

# **U.S. Fish and Wildlife Service Information Quality Guidelines**

Guidelines issued by the U.S. Fish and Wildlife Service (FWS) for ensuring the quality, objectivity, utility, and integrity of information disseminated by FWS.

## **PART I INTRODUCTION AND PURPOSE**

## **PART II BACKGROUND AND APPLICABILITY**

## **PART III DEFINITIONS**

## **PART IV LEGAL EFFECT**

## **PART V INFORMATION QUALITY REQUEST FOR CORRECTION PROCEDURES**

## **PART VI INFORMATION QUALITY METHODS**

## **PART I INTRODUCTION AND PURPOSE**

The mission of the U.S. Fish and Wildlife Service (FWS) is working with others to conserve, protect, and enhance fish, wildlife and plants and their habitats for the continuing benefit of the American people. These guidelines establish FWS policy and procedures for reviewing, substantiating, and correcting the quality of information it disseminates to the public. Persons affected by that information may seek and obtain, where appropriate, correction of information that they believe may be in error or otherwise not in compliance with Section 515 of the Treasury and General Government Appropriations Act of 2001 (P.L. 106-554, HR 5658). Section 515 is also known as the Information Quality Act (IQA).

## **PART II BACKGROUND AND APPLICABILITY**

In December 2000, Congress required federal agencies to publish their own guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information that they disseminate to the public (44 U.S.C. 3502). The amended language is included in section 515(a) of the P.L. 106-554, HR 5658. The Office of Management and Budget (OMB) published guidelines pursuant to the IQA in the Federal Register on February 22, 2002 (67 FR 8452), directing agencies to address the requirements of the law. In a May 24, 2002, Federal Register notice (67 FR 36642), the Department of the Interior (DOI) issued Department-wide guidelines

and instructed bureaus to prepare specific guidelines for implementing the IQA within the context of their individual missions. The FWS issued its initial guidelines in October, 2002, with the expectation that they would be updated as the FWS gained experience with the process. This document provides the current guidance to the FWS regarding influential information disseminated to the public and informs the public of FWS policies and procedures to conform to these requirements.

The guidelines supplement existing procedures for commenting on information or correcting information. The guidelines may be revised periodically to best address and ensure information quality. The current version of the FWS guidelines was put into effect, on an interim basis, on December 19, 2006. The final version will be put into effect on \_\_\_\_\_.

The quality of the information that the FWS disseminates is always important, however, factors such as homeland security, threats to public health, statutory or court-ordered deadlines, circumstances beyond our control, or other unforeseen events may limit applicability of these guidelines. The application of these factors will be determined by the Director, FWS or his/her designee which may result in a deferral, waiver, or use of alternative procedures.

#### II-1 To whom do these guidelines apply?

These guidelines apply to all FWS offices that disseminate information to the public.

#### II-2 When do these guidelines become effective?

These guidelines apply to information disseminated on or after October 1, 2002, regardless of when it was first disseminated. Information disseminated and subsequently archived is exempt from the guidelines. Archived information, in this context, connotes information that has been removed from active use in FWS decision making. Information disseminated prior to October 1, 2002, but not archived and still being used in a decision-making process is not exempt from these guidelines.

#### II-3 Do these guidelines change requirements on the public?

These guidelines do not impose new requirements or obligations on the public.

#### II-4 What do these guidelines cover?

These guidelines apply to all information disseminated by the agency to the public if it represents an official view of the FWS or DOI except as described in II-6. This includes information initiated or sponsored by the agency that states that it represents the official position of the FWS. This also includes information from an outside party that is disseminated by the agency in a manner that a reasonable person would likely infer agency endorsement or agreement with the information. The DOI Information Quality Guidelines direct that all information disseminated by the Department must comply with basic standards of quality, thus, these guidelines apply to all information disseminated by the agency with the exceptions noted above. However, only influential information, (highly influential assessments are a subset thereof) must meet the stricter elements contained in these guidelines. The OMB guidelines direct agencies to weigh the costs and the benefits of higher information quality in determining

the level of quality to which the disseminated information will be held. In circumstances where the FWS disseminates information that is not influential, the concept of ensuring the quality, objectivity, utility, and integrity of that information remains but the FWS has greater latitude in how it is accomplished.

II-5 Where are the terms in this guidance further defined?

Terms are defined in Part III. Where a different or modified definition of any of these terms is applicable in a specific context, or associated with a specific information category, that definition will be provided in the context to which it applies.

II-6 What information does not fall under these guidelines?

These guidelines apply only to information that FWS sponsors and disseminates to the public. Examples of information that would generally not meet these criteria are:

- Testimony and information presented to Congress as part of legislative or oversight processes, including drafting assistance in connection with proposed or pending legislation;
- Information accessed via Internet hyperlinks to non-FWS sites;
- Opinions that are not FWS positions, where the FWS presentation makes it clear that what is being offered is someone's opinion rather than fact or the views of FWS;
- Petitions from third parties which the FWS is required to evaluate under the Endangered Species Act or other legislation. Such petitions represent the opinions of the petitioners and the Service does not control, endorse, or sponsor information that may be presented to it by petitioning members of the public;
- Correspondence limited to an individual and FWS concerning the status of the individual's particular issue, permit, land, or case is not considered information disseminated to the public (even though such information may be accessible via the Freedom of Information Act);
- Archival records, including library holdings;
- Information intended for distribution only to government employees or FWS contractors or grantees;
- Communications between federal agencies, including management, personnel and organizational information as well as intra- or inter-agency use or sharing of government information, even if the information becomes public at some point (for example, providing comments to another federal agency on its environmental impact statement);
- FWS responses to requests for agency records pursuant to the Freedom of Information Act (FOIA), the Privacy Act, the Federal Advisory Committee Act (FACA), or other similar laws;
- Solicitations (e.g., program announcements, requests for proposals);
- Press releases, press conferences or similar communications in any medium that announce, support the announcement, or give public notice of the availability of information FWS has disseminated elsewhere or that summarize recent events or agency actions;
- Distributions of information by outside parties unless a disclaimer is attached explaining

- that the distribution is being done at the direction or sponsorship of the FWS;
- Draft FWS documents that are disseminated solely for the purpose of soliciting peer review provided that the information contains the following disclaimer: “This information is distributed solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. It has not been formally disseminated by the FWS. It does not represent and should not be construed to represent any agency determination or policy”;
- Research by federal employees and recipients of FWS grants, cooperative agreements, or contracts, where the researcher (and not FWS) decides whether and how to publish the research, does so in a manner consistent with academic protocols, and distributes the research with a disclaimer that the research does not represent an official position of the FWS. Distribution of research in this manner is not subject to these guidelines even if FWS retains ownership or other intellectual property rights because the federal government paid for the research;
- Public filings including information submitted by applicants for a permit, license, approval, authorization, grant, or other benefit or permission; information submitted voluntarily as part of public comment during rulemaking;
- Dissemination intended to be limited to subpoenas or information for adjudicative processes, including ongoing criminal or civil action or administrative enforcement action, investigation, or audit;
- Forensic reports issued in connection with ongoing criminal investigations;
- Statements of administration policy; however, any underlying information published by FWS upon which a statement is based may be subject to these guidelines;
- Descriptions of the agency, its responsibilities, ties and its organizational components; and,
- Statements related solely to the internal personnel rules and practices of FWS and other materials produced for FWS employees, contractors, agents or alumni.

II-7 What happens if information is initially not covered by these guidelines, but FWS subsequently disseminates it to the public?

If a particular distribution of information is not covered by these guidelines, the guidelines may still apply to a subsequent distribution of the information in which FWS adopts, endorses or uses the information to formulate or support a regulation, guidance, or other decision or position.

II-8 When FWS receives a request for information correction under the IQA, can members of the public submit comments or information on that request?

The FWS process, generally, does not include solicitation or acceptance of comments or information from third parties not directly involved in the IQA challenges. However, FWS reserves the right to consider such comments or information if it believes they are significant to its decision.

II-9 Who is the official responsible for FWS compliance with the guidelines?

The Director of FWS delegated authority to the Office of the Science Advisor to be the official responsible for compliance with the guidelines. The Senior Science Advisor is the responsible

official.

### **PART III     DEFINITIONS**

III-1 *Information*, in this context, is an encompassing term, meaning any communication or representation of knowledge such as facts or data, in a textual, numerical, graphic, cartographic, narrative, or audiovisual form including digital or electronic formats. Verbal presentations that are not documented by any of these media or forms are exempt from the information definition. 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 presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views. For example, a presentation, by a FWS employee in his/her official capacity, that includes interpretation of data would meet the definition of information unless the presentation included a disclaimer that the interpretation was that of the author and did not represent the position of FWS. The term also applies both to documents produced by FWS as well as the underlying data, models, scientific papers and the like that is used by FWS to create that document.

III-2 *Disseminated to the public* means publication (electronic or written) of information to a community or audience. Dissemination does not include distribution limited to government employees (federal, state, tribal or local) 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, nor does it include information from third parties that is hyper-linked directly or indirectly to the FWS web site through the Internet (see II-6).

III-3 *Sponsored information* is information FWS initiates or sponsors for distribution to the public. When information is prepared or submitted by a third party to the FWS and FWS, in turn, distributes that information or uses it to support its viewpoint in a manner that a reasonable person would likely infer FWS endorsement or agreement with it, that information is considered sponsored. For example, FWS may sponsor information that is disseminated to the public to support or represent its viewpoint, formulate or support a FWS regulation or FWS guidance, or otherwise communicate a bureau decision or position

III-4 *Government information* means information created, collected, processed, disseminated, or disposed of, by or for the federal government.

III-5 *Affected persons or organizations* are those who may use, benefit from or be harmed by the disseminated information with a material impact to their interests. An affected person or organization bears the burden of proof that a material impact to their interests has occurred or will occur as a result of information disseminated by FWS.

III-6 *Quality* is an encompassing term that includes the terms utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms collectively as *quality*.

III-7 *Utility* refers to the usefulness of the information to its intended users, including the public.

III-8 *Objectivity* includes whether the disseminated information is presented accurately, clearly, and completely, and in an unbiased manner. Objectivity involves two distinct elements: presentation and substance.

(a) Information disseminated by the FWS will be presented accurately, clearly, and completely.

(b) Information disseminated by the FWS will be treated in an unbiased fashion. In a scientific, financial, or statistical context, we will analyze the original and supporting data and develop our results using sound statistical and research methods to ensure, to the best of our knowledge that our results are not subject to bias. Where a potential for bias is identified, the FWS will address it.

(c) The limitations of the information disseminated by FWS will be explicitly stated.

III-9 *Integrity* refers to the security and protection of information from unauthorized access or revision to ensure that the information is not compromised through corruption or falsification.

III-10 *Influential*, when used in the phrase “influential scientific, financial, or statistical information,” means that we can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policy or private sector decisions, and thus, a decision or action to be taken by the Director, FWS. We are authorized to define *influential* in ways appropriate for us, given the nature and multiplicity of issues for which we are responsible. As a general rule, FWS considers an impact clear and substantial when a specific piece of information or body of information is a principal basis for a FWS position (see section VI-5). Information is influential if the same decision would be difficult to arrive at if that information was absent. It should also be noted that the definition applies to “information” itself, not to decisions that the information may support. Even if a decision or action by FWS is itself very important, a particular piece of information supporting it may or may not be “influential.”

III-11 *Reproducible* means information is capable of being substantially reproduced, subject to an acceptable degree of precision. .

#### **PART IV      LEGAL EFFECT**

These guidelines are intended only to improve the internal management of FWS relating to information quality. Nothing in these guidelines is intended to create any right or benefit,

substantive or procedural, enforceable by law or equity by a party against the United States, its agencies, its offices, or another person. These guidelines do not provide, in and by themselves, any right to judicial review.

## **PART V INFORMATION QUALITY REQUEST FOR CORRECTION PROCEDURES**

Each FWS office will incorporate the information quality principles outlined in these guidelines into existing review procedures as appropriate. Offices and Regions may develop unique and new procedures, as needed, to provide additional assurance that the information disseminated by or on behalf of their organizations is consistent with these guidelines. All FWS information (publications, reports, data, web pages, etc.) must contain a contact name/office and a means of contacting the person/office (e.g., email address, mailing address, fax or phone number). Persons seeking correction of information are encouraged to first contact the office or individual identified on an information product before submitting an official request for correction under the IQA procedures outlined below.

The FWS website ([www.fws.gov/informationquality/](http://www.fws.gov/informationquality/)) will provide the primary means for affected persons to challenge the quality of disseminated information.

Affected persons may also file a challenge with FWS by mail at:

Correspondence Control Unit  
Attention: Information Quality Correction Request Processing  
U.S. Fish and Wildlife Service  
1849 C Street, NW, Mail Stop 3238-MIB  
Washington, D.C. 20240

### V-1 Who may request a correction of information?

Any affected person or organization may request a correction of information from FWS pursuant to these guidelines.

### V-2 What are the responsibilities of the requester in seeking a request for correction of information?

A request for correction of information should always include the following:

- Statement that the Request for Correction of Information is submitted under FWS Information Quality Guidelines.
- Requester Contact Information. The name of the individual requesting correction, mailing address, telephone number, fax number or email address.
- Description of Information to Correct. The name of the FWS publication, report, or data product; the date of issuance or other identifying information, such as the URL of the web page, and a detailed description that clearly identifies the specific information

contained in that publication, report, or data production for which a correction is being sought.

- Effect of the Alleged Error. Provide an explanation that describes how the requester specifically uses the information, how the alleged error affects the requester in a material way and how a correction would resolve the error.
- A specific description of how the information does not comply with OMB, DOI, and/or FWS Information Quality Guidelines. The requester should cite the specific locations in the text of the document where the alleged error occurs and should state specifically how the information should be corrected.
- Whether the information being challenged should be considered influential within the context of the FWS guidelines (see Section VI, below), e.g., how the information constitutes a principal basis for a substantive decision by FWS.
- Supporting Documentary Evidence. Provide any supporting documentary evidence, such as comparable data or research results on the same topic. Wherever possible, the requester should link this supporting evidence to specific locations in the text of the document being challenged so that it is clear how the supporting documentation relates to the challenged information.
- Identification of any other public proceeding, including public comments, legal proceedings, or communications in which the requester has previously or is simultaneously requesting consideration of the same or similar corrections. .

V-3 Will FWS consider all requests for correction of information?

Yes. FWS will consider all requests submitted pursuant to these guidelines, and consider it for correction unless the request itself has been made in bad faith or without justification, or deemed inconsequential, and for which a response would be duplicative of existing processes, unnecessary, or unduly burdensome on the Agency. The burden of proof is on the requester with respect to showing that the information needs to be corrected as well as with respect to the type of correction sought.

V-4 How will FWS integrate its response to a request for a correction with the rulemaking process?

When the FWS engages in proposed rulemaking, the public should submit comments on the information used in support of the rulemaking as part of the public comment process rather than as a request for correction. If a request for correction is received on a rulemaking, the FWS will respond to the request for correction in the next rulemaking document, which will generally be the final rule. If the FWS determines that an earlier response would not unduly delay issuance of the FWS action and the requester has shown a reasonable likelihood of suffering harm from the unresolved request, the FWS will consider responding to the requester prior to issuing the next rulemaking document.

V-5 What type of requests would be considered duplicative, unnecessary, or unduly burdensome?

The FWS will not consider a request for correction if it is not from an “affected person”. The FWS may choose to simply refer to a parallel process if a request for correction substantially

duplicates a previous request. FWS may choose not to invest substantial staff resources to evaluate a request for correction when the information is not influential (e.g., the challenged information is not a principal basis for a FWS position). The Director of the FWS, or designee, reserves the right to judge requests as duplicative, unnecessary or duly burdensome if the requester does not meet the requirements set forth in section V-2.

The federal rulemaking process imposes a legal obligation on federal agencies to conduct a comprehensive public comment process. As such, we must solicit comments on our rulemaking actions, consider all comments received during the public comment period, and respond to the comments germane to the action. In order to prevent unnecessary delay in the rule making process, if a request is submitted after the comment period closes, the requester must clearly demonstrate that the information in question is pivotal to the decision being made.

V-6 How will FWS respond to a request for correction of information?

All requests about FWS information quality will be tracked by the Service's Correspondence Control Unit (CCU), which will route requests to the Program or Regional Office responsible for the information. CCU will notify the requester of receipt of the request within 14 calendar days.

If a request for correction of information is appropriate for consideration, FWS will review the request and issue a decision within 90 calendar days from receipt of the challenge. FWS will send the results of this decision to the requester with an explanation for the decision. If the request requires more than 90 calendar days to resolve, the agency will inform the requester that more time is required, indicating the reason(s) why and providing an alternative timeline for reaching a decision. If a request is approved, FWS will take corrective action. The time required for corrective action to be taken will depend on the circumstances of each situation. Corrective measures may include personal contacts via a letter, form letters, press releases or postings on the FWS website to correct a widely disseminated error or address a frequently raised request. Corrective measures, where appropriate, will be designed to provide notice to directly affected persons of any corrections made.

V-7 Will FWS reconsider its decision on a request for the correction of information?

Requesters of corrective actions who are dissatisfied with a FWS decision regarding their request may appeal the decision. Appeals for reconsideration must be submitted within 21 calendar days from the date on the decision letter to the requester and should contain the following:

- Indication that the person is seeking an appeal of a FWS decision on a previously submitted request for a correction of information, including the date of the original submission and date of FWS decision;
- Indication of how the individual is an "affected person" under the provisions of these guidelines;
- Name and contact information.
- Explanation of the disagreement with the FWS decision and, if possible, a recommendation of corrective action; and,
- A copy of the original request for the correction of information.

V-8 How does FWS process requests for reconsideration of FWS decisions?

Requests for reconsideration of FWS decisions related to IQA will be logged and tracked by the CCU. Appellants must limit their request for reconsideration to the FWS' decision on issues raised in the original IQA challenge. Appeals will be reviewed by a panel consisting of Directorate-level officials from the FWS and, when available, another Department of the Interior agency such as the U.S. Geological Survey. The appeals panel will make a recommendation which will be forwarded to the Director of the FWS. The Director of the FWS or his/her designated representative will make the final decision on the appeal within 60 calendar days from receipt of the appeal in FWS.

V-9 What is the reporting requirement for oversight of these guidelines?

The Senior Science Advisor, Office of the Science Advisor, will submit reports to the DOI, via the Assistant Secretary-Fish, Wildlife and Parks for consolidated submission to OMB on an annual basis. The report will include the number, nature, and resolution of complaints received by FWS under the provisions of these guidelines in the format requested by OMB.

## **PART VI INFORMATION QUALITY METHODS**

All information that is disseminated to the public is covered under the IQA and measures must be taken to ensure its quality. Disseminated information that can reasonably be determined to have a clear and substantial impact on important public policy and private sector decisions is influential. This section describes general methods for ensuring information quality of all disseminated information and more rigorous methods for ensuring the quality of influential information.

VI-1 How does FWS ensure the quality of disseminated information?

FWS ensures the quality of information by using policies and procedures appropriate to the information product. These procedures include senior management oversight and controls, formal and informal peer review, peer editing, product review, internal approval via surname, and error correction. Higher levels of scrutiny are applied to influential scientific, financial or statistical information, which must adhere to a higher standard of quality. Specifically, influential information be reproducible (see III-11). Offices that disseminate information to the public will ensure the quality of the information using the appropriate and feasible means, such as but not limited to, internal review, independent peer review, and repeating studies to verify results. FWS will review original information from other sources for adequacy of prior peer review, and for suitability or strength of the information to advise the issues at hand. FWS may conduct a post hoc peer review of original information from other sources when circumstances warrant.

For example, an analysis of data may create a result that can be displayed on a map. Such an analysis is subject to these guidelines. Interactive mapping sites that contain data from non-FWS sources will clearly inform the user of the source of the information.

VI-2 How does FWS ensure the quality of "influential" scientific information?

Per OMB's guidelines, FWS facilitates the reproducibility of influential information. Independent investigators using the same experimental design and methods should have the capability of reproducing the results of an investigation originally conducted by another researcher or group of researchers with an acceptable degree of imprecision or error.

In addition, FWS adheres to the OMB Memorandum (M-05-030) "Final Information Quality Bulletin for Peer Review" dated December 16, 2004, to ensure that influential scientific information disseminated to the public is subject to peer review. The Bulletin directs agencies to choose an adequate peer review mechanism considering the complexity and novelty of the science, the relevance of the information to decision making, the significance of the policy decision, the extent of prior peer review and the expected benefits and costs. In addition, the agencies are directed to consider tradeoffs between depth of peer review and timeliness. FWS publishes its agenda of influential scientific information and highly influential scientific assessments on its website at [http://www.fws.gov/informationquality/peer\\_review/index.html](http://www.fws.gov/informationquality/peer_review/index.html). Information types and sources, analytical methods, and assumptions will be described in administrative records for influential information.

VI-3 What is the context in which the information deemed "influential" will be changed?

FWS will correct errors in influential information in draft documents or proposed management actions before final decisions are made, if possible (see section V-4). Corrections to information in approved management documents typically will be treated as addendums to decision documents or administrative records. The decisions will be revisited according to the regulatory, statutory, or policy guidance for the type of management decision being made, unless circumstances warrant more immediate attention.

VI-4 Does FWS ensure the quality of information from external sources?

The FWS does not take responsibility for the quality of the information produced by other entities unless that information is referenced in FWS documents and is a principal basis for a FWS position. In these cases FWS will ensure the quality and transparency of information provided by external sources (e.g., state and local governments). When prior review of information is insufficient, the FWS will conduct post hoc peer review of influential scientific information from external sources as appropriate.

VI-5 How will FWS determine whether specific information is "influential?"

Influential information means that FWS can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public or private sector decisions. FWS interprets the phrase "can reasonably determine" to mean that the agency is convinced that the impact has a high probability (certainty) of occurring. As a general rule, FWS considers an impact clear and substantial when a specific piece of information or body of information is a principal basis for a FWS position. If a FWS position would lose its fundamental scientific, financial or statistical underpinnings if the information was absent, then this information is the principal basis for the position, and its presence has a clear and substantial impact. Finally, the clear and substantial impact must be on an important public policy or private sector decision.

VI-6 How will FWS determine what is “important” public policy or private sector decisions?

The FWS will generally consider important decisions as those in support of the Director’s decisions or actions (e.g., rules, substantive notices, policy documents, studies, guidance) and issues that are highly controversial or have cross-agency interest or affect cross-agency policies.

Important public policy or private sector decisions reflect both breadth and intensity of effect, which may include environmental, economic, social, cultural or other effects. Every decision that FWS makes is important at some level. Even if information has a clear and substantial impact, it is not influential if the impact is not on important policy, economic, or other decisions.

Influential information must be a basis for or strong component of important public policy or private sector decision.

VI-7 How will FWS determine the “utility” of information?

While assessing the usefulness of information that we disseminate to the public, FWS will consider the uses of the information not only from our perspective, but also from the perspective of the public. “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.

VI-8 How will FWS determine “integrity” of information?

Prior to dissemination, FWS information 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 FWS 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 FWS is safeguarded under legislation such as the Privacy Act and Titles 13, 15, and 22 of the U.S. Code.

VI-9 How will FWS determine the objectivity of FWS information?

The FWS definition of objectivity includes whether the disseminated information is presented accurately, clearly, and completely, and in an unbiased manner. To achieve this end, FWS will subject information to review by persons qualified to judge objectivity (as defined by the type of information and the circumstances in which it will be used). Such a review will be conducted before decision making, unless legal deadlines or other constraints prevent such a timely review. In such cases, the review may have to be post hoc. To the extent they are understood, we will explicitly state assumptions, limitations or biases related to the information

Sometimes, supporting documentation must also be disseminated in order to ensure a more clear, complete, and unbiased presentation. In those cases, FWS will identify the sources of supporting information.

If data and analytical results have been subjected to formal, independent, peer review, we will generally presume that the information is of acceptable objectivity. However, a request for correction or the FWS may rebut this presumption based on a persuasive showing in a particular instance. If we use peer review to help satisfy the objectivity standard, the review process employed must meet the general criteria for competent and credible peer review (OMB M-05-03, “Final Information Quality Bulletin for Peer Review”).

Transparency about research design and methods is pivotal to reproducibility. With regard to analytical results, we will generally require sufficient transparency about data and methods that a qualified member of the public could undertake an independent reanalysis. These transparency standards apply to our analysis of data from a single study as well as to analyses that combine information from multiple studies. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

In situations where public access to data and methods will not occur due to other compelling interests, we will apply especially rigorous checks to analytical results and documents. We will, however, disclose the specific data sources used, and the specific quantitative methods and assumptions we employed. We will define the type of checks, and the level of detail for documentation, given the nature and complexity of the issues. With regard to analysis of risks, human health, safety, and the environment, we will use or adapt the quality principles applied by Congress to risk information used and disseminated under the Safe Drinking Water Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)).

VI – 10 How will FWS describe the strengths and weaknesses of the data used in influential scientific information and highly influential scientific assessments?

The preparer of a highly influential assessment or of influential information will document the strengths and weaknesses of the data underlying the assessment/information so that the reader will understand the context for the FWS decision. The narrative will be contained in the administrative record of the issue under consideration. The documentation may be done in a narrative that includes a complete literature cited section, and an assessment of the strengths and weaknesses of the information used for advising the decision at hand. The narrative’s form and length is left to the preparer. The following bullet points provide questions to consider in the narrative.

- What types of research studies does the assessment/information rely upon (e.g. experimental studies with controls, statistically designed observational studies that test hypotheses, monitoring studies, information synthesis, professional judgment etc.)?
- How recent is the research?

- What are the sources for the underlying data that support the assessment/information (e.g. peer reviewed article reporting primary data or data synthesis, unpublished peer reviewed reports, on-line publication, textbook, personal communication etc.)?
- Which of the sources were most crucial to the conclusions reached in the assessment/information?
- What type of review did each source receive (anonymous independent peer review, external peer review, agency review, public review and comment etc.)?
- Were the reviewers independent of the FWS? Were the reviewers independent of individuals or groups advocating a certain course of action by FWS?
- Were the reviews in compliance with OMB M-05-03, “Final Information Quality Bulletin for Peer Review”?

Two examples of how one might provide such a characterization are provided below:

Example 1: (A number of references are listed.) These references were the primary sources of data that provided the basis for the decision. They are peer reviewed studies with an experimental design that includes controls and testable hypotheses. They were completed within the last 5 years and were independently reviewed by non-FWS personnel and published in scientific journals.

Example 2: (A number of references are listed.) These references were articles and sources of data that provided specific data points that were included in the decision document, but by themselves did not primarily contribute to the decision. These citations are a combination of fact sheets, summaries of information, professional judgments, and personal communications that have not been peer reviewed. Most of the data is current (within the last 7 years).

VI-11 How will scientific citations be organized in documents prepared for notice and comment in the Federal Register?

The FWS standard for scientific citations in this circumstance is: *Council of Biology Editors Style Manual: A Guide for Authors, Editors, and Publishers in the Biological Sciences*. CBE Style Manual Committee. 5<sup>th</sup> ed. Council of Biology Editors, 1983.

The FWS usually does not include a literature cited section in the document actually published in the Federal Register because of the cost and our experience that interested persons will contact the FWS to request supporting documents that will include the literature cited section. However, even though the literature cited section does not actually appear in the Federal Register, it must be made available to the public and prepared as a part of the administrative record.