision maker considers, and, in court, it provides the evidence that the agency complied with required procedures and that the final decision was not “arbitrary and capricious.”

There is no objective test for what is reasonable. Rather, “reasonableness” is a subjective evaluation of whether a decision is sufficiently explained and justified in light of available information. An agency can both ensure sound decision-making and bolster its likelihood of success in litigation by utilizing the three “Ds” of decision-making. For each decision, the agency should describe the issues, discuss the pros and cons and document the rationale for the final decision (i.e., describe, discuss, and document).

Dealing with uncertainty or conflicting values: The APA does not require a particular outcome, as long as the final decision is supported by facts in the record. Show your work. Respond to all comments. Acknowledge, even highlight, areas of contention, and explain your decision.

Case law demonstrates that when, based on the record, there is no perfect solution; the Secretary’s decision can stand as long as it is reasonable. For instance, note the following excerpts from a summer flounder case:

“What is apparent from the record is that there may not be a perfect conservation management system for summer flounder that satisfies all the groups...”

“When the Secretary is faced with conflicting views and chooses among them, his decision cannot be termed arbitrary and capricious by that fact alone.”³

Don’t Stretch Common Sense. However, applying discretion in a manner that defies common sense can be found to be “unreasonable.” Excerpts from a different summer flounder case show that there are limits on an agency’s discretion, and decisions that appear to go against the facts in the record will be struck down. In *Natural Resources Defense Council v. Mineta*, and *Natural Resources Defense Council, Inc. v. Daley*, the court ruled that a summer flounder quota with only an 18% chance of meeting mandatory conservation goals was arbitrary and capricious. The DC Circuit Court wrote that where a disputed limit had “at most an 18% percent likelihood of achieving the target F, and “viewed differently, it had at least an 82% chance of resulting in an F greater than the target F, “the agency’s decision that the recommended quota complied with the MSA was arbitrary and capricious. The Court wrote:

¹ 5 USC 706. Note that the APA also provides for setting aside actions that are “unsupported by substantial evidence” or “unwarranted by the facts.” However, the MSA exempts fishery management actions from review under these two criteria. See 16 U.S.C. 1855(f)(1)(B)).

² 5 USC Sec. 706.

³ From *Connecticut v. Daley*, 204 F.3d 413, 2000 U.S. App. LEXIS, 30 ELR 20343 (2nd Cir., Feb. 25, 2000) (NO. 99-6170) (*Connecticut v. Daley I*); *Connecticut v. Daley*, 53 F. Supp.2d 147 (D.Conn., May 04, 1999) (NO. CIV.A3:97CV2726(CFD)) (*Connecticut v. Daley II*).

“Only in Superman Comics’ Bizarro world, where reality is turned upside down, could the Service reasonably conclude that a measure that is at least four times as likely to fail as it is to succeed offers a ‘fairly high level of confidence.’”

2. Not in accordance with the law

Likewise, the requirements of other applicable laws can constrain agency discretion. For example, the MSA, the ESA, require fishery management measures to achieve optimum yield and prevent jeopardy to endangered and threatened species. All such required determinations must be addressed on the record as discussed in greater detail below.

The APA requires adherence to other statutory mandates. A decision, even if it is reasonable and strikes a logical balance between competing interests, will be struck down if it does not comply with applicable law. The agency must follow the prescribed statutory parameters and facts in the record. For example, because the MSA requires fishery management measures to be based on science and the policy goals articulate in the national standards, it is not acceptable to base a fishery management decision on pure political compromise.

In *Midwater Trawlers Coop. et al v. Commerce*, applicable law, including the MSA and tribal treaty rights, required that NMFS allocate 50% of the whiting harvest to the Makah tribe. NMFS acknowledged potential flaws in earlier methodology to quantify 50% treaty allocation, and settled on an amount within a range of reasonable allocations, while also adequately accounting for the “conservation necessity principal.” The 9th Circuit Court found that the compromise-based allocation was “inconsistent with the scientific principles set forth in the Magnuson-Stevens Act.” The 9th Circuit Court ruled that the allocation must be based on the best scientific information available. The rule was struck down.

The court wrote: “A plain reading of the proposed NMFS rule, and the undisputed history leading up to the allocation decision, demonstrate that the rule was a product of pure political compromise, not reasoned scientific endeavor. Although the NMFS allocation may well be eminently fair, the Act requires that it be founded on science and law, not pure diplomacy.”⁴

B. Procedure

There are two specific procedural requirements the APA imposes on regulation writers: they must provide advance public notice and an opportunity for comment on proposed regulations unless an exception applies; and they must provide a 30-day delay in the effective date of final regulations unless an exception applies.

1. Notice and Comment

The APA requires the agency to provide public notice and an opportunity for comment on all rules with limited exceptions. This means that a proposed rule must be published and public comments invited unless the rule is an:

- “Interpretative rule, general statement of policy, or rule of agency organization, procedure, or practice;” or
- “When the agency for good cause finds...that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”

There are three potential reasons to assert a waiver of the public comment period pursuant to the “Good Cause” exception: impracticable, unnecessary, or contrary to the public interest. In considering whether to assert one of these reasons, you should consider the following:

⁴ *Midwater Trawlers Coop. et al v. Commerce*, 2002 U.S. App. LEXIS 3419 (9th Cir. (Wash.) (March 5, 2002).

- “Impracticable” does not just mean difficult or not practical, it means you absolutely can’t do it. You can’t claim the exception if the agency caused the delay that is creating the urgency
- “Unnecessary” applies to situations where there would be no public interest in providing advance comment, e.g., in situations involving no agency discretion, or in situations having no substantive effect on the public
- “Contrary to the Public Interest” refers to situations where effectiveness of the rule would be undermined by providing an opportunity for advance public comment. It generally should not be asserted as a stand-alone basis for waiving notice and comment. Instead, it should supplement good cause based on “impracticability” and “unnecessariness”.

MSA Emergency Rules: Note that there is no “per se” exemption from APA notice and comment requirements for actions taken as “emergencies” under the MSA. However, if there is a factual justification for an action to be processed as an emergency under the MSA, the same facts may support waiver of notice and comment under the APA. This is a case-by-case determination. Note that it may be more difficult to justify waiver of notice and comment rulemaking under the APA than to justify emergency status under the MSA in that the time periods involved to develop and FMP are longer than those to take public comment on a proposed rule. So, one may end up with a proposed rule to implement an emergency action under the MSA.

Note: The rationale for waiving the public comment period must be published in the classification section of the rule.

There is a strong presumption in favor of the public’s interest in having a public comment period. For example, in *NRDC v. Evans*, NMFS’ asserted good cause to waive advance notice and comment for fishery management specifications. Despite NMFS’ explanation of the timing constraints involved with managing fisheries based on current data, the need for immediate management of overfished stocks, and the ability of the public to participate through the Council process, the 9th Circuit Court found NMFS’ good cause waiver did not sufficiently explain why the agency was not able to provide for, at least, a shortened public comment period. NMFS needed to show that some “exigency,” apart from generic data collection and timing concerns, that interfered with its ability to promulgate the regulations at issue.⁵

If one improperly waives the notice and comment requirement, the one faces the risk that a court will invalidate the final rule and will have to start the rulemaking process over from the beginning.

Timing of notice and comment: This procedural requirement must be read in conjunction with the procedural requirements of the MSA, which specify time periods for public comment on FMPs and amendments (i.e., 60 days on FMPs and amendments; 15 – 60 days on regulations, with an agency preference for 45 days).

C. Timing: 30 day delay

As mentioned above, agencies must provide a 30-day delay in the effective date of “substantive” final regulations unless an exception applies.

“The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except–

- A substantive rule which grants or recognizes an exemption or relieves a restriction;
- Interpretative rules and statements of policy;
- Or as otherwise provided by the agency for good cause found and published with the rule.”

⁵ *NRDC v. Evans*, 2003 U.S. App. LEXIS 388 (9th Cir., Jan. 13, 2003)(No. 01-17143).

“Good cause” for waiving the 30-day delay should be based on:

- A demonstration of inescapable or unavoidable limitations of time,
- And demonstrable urgency.

If one improperly waive the 30-day delay in effectiveness, it is possible that a court would prohibit us from enforcing the rule during the 30-day period.

III. FOIA links to MSA

FOIA affects our regulatory environment by ensuring public access to almost all agency “records.” In this section, we will be discussing what an agency record is (a FOIA record can be different from the “administrative record”); how to recognize and respond to a FOIA request; and the special types of information that are exempt from the public disclosure requirement.

A. Provides for public access to almost all agency records.

In general, FOIA requires agencies to disclose certain types of information to the public, to publish rules in the Federal Register, and, when requested, to disclose “records” unless an exemption applies. When handling a FOIA request, an agency must make reasonable efforts to search its files.

The Department of Commerce has published regulations explaining the FOIA process for our agency.⁶ These regulations explain what constitutes a “record” for FOIA purposes. Note that the definition of “records” under FOIA is broader than what is included in an “administrative record” on a rulemaking.

Records under FOIA. Records under the FOIA include all Government records, regardless of format, medium or physical characteristics, and include electronic records and information, x audiotapes, videotapes, and photographs. The agency has no obligation to create, compile, or obtain from outside the Department a new record to satisfy a request (e.g., produce a report from raw materials). However, the agency may, upon request, create and provide new records. If the agency does so, it may charge a fee.

Because the definition of “records” is so broad, almost anything you produce could be disclosed pursuant to a FOIA request. Even if you do not expect the document or e-mail you are working on to become part of the administrative record, always write in a professional manner, and never put anything in writing that you would not want to become public.

B. Exemptions

All responsive records will be released unless covered by one or more of the nine exemptions, which are:

1. Classified secret matters or national defense or foreign policy
2. Internal Personnel Rules and Practices
3. Information Specifically Exempted by Other Statutes
4. Trade Secrets, Commercial or Financial Information
5. Privileged Interagency or Intra-Agency Memoranda or Letters
6. Personal Information Affecting and Individual's Privacy
7. Investigatory Records Compiled for Law Enforcement Purposes
8. Records of Financial Institutions
9. Geographical and Geophysical Information Concerning Wells.

Exemptions 3, 4, and 5 are particularly relevant to MSA actions. The MSA does provide statutory protection for information that is required to be submitted via an FMP or the Act.⁷

⁶ 15 CFR 4.3

⁷ 16 U.S.C. 1881a(b)

C. The “FOIA Request”

A “request for information” under FOIA can be very simple. It merely needs to be in writing and identify the records being requested. The records requested must be described in enough detail to enable Department personnel to locate them with a reasonable amount of effort. If possible, a request should include specific information about each record sought, such as, the date, title or name, author, recipient, and subject matter of the record, and the name and location of the office where the record is located. Also, if records about a court case are sought, the title of the case, the court in which the case was filed, and the nature of the case should be included.

Requests will be processed as FOIA requests regardless of whether FOIA is mentioned in the request.

There is an aggressive timeline for responding to FOIA requests. Once a FOIA request is received, the regional contact person should be notified immediately. According to the DOC regulations, (section 4.6), the agency has 20 working days from date of receipt to respond. An additional 10 days may be granted if the requester agrees in writing. FOIA requests are processed on a “First In First Out” basis. You should also work with your attorney to determine whether certain documents fall outside the scope of “records” (e.g., personal notes), and/or whether an exemption may apply.

IV. IQA links to MSA

The IQA is another law that affects the use of information in a regulatory context.⁸

A. Purpose

The purpose of the IQA is to: ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.

B. Trigger: Dissemination of Information

In the MSA context, IQA applies anytime there is:

- An agency-sponsored or agency-initiated
- Dissemination of information.

Our NOAA guidance provides the following definitions of these terms.

Agency Initiated. Agency initiated distribution of information to the public refers to information that the Agency distributes or releases which reflects, represents, or forms any part of the support of the policies of the Agency. In addition, if the Agency, as an institution, distributes or releases information prepared by an outside party in a manner that reasonably suggests that the Agency agrees with the information, this would be considered Agency initiated distribution and hence Agency dissemination because of the appearance of having the information represent Agency views. By contrast, the Agency does not “initiate” the dissemination of information when an Agency scientist or grantee or contractor publishes and communicates his or her research findings in the same manner as his or her academic colleagues, even if the Agency retains ownership or other intellectual property rights because the Federal government paid for the research.

Agency Sponsored. Agency sponsored distribution of information to the public refers to situations where the Agency has directed a third party to distribute or release information, or where the Agency has the authority to review and approve the information before release. By contrast, if the Agency simply provides funding to

⁸ The IQA required OMB to issue “guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies.” It also required agencies to issue their own guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information; provide “administrative mechanisms” allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the; and report to OMB on the number and nature of complaints received and how such complaints were handled by the agency (Public Law 106-554 Title V, Sec. 515.)

support research, and if the researcher (not the Agency) decides whether to distribute the results and – if the results are to be released – determines the content and presentation of the distribution, then the Agency has not "sponsored" the dissemination even though it has funded the research and even if the Agency retains ownership or other intellectual property rights because the Federal government paid for the research. Note that subsequent Agency dissemination of such information would require that the information adhere to the Agency's information quality guidelines even if it was initially covered by a disclaimer.

Dissemination. Dissemination means agency initiated or sponsored distribution of information to the public. Dissemination does not include distribution limited to: government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to: correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

Information. Information means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.

Information Dissemination Product. Information dissemination product means any books, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD-ROM, or web page.

As a result of these definitions, the term "dissemination of information" has broad applicability. For example, it may include:

- Biological surveys
- Catch statistics
- Model output
- Web sites
- Third-party (e.g., states, industry) information used in NOAA products
- Speeches
- Outreach materials

In addition, it may include other types of materials and forms of communication such as: Textual, machine-readable material, Numerical, Paper, Graphic, Speech, Cartographic, CD-ROM, Maps, Web pages, Narrative, Broadcast, Audiovisual, Skywriting, Books, and Policies

C. Requirements of the IQA (and NOAA Guidelines):

The IQA required OMB to establish guidelines requiring agencies to establish their own guidelines for maximizing the "Quality, objectivity, utility, and integrity" of disseminated information, ... disseminated by federal agencies" and providing for administrative review. The result is NOAA Guidance applicable to the development and dissemination of information, explaining our approach to assuring the quality of information disseminated. The basic approach set forth in the NOAA Guidance is to assure quality, adhere to articulated standards for "objectivity," and to document this compliance.

1. Definitions.

The NOAA Guidance defines the terms quality, objectivity, utility, and integrity as follows.

Overview of the Fishery Management Process

Quality is an encompassing term and it includes the concepts of “utility,” “objectivity”, and “integrity”. The NOAA guidelines sometimes refer to these four statutory terms, collectively, as “quality.”

Utility: Utility means that disseminated information is useful to its intended users. "Useful" means that the content of the information is helpful, beneficial, or serviceable to its intended users, or that the information supports the usefulness of other disseminated information by making it more accessible or easier to read, see, understand, obtain, or use. Where the usefulness of information will be enhanced by greater transparency, care is taken that sufficient background and detail are available, either with the disseminated information or through other means, to maximize the usefulness of the information. The level of such background and detail is commensurate with the importance of the particular information, balanced against the resources required, and is appropriate to the nature and timeliness of the information to be disseminated.

Integrity: Prior to dissemination, NOAA information, independent of the specific intended distribution mechanism, is safeguarded from improper access, modification, or destruction, to a degree commensurate with the risk and magnitude of harm that could result from the loss, misuse, or unauthorized access to or modification of such information. All electronic information disseminated by NOAA adheres to the standards set out in Appendix III, "Security of Automated Information Resources," OMB Circular A-130; the Computer Security Act; and the Government Information Systems Reform Act. Confidentiality of data collected by NOAA is safeguarded under legislation such as the Privacy Act and Titles 13, 15, and 22 of the U.S. Code. Additional protections are provided as appropriate by 50 CFR Part 600, Subpart E, Confidentiality of Statistics of the Magnuson-Stevens Fishery Conservation and Management Act, NOAA Administrative Order 216 100 – Protection of Confidential Fisheries Statistics.

Objectivity: Standards vary by type of information (explained in greater detail below).

In order to assure the quality of disseminated information, the NOAA IQA guidance establishes a procedure we should follow. First, identify the type of information you are working with. The IQA guidance describes seven different types of data, and sets forth different standards for each type, described in greater detail below. Second, adhere to the standards for the particular type of data. Third, keep records of how you have adhered. Fourth, prior to dissemination, a designated official reviews the file to determine whether the information has been developed and maintained according to standards.

2. Types of Information and their Objectivity Standards:

NOAA’s IQA Guidelines identify seven categories of Information: Original data; Synthesized products; Interpreted products; Hydrometeorological, Hazardous Chemical Spill, and Space; Weather Warnings, Forecasts, and Advisories; Experimental products; Natural resource plans; Corporate and general information. The guidelines prescribe different standards depending on the category. Note that for fishery management actions, the most relevant types of information tend to be original data, synthesized products, Interpreted products, and Natural Resource Plans which are discussed in greater detail below.

Original Data. Original data are data in their most basic useful form. These are data from individual times and locations that have not been summarized or processed to higher levels of analysis. While these data are often derived from other direct measurements (e.g., spectral signatures from a chemical analyzer, electronic signals from current meters), they represent properties of the environment. These data can be disseminated in both real time and retrospectively. Examples of original data include buoy data, survey data (e.g., living marine resource and hydrographic surveys), biological and chemical properties, weather observations, and satellite data.

The Objectivity Standards for Original Data are that:

- Data are collected according to documented procedure/standard practice.
- Data are subjected to quality control prior to dissemination.

- There is an ongoing process to continually improve quality.
- There is transparency in collection, level of quality, and limitations.

Synthesized Products. Synthesized products are those that have been developed through analysis of original data. This includes analysis through statistical methods; model interpolations, extrapolations, and simulations; and combinations of multiple sets of original data. While some scientific evaluation and judgment is needed, the methods of analysis are well documented and relatively routine. Examples of synthesized products include summaries of fisheries landings statistics, weather statistics, model outputs, data display through Geographical Information System techniques, and satellite-derived maps.

The Objectivity Standards for synthesized products are that they:

- Identify data sources
- Use data of known quality
- Use published, documented, or generally accepted methods
- NOAA reviews the products or procedures
- The methods of creating the products are disclosed

Interpreted Products. Interpreted products are those that have been developed through interpretation of original data and synthesized products. In many cases, this information incorporates additional contextual and/or normative data, standards, or information that puts original data and synthesized products into larger spatial, temporal, or issue contexts. This information is subject to scientific interpretation, evaluation, and judgment. Examples of interpreted products include journal articles, scientific papers, technical reports, and production of and contributions to integrated assessments.

The Objectivity Standards for Interpreted Products are that they:

- Reference the data sources
- Are produced through documented or generally accepted methods
- Place the interpreted products into context
- Are reviewed
- Identify the methods of production

Natural Resource Plans. Natural Resource Plans are information products that are prescribed by law and have content, structure, and public review processes (where applicable) that are based upon published standards (e.g., statutory or regulatory guidelines). These plans are a composite of several types of information (e.g., scientific, management, stakeholder input, policy) from a variety of internal and external sources. Examples of Natural Resource Plans include fishery, protected resource, and sanctuary management plans and regulations, and natural resource restoration plans.

The Objectivity Standards for Natural Resource Plans are that they:

- Are developed according to published standards
- Are based on best information available
- Are clear, complete, and unbiased
- Are periodically reviewed

3. Documentation: Keep a file on how the information has been developed and maintained.

Prior to making a dissemination, a reviewing official will need to review records of how the information was developed and maintained. Therefore, a file should be maintained with each piece of information that records its compliance with the IQA requirements.

The Official who completes the Pre-dissemination Review will need to answer the following questions. Therefore, records should be maintained on the following:

- Explain how the information product meets the standards for utility.
- Explain how the information product meets the standards for integrity.
- Objectivity: (1) Indicate which of the following categories of information products apply for this product, and (2) Describe how this information product meets the applicable objectivity standards.

NOAA Guidance requires completion of a Pre-dissemination review form to accompany the product through the clearance process. A copy of this form is included in these materials. It requires the following information.

- Author/responsible official
- Title/description of document
- Release date
- Medium
- Statement of review by Reviewing Official at least one level above person generating the document with signature and date
- Includes statements as to affirming the utility, integrity, and objectivity of the product

D. Special Requirements for “Influential Information” that relates to risk to Human Health, Safety, and Environment

There are special provisions that apply if information is influential and constitutes a risk assessment of threats to human health, safety, or the environment.

Influential. “Influential information,” is defined as information which is expected to have a genuinely clear and substantial impact on major public policy and private sector decisions.

For influential information disseminated by federal agencies that constitutes assessment of risks to human health, safety or the environment, the following standards apply:

- To the degree that the agency action is based on science, NOAA will use: (a) the best available science and supporting studies (including peer-reviewed science and supporting studies when available), conducted in accordance with sound and objective scientific practices, and (b) data collected by accepted methods or best available methods.
- NOAA will ensure that disseminated information about risk effects is presented in a comprehensive, informative, and understandable manner.

Quantitative Risk Assessments. There are additional special requirements for Quantitative Risk Assessments. When NOAA performs and disseminates influential risk assessments that are quantitative in nature, in addition to the objectivity standards that apply, the documents must specify, to the extent practicable, the following information, adapted from the SDWA principles:

- Each ecosystem component, including population, addressed by any estimate of applicable risk effects;
- The expected or central estimate of risk for the specific ecosystem component, including population, affected;
- Each appropriate upper-bound and/or lower-bound estimate of risk;
- Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the uncertainties; and
- Additional studies known to the agency and not used in the risk estimate that support or fail to support the findings of the assessment and the rationale of why they were not used.

E. Peer Review Requirement for Certain Information

OMB issued "Final Information Quality Bulletin for Peer Review" on December 16, 2004. The Bulletin applies to "influential scientific information" and "highly influential scientific assessments," which are a subset of influential scientific information. The requirements for the peer review of influential scientific information and highly influential scientific information will apply to NMFS' dissemination of information to the public, including rule-makings under the MSA, beginning June 16, 2005. The Bulletin established minimum peer review standards, a transparent process for public disclosure, and the opportunity for public input with respect to these two categories of disseminated scientific information.

NMFS anticipates that some, but not most, of its stock assessments and other scientific information developed by its Science Centers and provided to the Councils for use in developing regulatory proposals will qualify as "influential scientific information" that must meet the Bulletin's specific peer review standards and procedures. For this category of scientific information, NMFS believes that the peer review processes that were adopted by its Science Centers within the last several years (in part in response to National Academy and other outside reviews of the agency's compliance with MSA NS 2 (best available science)) will, with minor modifications, meet the OMB Bulletin's requirements.

NMFS Science Centers use the Center for Independent Experts (CIE) as a means of obtaining timely, independent peer review of the agency's scientific information products, including stock assessments, protected species reviews, and programmatic reviews of survey and statistical methodologies, research programs, and stock assessment methodologies. The CIE, administered by the University of Miami through a contract with NMFS, is a key component of NMFS' Science Quality Assurance Program. Since these peer review procedures are already in place and operating relatively smoothly, NMFS does not believe that the OMB Bulletin will adversely affect Council-initiated FMP/Amendment actions.

In the rare case where an MSA rulemaking or other action (e.g., designation of essential fish habitat or new/revised definitions of stock status determination criteria) is based on a highly influential scientific assessment, NMFS will have to undertake more extensive and time consuming peer review, including addressing the Bulletin's required provisions for public review and comment on draft peer review documents. In these circumstances, it is anticipated that the extensive peer review requirements may likely add to the time that the Councils will need to develop management proposals. NMFS will have to address the OMB Bulletin's peer review requirements as they apply to the disseminations of scientific information products in both categories (influential scientific information and highly influential scientific assessments) prior to the beginning of Secretarial review of a Council's proposal.

F. Request for Correction

Finally, the IQA allows "any affected person" to request a correction of information relied on by an agency. The request must assert that the information does not comply with applicable guidelines under the IQA. It may be based on quality, utility, integrity, or objectivity (in presentation or substance.) or it may simply allege that the information is "incorrect."

NMFS Correspondence Control (CCU) has responsibility for processing requests for correction. If you receive a request for correction, you should immediately notify CCU. Data on requests and responses will be maintained in a database to meet OMB reporting requirements on the time invested in review and response; the review procedures (who, what); and the review outcome.

The AA is normally the Appeal Official. Appeal decisions will be based on the content of the record produced in handling of the initial request. So – Document, document, and document your compliance throughout the process.