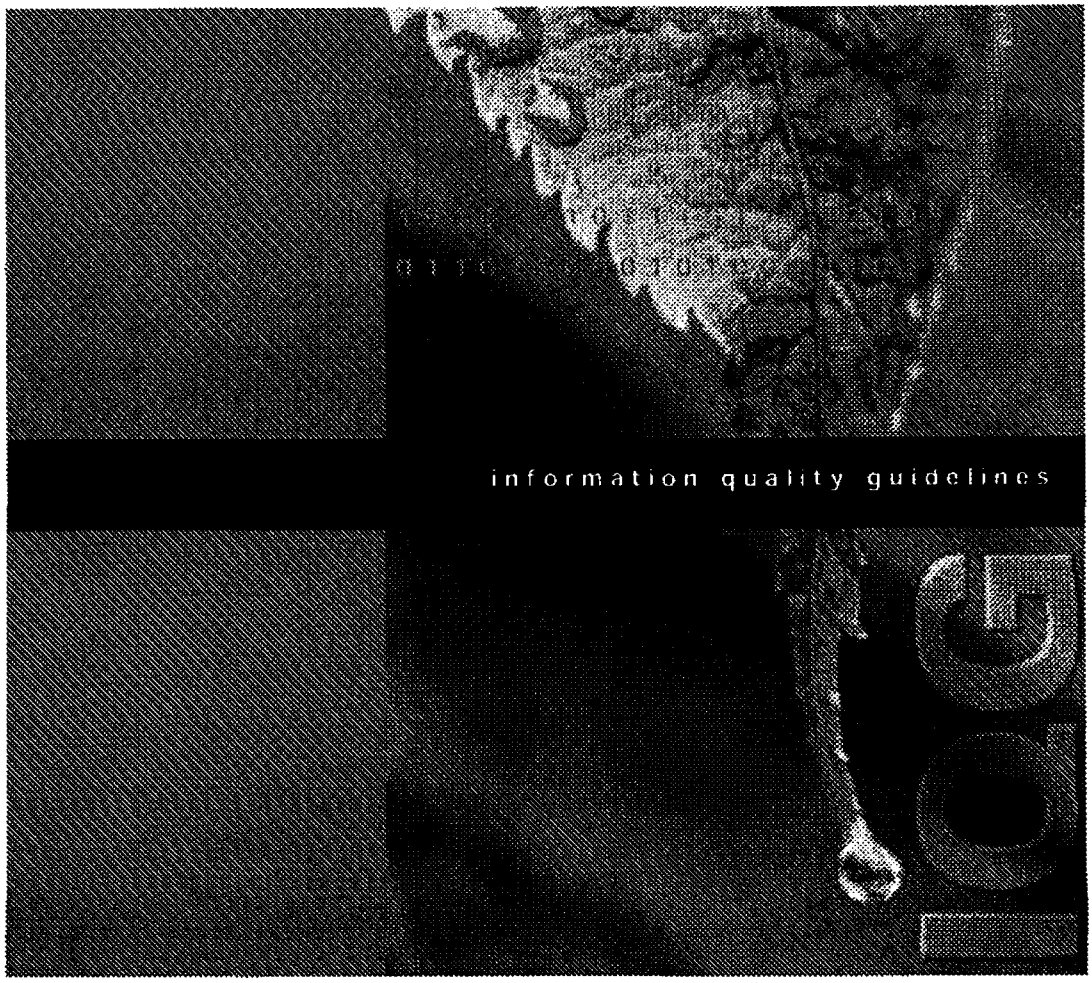
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Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency



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Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency

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Addendum
06/24/2004

This addendum updates the contact information for submittal of Requests for Correction under the Information Quality Guidelines (Section 8.2 of the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA*, October, 2002)

An affected person may submit an RFC via any one of the methods listed here:

- **E-mail** at quality@epa.gov
- **Fax** at (202) 565-2441
- **Mail** to Information Quality Guidelines Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, DC, 20460
- **By courier or in person** to Information Quality Guidelines Staff, Ronald Reagan Building, Room M1200, 1300 Pennsylvania Ave., N.W., Washington, DC

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency

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1 Introduction

The Environmental Protection Agency (EPA) is committed to providing public access to environmental information. This commitment is integral to our mission to protect human health and the environment. One of our goals is that all parts of society - including communities, individuals, businesses, State and local governments, Tribal governments - have access to accurate information sufficient to effectively participate in managing human health and environmental risks. To fulfill this and other important goals, EPA must rely upon information of appropriate quality for each decision we make.

Developed in response to guidelines issued by the Office of Management and Budget (OMB)[1] under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (the Guidelines) contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information we disseminate. The Guidelines also outline administrative mechanisms for EPA pre-dissemination review of information products and describe some new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB guidelines. Beyond policies and procedures these Guidelines also incorporate the following performance goals:

- Disseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity.
- The principles of information quality should be integrated into each step of EPA's development of information, including creation, collection, maintenance, and dissemination.
- Administrative mechanisms for correction should be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into EPA's information resources management and administrative practices.

OMB encourages agencies to incorporate standards and procedures into existing information resources management practices rather than create new, potentially duplicative processes. EPA has taken this advice and relies on numerous existing quality-related policies in these Guidelines. EPA will work to ensure seamless implementation into existing practices. It is expected that EPA managers and staff will familiarize themselves with these Guidelines, and will carefully review existing program policies and procedures in order to accommodate the principles outlined in this document.

[1]Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, OMB, 2002. (67 FR 8452) Herein after "OMB guidelines". http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

EPA's Guidelines are intended to carry out OMB's government-wide policy regarding information we disseminate to the public. Our Guidelines reflect EPA's best effort to present our goals and commitments for ensuring and maximizing the quality of information we disseminate. As such, they are not a regulation and do not change or substitute for any legal requirements. They provide non-binding policy and procedural guidance, and are therefore not intended to create legal rights, impose legally binding requirements or obligations on EPA or the public when applied in particular situations, or change or impact the status of information we disseminate, nor to contravene any other legal requirements that may apply to particular agency determinations or other actions. EPA's intention is to fully implement these Guidelines in order to achieve the purposes of Section 515.

These Guidelines are the product of an open, collaborative process between EPA and numerous EPA stakeholders. The Guidelines development process is described in the Appendix to this document. EPA received many public comments and has addressed most comments in these Guidelines. A discussion of public comments is also provided in the Appendix and is grouped by overarching themes and comments by Guidelines topic areas. EPA views these Guidelines as a living document, and anticipates their revision as we work to further ensure and maximize information quality.

2 EPA Mission and Commitment to Quality

2.1 EPA's Mission and Commitment to Public Access

The mission of the EPA is to protect human health and safeguard the natural environment upon which life depends. EPA is committed to making America's air cleaner, water purer, and land better protected and to work closely with its Federal, State, Tribal, and local government partners; with citizens; and with the regulated community to accomplish its mission. In addition, the United States plays a leadership role in working with other nations to protect the global environment.

EPA's commitment to expanding and enhancing access to environmental information is articulated in our Strategic Plan. EPA works every day to expand the public's right to know about and understand their environment by providing and facilitating access to a wealth of information about public health and local environmental issues and conditions. This enhances citizen understanding and involvement and provides people with tools to protect their families and their communities.

EPA statutory responsibilities to protect human health and safeguard the natural environment are described in the statutes that mandate and govern our programs. EPA manages those programs in concert with numerous other government and private sector partners. As Congress intended, each statute provides regulatory expectations including information quality considerations and principles. Some statutes are more specific than others, but overall, each directs EPA and other agencies in how we regulate to protect human health and the environment. For example, the Safe Drinking Water Act (SDWA) Amendments of 1996 set forth certain quality principles for how EPA should conduct human health risk assessments and characterize the potential risks to humans from drinking water contaminants. Information quality is a key component of every statute that governs our mission.

2.2 Information Management in EPA

The collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission. Information about human health and the environment -- environmental characteristics; physical, chemical, and biological processes; and chemical and other pollutants -- underlies all environmental management and health protection decisions. The availability of, and access to, information and the analytical tools to understand it are essential for assessing environmental and human health risks, designing appropriate and cost-effective policies and response strategies, and measuring environmental improvements.

EPA works every day to ensure information quality, but we do not wait until the point of dissemination to consider important quality principles. While the final review of a document before it is published is very important to ensuring a product of high quality, we know that in order to maximize quality, we must start much earlier. When you read an EPA report at your local library or view EPA information on our web site, that information is the result of processes

undertaken by EPA and our partners that assured quality along each step of the way. To better describe this interrelated information quality process, the following presents some of the major roles that EPA plays in its effort to ensure and maximize the quality of the information:

- **EPA is a collector and generator of information:** While most of our programs rely on States, Tribes, or the private sector to collect and report information to EPA, there are some programs in which EPA collects its own information. One example is the Agency's enforcement and compliance program, under which EPA collects samples in the field or conducts onsite inspections. We also conduct original, scientific research at headquarters, in Regional Offices, and at our research laboratories to investigate and better understand how our environment works, how humans react to chemical pollutants and other environmental contaminants, and how to model our natural environment to assess the potential impact of environmental management activities. Ensuring the quality of collected information is central to our mission.

- **EPA is a recipient of information:** EPA receives a large amount of information that external parties volunteer or provide under statutory and other mandates. Much of the environmental information submitted to EPA is processed and stored in Agency information management systems. While, we work to ensure and maximize the integrity of that information through a variety of mechanisms and policies, we have varying levels of quality controls over information developed or collected by outside parties. This information generally falls into one of four categories:

  - **Information collected through contracts with EPA.** Examples of this information include studies and collection and analysis of data by parties that are under a contractual obligation with EPA. Since EPA is responsible for managing the work assigned to contractors, EPA has a relatively high degree of control over the quality of this information.

  - **Information collected through grants and cooperative agreements with EPA.** Examples of this information include scientific studies that are performed under research grants and data collected by State agencies or other grantees to assess regulatory compliance or environmental trends. Although EPA has less control over grantees than contractors, EPA can and does include conditions in grants and cooperative agreements requiring recipients to meet certain criteria.

  - **Information submitted to EPA as part of a requirement under a statute, regulation, permit, order or other mandate.** Examples of this information include required test data for pesticides or chemicals, Toxics Release Inventory (TRI) submissions and compliance information submitted to EPA by States and the regulated community. EPA ensures

quality control of such information through regulatory requirements, such as requiring samples to be analyzed by specific analytical procedures and by certified laboratories. However, each EPA program has specific statutory authorities which may affect its ability to impose certain quality practices.

- The final category of information that is not included in any of the above three categories includes **information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision.** Examples of this information include scientific studies published in journal articles and test data obtained from other Federal agencies, industry, and others. EPA may not have any financial ties or regulatory requirements to control the quality of this type of information.

While the quality of information submitted to EPA is the responsibility of the original collector of the information, we nevertheless maintain a robust quality system, that addresses information related to the first three bullets above by including regulatory requirements for quality assurance for EPA contracts, grants, and assistance agreements. For the fourth category, we intend to develop and publish factors that EPA would use in the future to assess the quality of voluntary submissions or information that the Agency gathers for its own use.

- **EPA is a user of information:** Upon placement in our information management systems, information becomes available for use by many people and systems. EPA users may include Program managers, information product developers, or automated financial tracking systems. Depending on the extent of public release, users may also include city planners, homeowners, teachers, engineers, or community activists, to name a few. To satisfy this broad spectrum of users, it is critical that we present information in an unbiased context with thorough documentation.

  EPA is moving beyond routine administration of regulatory information and working in concert with States and other stakeholders to provide new information products that are responsive to identified users. Increasingly, information products are derived from information originally collected to support State or Federal regulatory programs or management activities. Assuring the suitability of this information for new applications is of paramount importance.

- **EPA is a conduit for information:** Another major role that EPA plays in the management of information is as a provider of public access. Such access enables public involvement in how EPA achieves it mission. We provide access to a variety of information holdings. Some information distributed by EPA includes information collected through contracts; information collected through grants and

cooperative agreements; information submitted to EPA as part of a requirement under a statute, regulation, permit, order, or other mandate; and information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision. In some cases, EPA serves as an important conduit for information generated by external parties; however, the quality of that information is the responsibility of the external information developer, unless EPA endorses or adopts it.

2.3 EPA's Relationship with State, Tribal, and Local Governments

As mentioned in the previous section, EPA works with a variety of partners to achieve its mission. Our key government partners not only provide information, they also work with EPA to manage and implement programs and communicate with the public about issues of concern. In addition to implementing national programs through EPA Headquarters Program Offices, a vast network of EPA Regions and other Federal, State, Tribal and local governments implement both mandated and voluntary programs. This same network collects, uses, and distributes a wide range of information. EPA plans to coordinate with these partners to ensure the Guidelines are appropriate and effective.

One major mechanism to ensure and maximize information integrity is the National Environmental Information Exchange Network (NEIEN, or Network). The result of an important partnership between EPA, States and Tribal governments, the Network seeks to enhance the Agency's information architecture to ensure timely and one-stop reporting from many of EPA's information partners. Key components include the establishment of the Central Data Exchange (CDX) portal and a System of Access for internal and external users. When fully implemented, the Network and its many components will enhance EPA and the public's ability to access, use, and integrate information and the ability of external providers to report to EPA.

3 OMB Guidelines

In Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), Congress directed OMB to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies...." The OMB guidelines direct agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to:

- Issue their own information quality guidelines to ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, by no later than one year after the date of issuance of the OMB guidelines;
- Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the OMB or agency guidelines; and
- Report to the Director of OMB the number and nature of complaints received by the agency regarding agency compliance with OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

The OMB guidelines provide some basic principles for agencies to consider when developing their own guidelines including:

- Guidelines should be flexible enough to address all communication media and variety of scope and importance of information products.
- Some agency information may need to meet higher or more specific expectations for objectivity, utility, and integrity. Information of greater importance should be held to a higher quality standard.
- Ensuring and maximizing quality, objectivity, utility, and integrity comes at a cost, so agencies should use an approach that weighs the costs and benefits of higher information quality.
- Agencies should adopt a common sense approach that builds on existing processes and procedures. It is important that agency guidelines do not impose unnecessary administrative burdens or inhibit agencies from disseminating quality information to the public.

4 Existing Policies and Procedures that Ensure and Maximize Information Quality

EPA is dedicated to the collection, generation, and dissemination of high quality information. We disseminate a wide variety of information products, ranging from comprehensive scientific assessments of potential health risks,[2] to web-based applications that provide compliance information and map the location of regulated entities,[3] to simple fact sheets for school children.[4] As a result of this diversity of information-related products and practices, different EPA programs have evolved specialized approaches to information quality assurance. The OMB guidelines encourage agencies to avoid the creation of "new and potentially duplicative or contradictory processes." Further, OMB stresses that its guidelines are not intended to "impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public." In this spirit, EPA seeks to foster the continuous improvement of existing information quality activities and programs. In implementing these guidelines, we note that ensuring the quality of information is a key objective alongside other EPA objectives, such as ensuring the success of Agency missions, observing budget and resource priorities and restraints, and providing useful information to the public. EPA intends to implement these Guidelines in a way that will achieve all these objectives in a harmonious way in conjunction with our existing guidelines and policies, some of which are outlined below. These examples illustrate some of the numerous systems and practices in place that address the quality, objectivity, utility, and integrity of information.

4.1 Quality System

The EPA Agency-wide Quality System helps ensure that EPA organizations maximize the quality of environmental information, including information disseminated by the Agency. A graded approach is used to establish quality criteria that are appropriate for the intended use of the information and the resources available. The Quality System is documented in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and the "EPA Quality Manual."[5] To implement the Quality System, EPA organizations (1) assign a quality assurance manager, or person assigned to an equivalent position, who has sufficient technical and management expertise and authority to conduct independent oversight of the implementation of the organization's quality system; (2) develop a Quality Management Plan, which documents the organization's quality system; (3) conduct an annual assessment of the organization's quality system; (4) use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information

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[2] http://cfpub.epa.gov/ncea/cfm/partmatt.cfm

[3] http://www.epa.gov/enviro/wmc/

[4] http://www.epa.gov/kids

[5] EPA Quality Manual for Environmental Programs 5360 A1. May 2000. http://www.epa.gov/quality/qs-docs/5360.pdf

collection and/or use; (5) develop Quality Assurance Project Plan(s), or equivalent document(s) for all applicable projects and tasks involving environmental data; (6) conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use; (7) implement all Agency-wide Quality System components in all applicable EPA-funded extramural agreements; and (8) provide appropriate training, for all levels of management and staff.

The EPA Quality System may also apply to non-EPA organizations, with key principles incorporated in the applicable regulations governing contracts, grants, and cooperative agreements. EPA Quality System provisions may also be invoked as part of negotiated agreements such as memoranda of understanding. Non-EPA organizations that may be subject to EPA Quality System requirements include (a) any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 CFR part 46, (including applicable work assignments, delivery orders, and task orders); and (b) other government agencies receiving assistance from EPA through interagency agreements. Separate quality assurance requirements for assistance recipients are set forth in 40 CFR part 30 (governing assistance agreements with institutions of higher education, hospitals, and other non-profit recipients of financial assistance) and 40 CFR parts 31 and 35 (government assistance agreements with State, Tribal, and local governments).

4.2 Peer Review Policy

In addition to the Quality System, EPA's Peer Review Policy provides that major scientifically and technically based work products (including scientific, engineering, economic, or statistical documents) related to Agency decisions should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories, and field offices determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made consistent with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. For other work products, internal peer review is an acceptable alternative to external peer review. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial. The basis for EPA peer review policy is articulated in *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency*.[6] The Peer Review Policy was first issued in January, 1993, and was updated in June, 1994. In addition to the policy, EPA has published a Peer Review Handbook,[7] which provides detailed guidance for implementing the policy. The handbook was last revised December, 2000.

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[6]Peer Review and Peer Involvement at the U.S. EPA. June 7, 1994. http://www.epa.gov/osp/spc/perevmem.htm

[7]Peer Review Handbook, 2nd Edition, U.S. EPA, Science Policy Council, December 2000, EPA 100-B-00-001. http://www.epa.gov/osp/spc/prhandbk.pdf

4.3 Action Development Process

The Agency's Action Development Process also serves to ensure and maximize the quality of EPA disseminated information. Top Agency actions and Economically Significant actions as designated under Executive Order 12866 are developed as part of the Agency's Action Development Process. The Action Development Process ensures the early and timely involvement of senior management at key decision milestones to facilitate the consideration of a broad range of regulatory and non-regulatory options and analytic approaches. Of particular importance to the Action Development Process is ensuring that our scientists, economists, and others with technical expertise are appropriately involved in determining needed analyses and research, identifying alternatives, and selecting options. Program Offices and Regional Offices are invited to participate to provide their unique perspectives and expertise. Effective consultation with policy advisors (e.g., Senior Policy Council, Science Policy Council), co-regulators (e.g., States, Tribes, and local governments), and stakeholders is also part of the process. Final Agency Review (FAR) generally takes place before the release of substantive information associated with these actions. The FAR process ensures the consistency of any policy determinations, as well as the quality of the information underlying each policy determination and its presentation.

4.4 Integrated Error Correction Process

The Agency's Integrated Error Correction Process[8] (IECP) is a process by which members of the public can notify EPA of a potential data error in information EPA distributes or disseminates. This process builds on existing data processes through which discrete, numerical errors in our data systems are reported to EPA. The IECP has made these tools more prominent and easier to use. Individuals who identify potential data errors on the EPA web site can contact us through the IECP by using the "Report Error" button or error correction hypertext found on major data bases throughout EPA's web site. EPA reviews the error notification and assists in bringing the notification to resolution with those who are responsible for the data within or outside the Agency, as appropriate. The IECP tracks this entire process from notification through final resolution.

[8]Integrated Error Correction Process for Environmental Data. http://www.epa.gov/edx/iecp.html

4.5 Information Resources Management Manual

The EPA Information Resources Management (IRM) Manual[9] articulates and describes many of our information development and management procedures and policies, including information security, data standards, records management, information collection, and library services. Especially important in the context of the Guidelines provided in this document, the IRM Manual describes how we maintain and ensure information integrity. We believe that maintaining information integrity refers to keeping information "unaltered," i.e., free from unauthorized or accidental modification or destruction. These integrity principles apply to all information. Inappropriately changed or modified data or software impacts information integrity and compromises the value of the information system. Because of the importance of EPA's information to the decisions made by the Agency, its partners, and the public, it is our responsibility to ensure that the information is, and remains, accurate and credible.

Beyond addressing integrity concerns, the IRM Manual also includes Agency policy on public access and records management. These are key chapters that enable EPA to ensure transparency and the reproducibility of information.

4.6 Risk Characterization Policy and Handbook

The EPA Risk Characterization Policy and Handbook[10] provide guidance for risk characterization that is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk. The Policy calls for a transparent process and products that are clear, consistent and reasonable. The Handbook is designed to provide risk assessors, risk managers, and other decision-makers an understanding of the goals and principles of risk characterization.

4.7 Program-Specific Policies

We mentioned just a few of the Agency's major policies that ensure and maximize the quality of information we disseminate. In addition to these Agency-wide systems and procedures, Program Offices and Regions implement many Office-level and program-specific procedures to ensure and maximize information quality. The purpose of these Guidelines is to serve as a common thread that ties all these policies together under the topics provided by OMB: objectivity, integrity and utility. EPA's approach to ensuring and maximizing quality is necessarily distributed across all levels of EPA's organizational hierarchy, including Offices, Regions, divisions, projects, and even products. Oftentimes, there are different quality considerations for different types of products. For example, the quality principles associated with a risk assessment

[9] EPA Directive 2100 Information Resources Management Policy Manual. http://www.epa.gov/irmpoli8/polman/

[10] Risk Characterization Handbook, U.S. EPA, Science Policy Council, December 2000. http://www.epa.gov/osp/spc/2riskchr.htm

differ from those associated with developing a new model. The Agency currently has a comprehensive but distributed system of policies to address such unique quality considerations. These Guidelines provide us with a mechanism to help coordinate and synthesize our quality policies and procedures.

4.8 EPA Commitment to Continuous Improvement

As suggested above, we will continue to work to ensure that our many policies and procedures are appropriately implemented, synthesized, and revised as needed. One way to build on achievements and learn from mistakes is to document lessons learned about specific activities or products. For example, the documents that present guidance and tools for implementing the Quality System are routinely subjected to external peer review during their development; comments from the reviewers are addressed and responses reviewed by management before the document is issued. Each document is formally reviewed every five years and is either reissued, revised as needed, or rescinded. If important new information or approaches evolve between reviews, the document may be reviewed and revised more frequently.

4.9 Summary of New Activities and Initiatives

In response to OMB's guidelines, EPA recognizes that it will be incorporating new policies and administrative mechanisms. As we reaffirm our commitment to our existing policies and procedures that ensure and maximize quality, we also plan to address the following new areas of focus and commitment:

- Working with the public to develop assessment factors that we will use to assess the quality of information developed by external parties, prior to EPA's use of that information.

- Affirming a new commitment to information quality, especially the transparency of information products.

- Establishing Agency-wide correction process and request for reconsideration panel to provide a centralized point of access for all affected parties to seek and obtain the correction of disseminated information that they believe does not conform to these Guidelines or the OMB guidelines.

5 Guidelines Scope and Applicability

5.1 What is "Quality" According to the Guidelines?

Consistent with the OMB guidelines, EPA is issuing these Guidelines to ensure and maximize the quality, including objectivity, utility and integrity, of disseminated information. Objectivity, integrity, and utility are defined here, consistent with the OMB guidelines. "Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. "Utility" refers to the usefulness of the information to the intended users.

5.2 What is the Purpose of these Guidelines?

The collection, use, and dissemination of information of known and appropriate quality is integral to ensuring that EPA achieves its mission. Information about the environment and human health underlies all environmental management decisions. Information and the analytical tools to understand it are essential for assessing environmental and human health risks, designing appropriate and cost-effective policies and response strategies, and measuring environmental improvements.

These Guidelines describe EPA's policy and procedures for reviewing and substantiating the quality of information before EPA disseminates it. They describe our administrative mechanisms for enabling affected persons to seek and obtain, where appropriate, correction of information disseminated by EPA that they believe does not comply with EPA or OMB guidelines.

5.3 When Do these Guidelines Apply?

These Guidelines apply to "information" EPA disseminates to the public. "Information," for purposes of these Guidelines, generally includes any communication or representation of knowledge such as facts or data, in any medium or form. Preliminary information EPA disseminates to the public is also considered "information" for the purposes of the Guidelines. Information generally includes material that EPA disseminates from a web page. However not all web content is considered "information" under these Guidelines (e.g., certain information from outside sources that is not adopted, endorsed, or used by EPA to support an Agency decision or position).

For purposes of these Guidelines, EPA disseminates information to the public when EPA initiates or sponsors the distribution of information to the public.

- EPA initiates a distribution of information if EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.

- EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA's viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position.

- Agency-sponsored distribution includes instances where EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

EPA intends to use notices to explain the status of information, so that users will be aware of whether the information is being distributed to support or represent EPA's viewpoint.

5.4 What is Not Covered by these Guidelines?

If an item is not considered "information," these Guidelines do not apply. Examples of items that are not considered information include Internet hyperlinks and other references to information distributed by others, and opinions, where EPA's presentation makes it clear that what is being offered is someone's opinion rather than fact or EPA's views.

"Dissemination" for the purposes of these Guidelines does not include distributions of information that EPA does not initiate or sponsor. Below is a sample of various types of information that would not generally be considered disseminated by EPA to the public:

- Distribution of information intended only for government employees (including intra- or interagency use or sharing) or recipients of government contracts, grants, or cooperative agreements. Intra-agency use of information includes use of information pertaining to basic agency operations, such as management, personnel, and organizational information.

- EPA's response to requests for agency records under the Freedom of Information Act (FOIA), the Privacy Act, the Federal Advisory Committee Act (FACA), or other similar laws.

- Distribution of information in correspondence directed to individuals or persons (i.e., any individual, group, or entity, including any government or political subdivision thereof, or Federal governmental component/unit).

- Information of an ephemeral nature, such as press releases, fact sheets, press conferences, and similar communications, in any medium that advises the public of an event or activity or announces information EPA has disseminated

elsewhere; interviews, speeches, and similar communications that EPA does not disseminate to the public beyond their original context, such as by placing them on the Internet. If a speech, press release, or other "ephemeral" communication is about an information product disseminated elsewhere by EPA, the product itself will be covered by these Guidelines.

- Information presented to Congress as part of the legislative or oversight processes, such as testimony of officials, information, or drafting assistance provided to Congress in connection with pending or proposed legislation, unless EPA simultaneously disseminates this information to the public.

- Background information such as published articles distributed by libraries or by other distribution methods that do not imply that EPA has adopted or endorsed the materials. This includes outdated or superseded EPA information that is provided as background information but no longer reflects EPA policy or influences EPA decisions, where the outdated or superseded nature of such material is reasonably apparent from its form of presentation or date of issuance, or where EPA indicates that the materials are provided as background materials and do not represent EPA's current view.

- These Guidelines do not apply to information distributed by recipients of EPA contracts, grants, or cooperative agreements, unless the information is disseminated on EPA's behalf, as when EPA specifically directs or approves the dissemination. These Guidelines do not apply to the distribution of any type of research by Federal employees and recipients of EPA funds, where the researcher (not EPA) decides whether and how to communicate and publish the research, does so in the same manner as his or her academic colleagues, and distributes the research in a manner that indicates it does not necessarily represent EPA's official position (for example, by including an appropriate disclaimer). The Guidelines do not apply even if EPA retains ownership or other intellectual property rights because the Federal government paid for the research.

- Distribution of information in public filings to EPA, including information submitted to EPA by any individual or person (as discussed above), either voluntarily or under mandates or requirements (such as filings required by statutes, regulations, orders, permits, or licenses). The Guidelines do not apply where EPA distributes this information simply to provide the public with quicker and easier access to materials submitted to EPA that are publicly available. This will generally be the case so long as EPA is not the author, and is not endorsing, adopting, using, or proposing to use the information to support an Agency decision or position.

- Distribution of information in documents filed in or prepared specifically for a judicial case or an administrative adjudication and intended to be limited to such

actions, including information developed during the conduct of any criminal or civil action or administrative enforcement action, investigation, or audit involving an agency against specific parties.

5.5 What Happens if Information is Initially Not Covered by these Guidelines, but EPA 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 dissemination of the information in which EPA adopts, endorses, or uses the information to formulate or support a regulation, guidance, or other Agency decision or position. For example, if EPA simply makes a public filing (such as facility data required by regulation) available to the public, these Guidelines would not apply to that distribution of information. However, if EPA later includes the information in a background document in support of a rulemaking, these Guidelines would apply to that later dissemination of the information in that document.

5.6 How does EPA Ensure the Objectivity, Utility, and Integrity of information that is not covered by these Guidelines?

These Guidelines apply only to information EPA disseminates to the public, outlined in section 5.3, above. Other information distributed by EPA that is not covered by these Guidelines is still subject to all applicable EPA policies, quality review processes, and correction procedures. These include quality management plans for programs that collect, manage, and use environmental information, peer review, and other procedures that are specific to individual programs and, therefore, not described in these Guidelines. It is EPA's policy that all of the information it distributes meets a basic standard of information quality, and that its utility, objectivity, and integrity be scaled and appropriate to the nature and timeliness of the planned and anticipated uses. Ensuring the quality of EPA information is not necessarily dependent on any plans to disseminate the information. EPA continues to produce, collect, and use information that is of the appropriate quality, irrespective of these Guidelines or the prospects for dissemination of the information.

6 Guidelines for Ensuring and Maximizing Information Quality

6.1 How does EPA Ensure and Maximize the Quality of Disseminated Information?

EPA ensures and maximizes the quality of the information we disseminate by implementing well established policies and procedures within the Agency as appropriate to the information product. There are many tools that the Agency uses such as the Quality System,[11] review by senior management, peer review process,[12] communications product review process,[13] the web guide,[14] and the error correction process.[15] Beyond our internal quality management system, EPA also ensures the quality of information we disseminate by seeking input from experts and the general public. EPA consults with groups such as the Science Advisory Board and the Science Advisory Panel, in addition to seeking public input through public comment periods and by hosting public meetings.

For the purposes of the Guidelines, EPA recognizes that if data and analytic results are subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption of objectivity is rebuttable. The Agency uses a graded approach and uses these tools to establish the appropriate quality, objectivity, utility, and integrity of information products based on the intended use of the information and the resources available. As part of this graded approach, EPA recognizes that some of the information it disseminates includes influential scientific, financial, or statistical information, and that this category should meet a higher standard of quality.

6.2 How Does EPA Define Influential Information for these Guidelines?

"Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions.[16] For the purposes of the EPA's

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[11]EPA Quality Manual for Environmental Programs 5360 A1. May 2000. http://www.epa.gov/quality/qs-docs/5360.pdf

[12]Peer Review Handbook, 2nd Edition, U.S. EPA, Science Policy Council, December 2000, EPA 100-B-00-001. http://www.epa.gov/osp/spc/prhandbk.pdf

[13]EPA's Print and Web Communications Product Review Guide. http://www.epa.gov/dced/pdf/review.pdf

[14]Web Guide. U.S. EPA. http://www.epa.gov/webguide/resources/webserv.html

[15]Integrated Error Correction Process. http://www.epa.gov/cdx/iecp.html

[16]The term "clear and substantial impact" is used as part of a definition to distinguish different categories of information for purposes of these Guidelines. EPA does not intend the classification of information under this definition to change or impact the status of the information in any other setting, such as for purposes of determining whether the dissemination of the information is a final Agency action.

Information Quality Guidelines, EPA will generally consider the following classes of information to be influential, and, to the extent that they contain scientific, financial, or statistical information, that information should adhere to a rigorous standard of quality:

- Information disseminated in support of top Agency actions (i.e., rules, substantive notices, policy documents, studies, guidance) that demand the ongoing involvement of the Administrator's Office and extensive cross-Agency involvement; issues that have the potential to result in major cross-Agency or cross-media policies, are highly controversial, or provide a significant opportunity to advance the Administrator's priorities. Top Agency actions usually have potentially great or widespread impacts on the private sector, the public or state, local or tribal governments. This category may also include precedent-setting or controversial scientific or economic issues.

- Information disseminated in support of Economically Significant actions as defined in Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), Agency actions that are likely to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, Tribal, or local governments or communities.

- Major work products undergoing peer review as called for under the Agency's Peer Review Policy. Described in the *Science Policy Council Peer Review Handbook*, the EPA Peer Review Policy regards major scientific and technical work products as those that have a major impact, involve precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review. These Major work products are typically subjected to external peer review. Some products that may not be considered "major" under the EPA Peer Review Policy may be subjected to external peer review but EPA does not consider such products influential for purposes of these Guidelines.

- Case-by-case: The Agency may make determinations of what constitutes "influential information" beyond those classes of information already identified on a case-by-case basis for other types of disseminated information that may have a clear and substantial impact on important public policies or private sector decisions.

6.3 How Does EPA Ensure and Maximize the Quality of "Influential" Information?

EPA recognizes that influential scientific, financial, or statistical information should be subject to a higher degree of quality (for example, transparency about data and methods) than information that may not have a clear and substantial impact on important public policies or private sector decisions. A higher degree of transparency about data and methods will facilitate

the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. For disseminated influential original and supporting data, EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. It is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also important that the degree of rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed. In addition, if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.

Several Agency-wide and Program- and Region-specific policies and processes that EPA uses to ensure and maximize the quality of environmental data, including disseminated information products, would also apply to information considered "influential" under these Guidelines. Agency-wide processes of particular importance to ensure the quality, objectivity, and transparency of "influential" information include the Agency's Quality System, Action Development Process, Peer Review Policy, and related procedures. Many "influential" information products may be subject to more than one of these processes.

6.4 How Does EPA Ensure and Maximize the Quality of "Influential" Scientific Risk Assessment Information?

EPA conducts and disseminates a variety of risk assessments. When evaluating environmental problems or establishing standards, EPA must comply with statutory requirements and mandates set by Congress based on media (air, water, solid, and hazardous waste) or other environmental interests (pesticides and chemicals). Consistent with EPA's current practices, application of these principles involves a "weight-of-evidence" approach that considers all relevant information and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment. In our dissemination of influential scientific information regarding human health, safety[17] or environmental[18] risk assessments, EPA will ensure, to the extent practicable

[17]"Safety risk assessment" describes a variety of analyses, investigations, or case studies conducted by EPA to respond to environmental emergencies. For example, we work to ensure that the chemical industry and state and local entities take action to prevent, plan and prepare for, and respond to chemical emergencies through the development and sharing of information, tools, and guidance for hazards analyses and risk assessment.

[18]Because the assessment of "environmental risk" is being distinguished from "human health risk," the term "environmental risk" as used in these Guidelines does not directly involve human health concerns. In other words, an "environmental risk assessment" is in this case the equivalent to what EPA commonly calls an "ecological risk

and consistent with Agency statutes and existing legislative regulations, the objectivity[19] of such information disseminated by the Agency by applying the following adaptation of the quality principles found in the Safe Drinking Water Act[20] (SDWA) Amendments of 1996[21]:

(A) The substance of the information is accurate, reliable and unbiased. This involves the use of:

(i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and

(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

(B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. In a document made available to the public, EPA specifies:

(i) each population addressed by any estimate of applicable human health risk or each risk assessment endpoint, including populations if applicable, addressed by any estimate of applicable ecological risk[22];

(ii) the expected risk or central estimate of human health risk for the specific

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assessment".

[19]OMB stated in its guidelines that in disseminating information agencies shall develop a process for reviewing the quality of the information. "Quality" includes objectivity, utility, and integrity. "Objectivity" involves two distinct elements, presentation and substance. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, OMB, 2002. (67 FR 8452) http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

[20]Safe Drinking Water Act Amendments of 1996, 42 U.S.C. 300g-1(b)(3)(A) & (B)

[21]The exception is risk assessments conducted under SDWA which will adhere to the SDWA principles as amended in 1996.

[22]Agency assessments of human health risks necessarily focus on populations. Agency assessments of ecological risks address a variety of entities, some of which can be described as populations and others (such as ecosystems) which cannot. The phrase "assessment endpoint" is intended to reflect the broader range of interests inherent in ecological risk assessments. As discussed in the *EPA Guidelines for Ecological Risk Assessment* (found at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460), assessment endpoints are explicit expressions of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes. Furthermore, those Guidelines explain that an ecological entity can be a species (e.g., eelgrass, piping plover), a community (e.g., benthic invertebrates), an ecosystem (e.g., wetland), or other entity of concern. An attribute of an assessment endpoint is the characteristic about the entity of concern that is important to protect and potentially at risk. Examples of attributes include abundance (of a population), species richness (of a community), or function (of an ecosystem). Assessment endpoints and ecological risk assessments are discussed more fully in those Guidelines as well as other EPA sources such as *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments - Interim Final* found at http://www.epa.gov/oerrpage/superfund/programs/risk/ecorisk/ecorisk.htm

populations affected or the ecological assessment endpoints[23], including populations if applicable;

(iii) each appropriate upper-bound or lower-bound estimate of risk;

(iv) each significant uncertainty identified in the process of the assessment of risk and studies that would assist in resolving the uncertainty; and

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.

In applying these principles, "best available" usually refers to the availability at the time an assessment is made. However, EPA also recognizes that scientific knowledge about risk is rapidly changing and that risk information may need to be updated over time. When deciding which influential risk assessment should be updated and when to update it, the Agency will take into account its statutes and the extent to which the updated risk assessment will have a clear and substantial impact on important public policies or private sector decisions. In some situations, the Agency may need to weigh the resources needed and the potential delay associated with incorporating additional information in comparison to the value of the new information in terms of its potential to improve the substance and presentation of the assessment.

Adaptation clarifications

In order to provide more clarity on how EPA adapted the SDWA principles in this guidance in light of our numerous statutes, regulations, guidance and policies that address how to conduct a risk assessment and characterize risk we discuss four adaptations EPA has made to the SDWA quality principles language.

EPA adapted the SDWA principles by adding the phrase "consistent with Agency statutes and existing legislative regulations, the objectivity of such information disseminated by the Agency" in the introductory paragraph, therefore applying to both paragraphs (A) and (B). This was done to explain EPA's intent regarding these quality principles and their implementation consistent with our statutes and existing legislative regulations. Also, as noted earlier, EPA intends to implement these quality principles in conjunction with our guidelines and policies. The procedures set forth in other EPA guidelines set out in more detail EPA's policies for conducting risk assessments, including Agency-wide guidance on various types of risk assessments and program-specific guidance. EPA recognizes that the wide array of programs within EPA have resulted not only in Agency-wide guidance, but in specific protocols that reflect the requirements, including limitations, that are mandated by the various statutes administered by the Agency. For example, the Agency developed several pesticide science policy papers that explained to the public in detail how EPA would implement specific statutory requirements in the Food Quality Protection Act (FQPA) that addressed how we perform risk assessments. We also recognize that emerging issues such endocrine disruption, bioengineered organisms, and genomics may involve some modifications to the existing paradigm for assessing human health

[23]Ibid.

and ecological risks. This does not mean a radical departure from existing guidance or the SDWA principles, but rather indicates that flexibility may be warranted as new information and approaches develop.

EPA introduced the following two adaptations in order to accommodate the range of real-world situations that we confront in the implementation of our diverse programs. EPA adapted the SDWA quality principles by moving the phrase "to the extent practicable" from paragraph (B) to the introductory paragraph in this Guidelines section to cover both parts (A) and (B) of the SDWA adaptation.[24] The phrase refers to situations under (A) where EPA may be called upon to conduct "influential" scientific risk assessments based on limited information or in novel situations, and under (B) in recognition that all such "presentation" information may not be available in every instance. The level of effort and complexity of a risk assessment should also balance the information needs for decision making with the effort needed to develop such information. For example, under the Federal Insecticide, Fungicide and Rodenticide Act[25] (FIFRA) and the Toxic Substances and Control Act[26] (TSCA), regulated entities are obligated to provide information to EPA concerning incidents/test data that may reveal a problem with a pesticide or chemical. We also receive such information voluntarily from other sources. EPA carefully reviews incident reports and factors them as appropriate into risk assessments and decision-making, even though these may not be considered information collected by acceptable methods or best available method as stated in A(ii). Incident information played an important role in the Agency's conclusion that use of chlordane/heptachlor termiticides could result in exposures to persons living in treated homes, and that the registrations needed to be modified accordingly. Similarly, incident reports concerning birdkills and fishkills were important components of the risk assessments for the reregistration of the pesticides phorate and terbufos, respectively. In addition, this adaptation recognizes that while many of the studies incorporated into risk assessments have been peer reviewed, data from other sources may not be peer reviewed. EPA takes many actions based on studies and supporting data provided by outside sources, including confidential or proprietary information that has not been peer reviewed. For example, industry can be required by regulation to submit data for pesticides under FIFRA or for chemicals under TSCA. The data are developed using test guidelines and Good Laboratory Practices (GLPs) in accordance with EPA regulations. While there is not a requirement to have studies peer reviewed, such studies are reviewed by Agency scientists to ensure that they were conducted according to the appropriate test guidelines and GLPs and that the data are valid.

The flexibility provided by applying "to the extent practicable" to paragraph (A) is appropriate in many circumstances to conserve Agency resources and those of the regulated community who otherwise might have to generate significant additional data. This flexibility is already provided

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[24]The discussion in this and following paragraphs gives some examples of the types of assessments that may under some circumstances be considered influential. These examples are representative of assessments performed under other EPA programs, such as CERCLA

[25]7 U.S.C. 136 et seq.

[26]15 U.S.C. 2601 et seq.

for paragraph (B) in the SDWA quality principles. Pesticide and chemical risk assessments are frequently performed iteratively, with the first iteration employing protective (conservative) assumptions to identify possible risks. Only if potential risks are identified in a screening level assessment, is it necessary to pursue a more refined, data-intensive risk assessment. This is exhibited, for example, in guidance developed for use in CERCLA and RCRA on tiered approaches. In other cases, reliance on "structure activity relationship" or "bridging data" allows the Agency to rely on data from similar chemicals rather than require the generation of new, chemical-specific data. While such assessments may or may not be considered influential under the Guidelines, this adaptation of the SDWA principles reflects EPA's reliance on less-refined risk assessments where further refinement could significantly increase the cost of the risk assessment without significantly enhancing the assessment or changing the regulatory outcome.

In emergency and other time critical circumstances, risk assessments may have to rely on information at hand or that can be made readily available rather than data such as described in (A). One such scenario is risk assessments addressing Emergency Exemption requests submitted under Section 18 of FIFRA[27] which, because of the emergency nature of the request, must be completed within a short time frame. As an example, EPA granted an emergency exemption under Section 18 to allow use of an unregistered pesticide to decontaminate anthrax in a Senate office building. The scientific review and risk assessment to support this action were necessarily constrained by the urgency of the action. Other time-sensitive actions include the reviews of new chemicals under TSCA. Under Section 5 of TSCA[28], EPA must review a large number of pre-manufacture notifications (more than 1,000) every year, not all of which necessarily include "influential" risk assessments, and each review must be completed within a short time frame (generally 90 days). The nature of the reviews and risk assessment associated with these pre-manufacture notifications are affected by the limited time available and the large volume of notifications submitted.

The flexibility provided by applying "to the extent practicable" to paragraph (A) is appropriate to account for safety risk assessment practices. This flexibility is already provided for paragraph (B) in the SDWA quality principles. We applied the same SDWA adaptation for use with human health risk assessments to safety risk assessments with the needed flexibility to apply the principles to the extent practicable. "Safety risk assessments" include a variety of analyses, investigations, or case studies conducted by EPA concerning safety issues. EPA works to ensure that the chemical industry and state and local entities take action to prevent, plan and prepare for, and respond to environmental emergencies and site specific response actions through the development and sharing of information, tools and guidance for hazard analyses and risk assessment. For example, although the chemical industry shoulders most of the responsibility for safety risk assessment and management, EPA may also conduct chemical hazard analyses, investigate the root causes and mechanisms associated with accidental chemical releases, and assess the probability and consequences of accidental releases in support of agency risk

[27] Section 18 of FIFRA, 7 U.S.C. 136p

[28] Section 5 of TSCA, 15 U.S.C. 2604

assessments. Although safety risk assessments can be different from traditional human health risk assessments because they may combine a variety of available information and may use expert judgement based on that information, these assessments provide useful information that is sufficient for the intended purpose.

Next, EPA adapted the SDWA quality principles by adding the clause "including, when available, peer reviewed science and supporting studies" to paragraph (A)(i). It now reads: "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies." In the Agency's development of "influential" scientific risk assessments, we intend to use all relevant information, including peer reviewed studies, studies that have not been peer reviewed, and incident information; evaluate that information based on sound scientific practices as described in our risk assessment guidelines and policies; and reach a position based on careful consideration of all such information (*i.e.*, a process typically referred to as the "weight-of-evidence" approach[29]). In this approach, a well-developed, peer-reviewed study would generally be accorded greater weight than information from a less well-developed study that had not been peer-reviewed, but both studies would be considered. Thus the Agency uses a "weight-of-evidence" process when evaluating peer-reviewed studies along with all other information.

Oftentimes under various EPA-managed programs, EPA receives information that has not been peer-reviewed and we have to make decisions based on the information available. While many of the studies incorporated in risk assessments have been peer reviewed, data from other sources, such as studies submitted to the Agency for pesticides under FIFRA[30] and for chemicals under TSCA, may not always be peer reviewed. Rather, such data, developed under approved guidelines and the application of Good Laboratory Practices (GLPs), are routinely used in the development of risk assessments. Risk assessments may also include more limited data sets such as monitoring data used to support the exposure element of a risk assessment. In cases where these data may not themselves have been peer reviewed their quality and appropriate use would be addressed as part of the peer review of the overall risk assessment as called for under the Agency's peer review guidelines.

Lastly, EPA adapted the SDWA principles for influential environmental ("ecological") risk assessments that are disseminated in order to use terms that are most suited for such risk assessments. Specifically, EPA assessments of ecological risks address a variety of entities,

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[29] The weight-of-evidence approach generally considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated of each type of evidence, and explains how the various types of evidence fit together. See, e.g., EPA's *Proposed Guidelines for Carcinogen Risk Assessment* (Federal Register 61(79): 17960-18011; April 23, 1996) and EPA's *Guidelines for Carcinogen Risk Assessment* (Federal Register 51(185): 33992-34003; September 24, 1986), available from: www.epa.gov/ncea/raf/, and EPA's Risk Characterization Handbook (*Science Policy Council Handbook: Risk Characterization*, EPA 100-B-00-002, Washington, DC: U.S. EPA, December 2000).

[30] 40 CFR part 158

some of which can be described as populations and others (such as ecosystems) which cannot. Therefore, a specific modification was made to include "assessment endpoints, including populations if applicable" in place of the term "population" for ecological risk assessments and EPA added a footnote directing the reader to various EPA risk policies for further discussion of these concepts in greater detail.

6.5 Does EPA Ensure and Maximize the Quality of Information from External Sources?

Ensuring and maximizing the quality of information from States, other governments, and third parties is a complex undertaking, involving thoughtful collaboration with States, Tribes, the scientific and technical community, and other external information providers. EPA will continue to take steps to ensure that the quality and transparency of information provided by external sources are sufficient for the intended use. For instance, since 1998, the use of environmental data collected by others or for other purposes, including literature, industry surveys, compilations from computerized data bases and information systems, and results from computerized or mathematical models of environmental processes and conditions has been within the scope of the Agency's Quality System[31].

For information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish factors that EPA would use to assess the quality of this type of information.

For all proposed collections of information that will be disseminated to the public, EPA intends to demonstrate in our Paperwork Reduction Act[32] clearance submissions that the proposed collection of information will result in information that will be collected, maintained and used in ways consistent with the OMB guidelines and these EPA Guidelines. These Guidelines apply to all information EPA disseminates to the public; accordingly, if EPA later identifies a new use for the information that was collected, such use would not be precluded and the Guidelines would apply to the dissemination of the information to the public.

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[31] EPA Quality Manual for Environmental Programs 5360 A1. May 2000, Section 1.3.1. http://www.epa.gov/quality/qs-docs/5360.pdf

[32] 44 U.S.C. 3501 et seq.

7 Administrative Mechanism for Pre-dissemination Review

7.1 What are the Administrative Mechanisms for Pre-dissemination Reviews?

Each EPA Program Office and Region will incorporate the information quality principles outlined in section 6 of these Guidelines into their existing pre-dissemination 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. EPA intends to facilitate implementation of consistent cross-Agency pre-dissemination reviews by establishing a model of minimum review standards based on existing policies. Such a model for pre-dissemination review would still provide that responsibility for the reviews remains in the appropriate EPA Office or Region.

For the purposes of the Guidelines, EPA recognizes that pre-dissemination review procedures may include peer reviews and quality reviews that may occur at many steps in development of information, not only at the point immediately prior to the dissemination of the information.

8 Administrative Mechanisms for Correction of Information

8.1 What are EPA's Administrative Mechanisms for Affected Persons to Seek and Obtain Correction of Information?

EPA's Office of Environmental Information (OEI) manages the administrative mechanisms that enable affected persons to seek and obtain, where appropriate, correction of information disseminated by the Agency that does not comply with EPA or OMB Information Quality Guidelines. Working with the Program Offices, Regions, laboratories, and field offices, OEI will receive complaints (or copies) and distribute them to the appropriate EPA information owners. "Information owners" are the responsible persons designated by management in the applicable EPA Program Office, or those who have responsibility for the quality, objectivity, utility, and integrity of the information product or data disseminated by EPA. If a person believes that information disseminated by EPA may not comply with the Guidelines, we encourage the person to consult informally with the contact person listed in the information product before submitting a request for correction of information. An informal contact can result in a quick and efficient resolution of questions about information quality.

8.2 What Should be Included in a Request for Correction of Information?

Persons requesting a correction of information should include the following information in their Request for Correction (RFC):

- Name and contact information for the individual or organization submitting a complaint; identification of an individual to serve as a contact.
- A description of the information the person believes does not comply with EPA or OMB guidelines, including specific citations to the information and to the EPA or OMB guidelines, if applicable.
- An explanation of how the information does not comply with EPA or OMB guidelines and a recommendation of corrective action. EPA considers that the complainant has the burden of demonstrating that the information does not comply with EPA or OMB guidelines and that a particular corrective action would be appropriate.
- An explanation of how the alleged error affects or how a correction would benefit the requestor.
- An affected person may submit an RFC via any one of methods listed here:
  - **Internet** at http://www.epa.gov/oei/qualityguidelines
  - **E-mail** at quality.guidelines@epa.gov
  - **Fax** at (202) 566-0255

- **Mail** to *Information Quality Guidelines Staff*, Mail Code 28221T, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, DC, 20460
- **By courier or in person** to *Information Quality Guidelines Staff*, OEI Docket Center, Room B128, EPA West Building, 1301 Constitution Ave., N.W., Washington, DC

8.3 When Does EPA Intend to Consider a Request for Correction of Information?

EPA seeks public and stakeholder input on a wide variety of issues, including the identification and resolution of discrepancies in EPA data and information. EPA may decline to review an RFC under these Guidelines and consider it for correction if:

- The request does not address information disseminated to the public covered by these Guidelines (see section 5.3 or OMB's guidelines). In many cases, EPA provides other correction processes for information not covered by these Guidelines.

- The request omits one or more of the elements recommended in section 8.2 and there is insufficient information for EPA to provide a satisfactory response.

- The request itself is "frivolous," including those made in bad faith, made without justification or trivial, and for which a response would be duplicative. More information on this subject may be found in the OMB guidelines.

8.4 How Does EPA Intend to Respond to a Request for Correction of Information?

EPA intends to use the following process:

- Each RFC will be tracked in an OEI system.

- If an RFC is deemed appropriate for consideration, the information owner office or region makes a decision on the request on the basis of the information in question, including a request submitted under section 8.2. Rejections of a request for correction should be decided at the highest level of the information owner office or region. EPA's goal is to respond to requests within 90 days of receipt, by 1) providing either a decision on the request, or 2) if the request requires more than 90 calendar days to resolve, informing the complainant that more time is required and indicate the reason why and an estimated decision date.

- If a request is approved, EPA determines what corrective action is appropriate. Considerations relevant to the determination of appropriate corrective action include the nature and timeliness of the information involved and such factors as the significance of the error on the use of the information and the magnitude of

the error. For requests involving information from outside sources, considerations may include coordinating with the source and other practical limitations on EPA's ability to take corrective action.

- Whether or not EPA determines that corrective action is appropriate, EPA provides notice of its decision to the requester.

- For approved requests, EPA assigns a steward for the correction who marks the information as designated for corrections as appropriate, establishes a schedule for correction, and reports correction resolution to both the tracking system and to the requestor.

OEI will provide reports on behalf of EPA to OMB on an annual basis beginning January 1, 2004 regarding the number, nature, and resolution of complaints received by EPA.

8.5 How Does EPA Expect to Process Requests for Correction of Information on Which EPA has Sought Public Comment?

When EPA provides opportunities for public participation by seeking comments on information, the public comment process should address concerns about EPA's information. For example, when EPA issues a notice of proposed rulemaking supported by studies and other information described in the proposal or included in the rulemaking docket, it disseminates this information within the meaning of the Guidelines. The public may then raise issues in comments regarding the information. If a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism. This approach would also generally apply to other processes involving a structured opportunity for public comment on a draft or proposed document before a final document is issued, such as a draft report, risk assessment, or guidance document. EPA believes that the thorough consideration provided by the public comment process serves the purposes of the Guidelines, provides an opportunity for correction of any information that does not comply with the Guidelines, and does not duplicate or interfere with the orderly conduct of the action. In cases where the Agency disseminates a study, analysis, or other information prior to the final Agency action or information product, it is EPA policy to consider requests for correction prior to the final Agency action or information product in those cases where the Agency has determined that an earlier response would not unduly delay issuance of the Agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the Agency's dissemination if the Agency does not resolve the complaint prior to the final Agency action or information product. EPA does not expect this to be the norm in rulemakings that it conducts, and thus will usually address information quality issues in connection with the final Agency action or information product.

EPA generally would not consider a complaint that could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period. If EPA cannot respond to a complaint in the response to comments for the action (for example, because the complaint is submitted too late to be considered and could not have been timely submitted, or because the complaint is not germane to the action), EPA will consider whether a separate response to the complaint is appropriate.

8.6 What Should be Included in a Request Asking EPA to Reconsider its Decision on a Request for the Correction of Information?

If requesters are dissatisfied with an EPA decision, they may file a Request for Reconsideration (RFR). The RFR should contain the following information:

- An indication that the person is seeking an appeal of an EPA decision on a previously submitted request for a correction of information, including the date of the original submission and date of EPA decision. A copy of EPA's original decision would help expedite the process.
- Name and contact information. Organizations submitting an RFR should identify an individual as a contact.
- An explanation of why the person disagrees with the EPA decision and a specific recommendation for corrective action.
- A copy of the original RFC of information.
- An affected person may submit a Request for Reconsideration (RFR) via any one of the methods listed here:
  - **Internet** at http://www.epa.gov/oei/qualityguidelines
  - **E-mail** at quality.guidelines@epa.gov
  - **Fax** at (202) 566-0255
  - **Mail** to *Information Quality Guidelines Staff*, Mail Code 28221T, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, DC, 20460
  - **By courier or in person** to *Information Quality Guidelines Staff*, OEI Docket Center, Room B128, EPA West Building, 1301 Constitution Ave., N.W., Washington, DC

EPA recommends that requesters submit their RFR within 90 days of the EPA decision. If the RFR is sent after that time, EPA recommends that the requester include an explanation of why the request should be considered at this time.

8.7 How Does EPA Intend to Process Requests for Reconsideration of EPA Decisions?

EPA intends to consider RFR using the following process:

- Each RFR will be tracked in an OEI system.
- OEI sends the RFR to the appropriate EPA Program Office or Region that has responsibility for the information in question.

- The Assistant Administrator (AA) or Regional Administrator (RA) information owner presents to an executive panel. The executive panel would be comprised of the Science Advisor/AA for the Office of Research and Development (ORD), Chief Information Officer/AA for OEI, and the Economics Advisor/AA for the Office of Policy, Economics and Innovation (OPEI.). The 3-member executive panel would be chaired by the Chief Information Officer/AA for OEI. When the subject of the RFR originated from a member office, that panel member would be replaced by an alternate AA or RA. While the executive panel is considering an RFR, the decision made on the initial complaint by the information owner office or region remains in effect.

- The executive panel makes the final decision on the RFR.

- EPA's goal is to respond to each RFR within 90 days of receipt, by 1) providing either a decision on the request or 2) if the request requires more than 90 calendar days to resolve, informing the complainant that more time is required and indicate the reason why and an estimated decision date.

- If a request is approved, EPA determines what type of corrective action is appropriate. Considerations relevant to the determination of appropriate corrective action include the nature and timeliness of the information involved and such factors as the significance of the error on the use of the information and the magnitude of the error. For requests involving information from outside sources, considerations may include coordinating with the source, and other practical limitations on EPA's ability to take corrective action.

- Whether or not EPA determines that corrective action is appropriate, EPA provides notice of its decision to the requester.

- For approved requests, EPA assigns a steward for the correction who marks the information as designated for corrections as appropriate, establishes a schedule for correction, and reports correction resolution to both the tracking system and to the requestor.

Appendix A
IQG Development Process and Discussion of Public Comments

A.1 Introduction

EPA's Guidelines are a living document and may be revised as we learn more about how best to address, ensure, and maximize information quality. In the process of developing these Guidelines, we actively solicited public input at many stages. While the public was free to comment on any aspect of the Guidelines, EPA explicitly requested input on key topics such as influential information, reproducibility, influential risk assessment, information sources, and error correction.

Public input was sought in the following ways:

- An online Public Comment Session was held March 19-22, 2002, as the first draft of the Guidelines was being developed. EPA received approximately 100 comments.
- A Public Meeting was held on May 15, 2002, after the draft Guidelines were issued. There were 99 participants, 13 of whom made presentations or commented on one or more issues.
- A 52 day Public Comment period lasted from May 1 to June 21, 2002, where comments could be mailed, faxed, or e-mailed to EPA. EPA received 55 comments during this period.
- A meeting with State representatives, sponsored and supported by the Environmental Council of the States (ECOS), was held on May 29, 2002.
- A conference call between EPA and Tribal representatives was held on June 27, 2002.

More detailed information on the public comments is available through an OEI web site, serving as the home page for the EPA Information Quality Guidelines through the development and implementation process. Please visit this site at http://www.epa.gov/oei/qualityguidelines.

We have established a public docket for the EPA Information Quality Guidelines under Docket ID No. OEI-10014. The docket is the collection of materials available for public viewing Information Quality Guidelines Staff, OEI Docket Center, Room B128, EPA West Building, 1301 Constitution Ave., N.W., Washington, DC, phone number 202-566-0284. This docket consists of a copy of the Guidelines, public comments received, and other information related to the Guidelines. The docket is open from 12:00 PM to 4:00 PM, Monday through Friday, excluding legal holidays. An index of docket contents will be available at http://www.epa.gov/oei/qualityguidelines.

A.2 General Summary of Comments

During the various public comment opportunities, EPA received input from a diverse set of organizations and private citizens. Comments came from many of EPA's stakeholders - the regulated community and many interest groups who we hear from frequently during the management of EPA's Programs to protect the nation's land, air, water, and public health. Government agencies at the Federal, State, Tribal, and local level also commented on the Guidelines. OMB sent comments to every Federal agency and EPA received comments from two members of Congress. Beyond our government colleagues, the private sector voiced many concerns and helpful recommendations for these Guidelines. We would like to take this opportunity to thank all commenters for providing their input on these Guidelines. Due to the tight time frame for this project, this discussion of public comments generally describes the major categories of comments and highlights some significant comments, but does not contain an individual response to each public comment.

Comments received by EPA during the public comment period reflect a diversity of views regarding EPA's approach to developing draft Guidelines as well as the general concept of information quality. Some commenters included detailed review of all Guidelines sections, while others chose to address only specific topics. In some cases, commenters provided examples to demonstrate how current EPA procedures may not ensure adequate information quality for a specific application. Commenters provided general observations such as stating that these Guidelines did not sufficiently address EPA's information quality problems. Some commenters offered that the Guidelines relied too much on existing policies. Interpretations of the intent of the Data Quality Act were offered by some commenters. One comment noted that improvement of data quality is not necessarily an end in and of itself. Another comment was that the goal of Guidelines should be more to improve quality, not end uncertainty. Public interest and environmental groups voiced concern over what they believed was an attempt by various groups to undermine EPA's ability to act in a timely fashion to protect the environment and public health. Some commenters stated that the directives of the Data Quality Act and OMB cannot override EPA's mission to protect human health and the environment per the statutory mandates under which it operates.

EPA was congratulated for the effort and, in some cases, encouraged to go even further in addressing information quality. Some commenters encouraged EPA to provide additional process details, provide more detailed definitions, augment existing policies that promote transparency, and share more information about the limitations of EPA disseminated information. In one case, EPA was encouraged to develop a rating scheme for its disseminated information.

This section discusses public comments and our responses to many of the important questions and issues raised in the comments. First, we provide responses to some overarching comments we received from many commenters, then we provide a discussion of public comments that were received on specific topics addressed in the draft Guidelines.

- **Tone:** Commenters criticized the "defensive tone", "legalistic tone", and the lack of detail afforded in the Guidelines. Some commenters said that it was not clear what the Guidelines were explaining, or how they might apply to various types of information. We understand and agree with many of these criticisms and have made attempts to better communicate the purpose, applicability, and content of these Guidelines.

- **Plan for implementation:** Commenters suggested that the Guidelines should describe EPA's plans for implementing the Guidelines. These Guidelines provide policy guidance, and as such, do not outline EPA's plan for implementation. That is, they do not describe in great detail how each Program and Regional Office will implement these principles. We do not intend to imply that each Office will implement them in conflict with one another, but rather assume that because each Program implements a different statutory mandate or mandates, there will be some inherent differences in approach. Beyond internal implementation, we agree that there is more work and communication to be conducted with information providers and users to optimize the provisions set forth in these Guidelines.

- **Commitment to public access:** One commenter suggested that we "remove outdated information" from our web site. Other commenters suggested that when a complaint has been filed that the information should be removed from public view while a complaint is being reviewed. This is generally unacceptable to EPA in light of our commitment to providing the public with access to information; however, in certain cases EPA may consider immediate removal of information (for example, when it is clear to us that the information is grossly incorrect and misleading and its status cannot be adequately clarified through a notice or other explanation). With respect to outdated information, sometimes it serves a historical purpose, and should continue to be disseminated for that purpose.

A.3 Response to Comments by Guidelines Topic Area

A.3.1 Existing Policy

Many commenters told us that we rely excessively on existing EPA information quality policies. Commenters provided specific examples of areas they believed were demonstrative of our lack of commitment to or uneven implementation of our existing policies. Some commenters also pointed out that there are key areas in which we lack policies to address quality and, as a result, the Guidelines should address such issues in more detail. Some commenters also noted that EPA itself has highlighted lessons learned with existing approaches to information product development.

Ongoing improvement in implementing existing processes is a key principle of quality management. We view these Guidelines as an opportunity to enhance existing policies and redouble our commitment to quality information.

The concept of peer review is considered in three Guidelines sections. (1) Application of the Agency's Peer Review Policy language for "major scientific and technical work products and economic analysis used in decision making" as a class of information that can be considered "influential" for purposes of the Guidelines; (2) Use of "peer-reviewed science" as a component of some risk assessments; and (3) Use of the Agency's Peer Review Policy as one of the Agency-wide processes to ensure the quality, objectivity, and transparency of "influential" scientific, financial, and statistical information under the Guidelines.

Some commenters expressed concerns regarding application of peer review in EPA. Commenters suggest that current peer reviews are not sufficiently standardized, independent, or consistently implemented. Peer review is a cornerstone to EPA's credibility and we must ensure that the process always works as designed. For this reason, we conduct routine assessments to evaluate and improve the peer review process.

Commenters also questioned whether peer review is an adequate means to establish "objectivity." We note that OMB guidelines specifically allow for the use of formal, external, independent peer review to establish a presumption of objectivity. OMB guidelines also state that the presumption of objectivity is rebuttable, although the burden of proof lies with the complainant. Some commenters asked for additional definitions for peer review terms. Our current peer review policy is articulated in Peer Review and Peer Involvement at the U.S. Environmental Protection Agency.[33] Additional discussion regarding the application of peer-reviewed science is provided in the discussion of comments on risk assessment.

A.3.2 Scope and Applicability

We received a number of comments on section 1.1 (What is the Purpose of these Guidelines?) of the draft Guidelines. Some commenters argued that the Guidelines should be binding on EPA, that they are legislative rules rather than guidance, or that the Guidelines must be followed unless we make a specific determination to the contrary. Others argued that the Guidelines should not be binding or that we should include an explicit statement that the Guidelines do not alter substantive agency mandates. Some suggested that our statements retaining discretion to differ from the Guidelines sent a signal that EPA was not serious about information quality.

With respect to the nature of these Guidelines, Section 515 specifies that agencies are to issue "guidelines." As directed by OMB's guidelines, we have issued our own guidelines containing nonbinding policy and procedural guidance. We see no indication in either the language or general structure of Section 515 that Congress intended EPA's guidelines to be binding rules.

We revised this section (now section 1 in this revised draft) by adding a fuller explanation of how EPA intends to ensure the quality of information it disseminates. This section includes language explaining the nature of our Guidelines as policy and procedural guidance. This language is intended to give clear notice of the nonbinding legal effect of the Guidelines. It

[33] http://epa.gov/osp/spc/perevmem.htm

notifies EPA staff and the public that the document is guidance rather than a substantive rule and explains how such guidance should be implemented. Although we believe these Guidelines would not be judicially reviewable, we agree that a statement to this effect is unnecessary and have deleted it. In response to comments that EPA clarify that the Guidelines do not alter existing legal requirements, we have made that change. In light of that change, we think it is clear that decisions in particular cases will be made based on applicable statutes, regulations, and requirements, and have deleted other text in the paragraph that essentially repeated that point. Elsewhere in the document, EPA has made revisions to be consistent with its status as guidance.

Some commenters argued that all EPA disseminated information should be covered by the Guidelines and that we lack authority to "exempt" information from the Guidelines. Others thought that the coverage in EPA's draft was appropriate. EPA does not view its Guidelines as establishing a fixed definition and then providing "exemptions." Rather, our Guidelines explain when a distribution of information generally would or would not be considered disseminated to the public for purposes of the Guidelines. As we respond to complaints and gain experience in implementing these Guidelines, we may identify other instances where information is or is not considered disseminated for the purposes of the Guidelines.

Some commenters cited the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., to support their argument that the Guidelines should cover all information EPA makes public. EPA's Guidelines are issued under Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, which directs OMB to issue government-wide guidelines providing policy and procedural guidance to Federal agencies. In turn, the OMB guidelines provide direction and guidance to Federal agencies in issuing their own guidelines. EPA's Guidelines are intended to carry out OMB's policy on information quality. One commenter cited in particular the term "public information" used in the PRA as evidence of Congress's intent under Section 515. In EPA's view, this does not show that Congress intended a specific definition for the key terms, "information" and "disseminated," used in Section 515. In the absence of evidence of Congressional intent regarding the meaning of the terms used in Section 515, EPA does not believe the PRA requires a change in EPA's Guidelines.

We agree with commenters who noted that even if a particular distribution of information is not covered by the Guidelines, the Guidelines would still apply to information disseminated in other ways. As stated in section 1.4, if information is not initially covered by the Guidelines, a subsequent distribution of that information will be subject to the Guidelines if EPA adopts, endorses, or uses it.

Some commenters made specific recommendations about what should and should not be covered by the Guidelines. In addition to the specific recommendations, some suggested that the "scope and applicability" section was too long, while others thought it had an appropriate level of detail. Based on other agencies' guidelines and public comments, EPA has removed much of the detail from the discussion of Guidelines coverage. These revisions were intended to shorten and simplify the discussion without changing the general scope of the Guidelines.

We revised our definition of "information" in section 5.3, in response to a comment requesting that the Agency make clear that information from outside sources is covered by the Guidelines if EPA adopts, endorses, or uses it to support an Agency decision or position. In section 5.4, we modified several of the provisions. We added statements of "intent" or similar language to define the scope of several of the provisions. Accordingly, dissemination would not include distribution of information "intended" for government employees or recipients of contracts, grants, or cooperative agreements. Nor would information in correspondence "directed to" individuals or persons be covered. This recognizes that there may be instances where EPA may use a letter written to an individual in a way that indicates it is directed beyond the correspondent and represents a more generally applicable Agency policy. The Guidelines would apply in such a case. EPA has created a category for information of an "ephemeral" nature, including press releases, speeches, and the like. The intent was that the Guidelines should not cover communications that merely serve as announcements, or for other reasons are intended to be fleeting or of limited duration. Consistent with other agency guidelines, we have added language indicating that the Guidelines do not cover information presented to Congress, unless EPA simultaneously disseminates this information to the public.

Some commenters thought all information from outside sources should be covered by the Guidelines, even if EPA does not use, rely on, or endorse it. Others wished to clarify the point at which the Guidelines cover information from outside sources. As noted above, section 1.4 of the Guidelines explains how subsequent distributions of information in public filings may become subject to the Guidelines. We continue to think that EPA's own public filings before other agencies should not generally be covered by the Guidelines as long as EPA does not simultaneously disseminate them to the public, since use of this information would be subject to the requirements and policies of the agency to which the information is submitted.

We received a number of comments, including from OMB, arguing that the provision regarding information related to adjudicative processes was too broad, and that the Guidelines should cover some or all information related to adjudicative processes, particularly administrative adjudications. In addition to shortening this section, we have limited this provision to information in documents prepared specifically for an administrative adjudication. This would include decisions, orders, findings, and other documents prepared specifically for the adjudication. As indicated in the Draft Guidelines, our view is that existing standards and protections in administrative adjudications would generally be adequate to assure the quality of information in administrative adjudications and to provide an adequate opportunity to contest decisions on the quality of information. For example, in permitting proceedings, parties may submit comments on the quality of information EPA prepares for the permit proceeding, and judicial review is available based on existing statutes and regulations. Narrowing the provision to information prepared specifically for the adjudication should make clear that the Guidelines would not generally provide parties with additional avenues of challenge or appeal during adjudications, but would still apply to a separate distribution of information where EPA adopts, endorses, or uses the information, such as when EPA disseminates it, on the Internet, or in a rulemaking, or guidance document. When we intend to adopt information such as models or risk assessments for use in a class of cases or determinations (e.g., for use in all determinations under

a particular regulatory provision), EPA often disseminates this information separately and in many instances requests public comment on it. Accordingly, it is not clear that there would be many instances where persons who are concerned about information prepared specifically for an adjudication would not have an opportunity to contest the quality of information.

We respectfully disagree with a commenter's recommendation that regulatory limits established by EPA should be subject to the Guidelines. The Guidelines apply to information disseminated by EPA, not to regulatory standards or other Agency decisions or policy choices. In response to comments regarding information disseminated in rulemakings and other matters subject to public comment, EPA considers that this information would be disseminated within the meaning of the Guidelines, although we would generally treat complaints regarding that information procedurally like other comments on the rulemaking or other matter.

A.3.3 Sources of Information

We received many comments on how the Guidelines apply to external parties, the shared quality responsibilities between EPA and external parties, and specific EPA responsibilities when using or relying on information collected or compiled by external parties.

EPA roles: Some commenters emphasized that ensuring quality of information at the point of dissemination is no substitute for vigorous efforts by EPA to receive quality information in the first place and therefore for information providers to produce quality information. One commenter stated that EPA cannot be responsible for all aspects of the quality of the information we disseminate. In response to this and other comments, we have provided additional language in these Guidelines on the various roles that EPA assumes in either ensuring the quality of the information we disseminate or ensuring the integrity of information EPA distributes. One comment suggested that we mention the role of the National Environmental Information Exchange Network in ensuring information integrity, which we have done in section 2.4 of the Guidelines.

Assessment factors: Overall, public input was positive and welcoming of our proposal to develop assessment factors to evaluate the quality of information generated by third parties. A few commenters offered their involvement in the development of these factors, their advice on how to develop such factors, and some examples of what assessment factors we should consider. EPA staff have provided such comments to the EPA Science Policy Council workgroup that was charged with developing the assessment factors. EPA welcomes stakeholder input in the development of these factors and published draft assessment factors for public comment in September 2002.

Coverage of State Information: Some commenters suggested that our Guidelines must apply to all information disseminated by EPA, including information submitted to us by States. Whereas some commenters stressed that the quality of information received by EPA is the responsibility of the providers, others expressed concern about the potential impact that EPA's Guidelines could have on States. We believe it is important to differentiate between information that we

generate and data or information generated by external parties, including States. State information, when submitted to EPA, may not be covered by these Guidelines, but our subsequent use of the information may in fact be covered. We note, however, that there may be practical limitations on the type of corrective action that may be taken, since EPA does not intend to alter information submitted by States. However, EPA does intend to work closely with our State counterparts to ensure and maximize the quality of information that EPA disseminates. Furthermore, one commenter stated that if regulatory information is submitted to an authorized or delegated State program, then the State is the primary custodian of the information and the Guidelines would not cover that information. We agree with that statement.

We also received comments regarding the use of labels, or disclaimers, to notify the public whether information is generated by EPA or an external party. We agree that disclaimers and other notifications should be used to explain the status of information wherever possible, and we are developing appropriate language and format.

A statement regarding Paperwork Reduction Act clearance submissions has been added in response to comment by OMB.

A.3.4 Influential Information

EPA received a range of comments on its definition of "influential." Below we provide a summary of the comments raised and EPA's response.

Several commenters generally assert that the definition is too narrow. Other commenters indicated that under EPA's draft definition, only Economically Significant actions, as defined in Executive Order 12866, or only Economically Significant actions and information disseminated in support of top Agency actions, are considered "influential." We disagree. To demonstrate the broad range of activities covered by our adoption of OMB's definition, we reiterate the definition below and include an example of each type of action, to illustrate the breadth of our definition. "Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. We will generally consider the following classes of information to be influential: information disseminated in support of top Agency actions; information disseminated in support of "economically significant" actions; major work products undergoing peer review; and other disseminated information that will have or does have a clear and substantial impact (i.e., potential change or impact) on important public policies or important private sector decisions as determined by EPA on a case-by-case basis. In general, influential information would be the scientific, financial or statistical information that provides a substantial basis for EPA's position on key issues in top Agency actions and Economically Significant actions. If the information provides a substantial basis for EPA's position, EPA believes it would generally have a clear and substantial impact.

Top Agency actions: An example of a top Agency action is the review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter. Under the Clean Air Act, EPA is to periodically review (1) the latest scientific knowledge about the effects on public health and public welfare (e.g., the environment) associated with the presence of such pollutants in the ambient air and (2) the standards, which are based on this science. The Act further directs that the Administrator shall make any revisions to the standards as may be appropriate, based on the latest science, that in her judgment are requisite to protect the public health with an adequate margin of safety and to protect the public welfare from any known or anticipated adverse effects. The standards establish allowable levels of the pollutant in the ambient air across the United States, and States must development implementation plans to attain the standards. The PM NAAQS were last revised in 1997, and the next periodic review is now being conducted.

"Economically significant" rules: An example of a rule found to be economically significant is the Disposal of Polychlorinated Biphenyls (PCBs) Final Rule. In 1998, EPA amended its rules under the Toxic Substances Control Act (TSCA), which addresses the manufacture, processing, distribution in commerce, use, cleanup, storage and disposal of PCBs. This rule provides flexibility in selecting disposal technologies for PCB wastes and expands the list of available decontamination procedures; provides less burdensome mechanisms for obtaining EPA approval for a variety of activities; clarifies and/or modifies certain provisions where implementation questions have arisen; modifies the requirements regarding the use and disposal of PCB equipment; and addresses outstanding issues associated with the notification and manifesting of PCB wastes and changes in the operation of commercial storage facilities. EPA would consider the information that provides the principal basis for this rule to be influential information.

Peer reviewed work products: An example of a major work product undergoing peer review is the IRIS Documentation: Reference Dose for Methylmercury. Methylmercury contamination is the basis for fish advisories. It is necessary to determine an intake to humans that is without appreciable risk in order to devise strategies for decreasing mercury emissions into the environment. After EPA derived a reference dose (RfD) of 0.0001 mg/kg-day in 1995, industry argued that it was not based on sound science. Congress ordered EPA to fund an National Research Council/National Academy of the Sciences panel to determine whether our RfD was scientifically justifiable. The panel concluded that the 0.0001 mg/kg-day was an appropriate RfD, based on newer studies than the 1995 RfD. The information in this document was evaluated, incorporated, and subjected to comment by the Office of Water, where it contributed in large part to Chapter 4 of *Drinking Water Criteria for the Protection of Human Health: Methylmercury* (EPA/823/R-01/001) January 2001. The peer review mechanism was an external peer review workshop and public comment session held on November 15, 2000, accompanied by a public comment period from October 30 to November 29, 2000.

Case-by-base determination – PBT Chemicals Rule: An example of a case-by-case determination is the Guidance Document for Reporting Releases and Other Waste

Management Activities of Toxic Chemicals: Dioxin and Dioxin-like Compounds (December, 2000). In a final rule published October 29, 1999, EPA lowered the reporting thresholds for certain persistent bioaccumulative toxic (PBT) chemicals that are subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and Section 6607 of the Pollution Prevention Act of 1990 (PPA). We also added a category of dioxin and dioxin-like compounds to the EPCRA Section 313 list of toxic chemicals and established a 0.1 gram reporting threshold for the category. In addition, EPA added certain other PBT chemicals to the EPCRA Section 313 list of toxic chemicals and established lower reporting thresholds for these chemicals. As a result of this rulemaking, we developed a guidance document on the reporting requirements for the dioxin and dioxin-like compounds category, as well as a number of other guidance documents. The dioxin guidance document provides guidance on how to estimate annual releases and other waste management quantities of dioxin and dioxin-like compounds to the environment from certain industries and industrial activities. Due to the high interest level of stakeholders, we solicited public comments on the draft guidance document and formed a workgroup of interested stakeholders. The workgroup reviewed all public comments, provided their own comments, and then reviewed and commented on the final draft.

Case-by-case determination – National Water Quality Inventory Report: A second example of a case-by-case determination is the National Water Quality Inventory Report to Congress. The National Water Quality Inventory Report to Congress is a biennial report to Congress and the public about the quality of our nation's waters. It is prepared under Section 305 (b) of the Clean Water Act (CWA), which requires States and other jurisdictions to assess the health of their waters and the extent to which water quality supports State water quality standards and the basic goals of the CWA. States' Section 305 (b) assessments are an important component of their water resource management programs. These assessments help States: implement their water quality standards by identifying healthy waters that need to be maintained and impaired waters that need to be restored, prepare their Section 303 (d) lists of impaired waters, develop restoration strategies such as total maximum daily loads and source controls, and evaluate the effectiveness of activities undertaken to restore impaired waters and protect healthy waters.

A number of commenters said that EPA created a limited definition of what types of information are to be considered "influential," and that we have no rational basis to do so. A number of commenters also stated that "all Agency information should be considered influential"; that "all data relied upon by the Agency should meet a high standard of quality regardless of the type"; or that "'influential' information includes information used to support any EPA action, not just 'top' Agency actions." EPA followed OMB's guidelines in establishing a definition for "influential" information that was not all-encompassing. OMB stated "the more important the information, the higher the quality standards to which it should be held, for example, in those situations involving "influential scientific, financial or statistical information...". OMB narrowed the definition of "influential" in their final guidance as follows:

> In this narrower definition, "influential", when used in the phrase "influential scientific, financial, or statistical information", is amended to mean that "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions" (67 FR 8455).

OMB also amended their definition to say that "each agency is authorized to define "influential" in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible" (67 FR 8455). We adopted OMB's "influential" definition. Once the Agency reviewed the wide range of information disseminated to the public, such as major rulemakings, risk assessments, rule related guidance, health advisories, annual reports, fact sheets, and coloring books, it became apparent that there were reasons to distinguish between "influential" information and other information. EPA adopted OMB's definition for "influential" and used types of information the Agency disseminates to further explain what information is included.

Another commenter suggested that EPA should not indicate whether disseminated information is "influential" when it is first disseminated but should wait to designate information as "influential" until either an information correction request is made or a final agency action is taken. We intend to consider this point, as well as other comments made about when disseminated information becomes influential, as the Agency implements the Guidelines.

One commenter suggests that the definition of the term "influential" should be more narrow. Specifically, the commenter states the following:

> Within the relatively narrow sphere of "disseminated" information, an agency should reserve the designation of "influential" for information disseminated in support of agency actions that are "major" regulations under Executive Order 12866, provide a "significant" opportunity to advance the agency's mandate by other means, or involve precedent-setting or reasonably controverted issues. This designation recognizes that procedures to promote the quality of information have significant costs, and that the most significant (and therefore the most costly) of such procedures should be reserved for information that is the most important in terms of the agency's mission.

EPA agrees with the commenter that there are significant costs associated with ensuring that information disseminated by the Agency is of high quality. Consequently, EPA chose a definition of the term "influential" to cover information that, when disseminated, will result in a clear and substantial impact on important public policies and private sector decisions. We believe that this definition balances the costs associated with implementing the Guidelines, the need to ensure high quality information, and the Agency's mission to protect human health and safeguard the natural environment.

Several commenters indicated that it is inappropriate for EPA to base its definition of "influential" on categories of actions. They suggest that the definition be based instead on the

content of the information. We consider our definition to be based on information content, given that those categories of disseminated information we defined as influential are those that EPA can reasonably determine will or do have a clear and substantial impact on important public policies or private sector decisions. We note here that, in addition to the specific classes of disseminated information we have defined as "influential," EPA has reiterated the "case-by-case" portion of the OMB "influential" definition. This general provision is intended to capture disseminated information, based on its content, that would not otherwise rise to the level of "influential" under the other parts of our definition (i.e., top Agency actions, Economically Significant actions, major peer reviewed products).

Several commenters assert that EPA should categorically state that certain specific types of disseminated information products are influential, and that we should categorically state that certain specific types of disseminated information products are not influential. Given the vast array of information disseminated by the Agency, and given the fact that certain information may have a clear and substantial impact on important public policies or private sector decisions at one time, but not have such an impact later on (and vice versa), classifying types of information as "influential" or otherwise upfront is difficult and could be misleading. We intend to rely on our definition in determining whether specific types of disseminated information products are to be considered "influential" for purposes of the Guidelines.

A.3.5 Reproducibility

Some commenters stated that there needs to be more clarity in the definition of "reproducibility" and related concepts. We have tried to provide definitions that are consistent with OMB guidelines. Also, our Guidelines now include that EPA intends to ensure reproducibility for disseminated original and supporting data according to commonly accepted scientific, financial, or statistical standards. Many commenters thought there should be some kind of method to consider reproducibility when proprietary models, methods, designs, and data are used in a dissemination. Some commenters discourage all use of proprietary models; others suggest proprietary model use be minimized with application limited to situations in which it is absolutely necessary. We understand this concern, but note that there are other factors that are appropriately considered when deciding whether to use proprietary models, including feasibility and cost considerations (e.g., it may be more cost-effective for the Agency to use a proprietary model in some situations than to develop its own model). In cases where the Agency relies on proprietary models, these model applications are still subject to our Peer Review Policy. Further, as recently directed by the Administrator, the Agency's Council on Regulatory Environmental Modeling is now revitalizing its development of principles for evaluating the use of environmental models with regard to model validation and certification issues, building on current good modeling practices. In addition, these Guidelines provide for the use of especially rigorous "robustness checks" and documentation of what checks were undertaken. These steps, along with transparency about the sources of data used, various assumptions employed, analytic methods applied, and statistical procedures employed should assure that analytic results are "capable of being substantially reproduced."

Regarding robustness checks, commenters were concerned that the EPA did not use the term "especially rigorous robustness checks." We have modified our Guidelines to include this term. Some commenters speculated on the ability of the Agency's Peer Review program to meet the intent of the Guidelines and were concerned about the process to rebut a peer review used to support the objectivity demonstration for disseminated information. Our Peer Review program has been subject to external review and we routinely verify implementation of the program. Affected persons wishing to rebut a formal peer review may do so using the complaint resolution process in these Guidelines, provided that the information being questioned is considered to be "disseminated" according to the Guidelines.

Regarding analytic results, some commenters indicated that the transparency factors identified by EPA (section 6.3 of the Guidelines) are not a complete list of the items that would be needed to demonstrate a higher degree of quality for influential information. EPA agreed with the list of four items that was initially provided by the OMB and recognizes that, in some cases, additional information regarding disseminated information would facilitate increased quality. However, given the variety of information disseminated by the Agency, we cannot reasonably provide additional details for such a demonstration at this time. Also, in regards to laboratory results, which were mentioned by several commenters, these Guidelines are not the appropriate place to set out for the science community EPA's view of what constitutes adequate demonstration of test method validation or minimum quality assurance and quality control. Those technical considerations should be addressed in the appropriate quality planning documentation or in regulatory requirements.

EPA has developed general language addressing the concept of reproducibility and may provide more detail after appropriate consultation with scientific and technical communities, as called for by OMB in its guidelines. We have already begun to consult relevant scientific and technical experts within the Agency, and also have planned an expedited consultation with EPA's Science Advisory Board (SAB) on October 1, 2002. Based on these initial consultations, EPA may seek additional input from the SAB in 2003. These consultations will allow EPA to constructively and appropriately refine the application of existing policies and procedures, to further improve reproducibility. In the interim, EPA intends to base the reproducibility of disseminated original and supporting data on commonly accepted scientific, financial, or statistical standards.

A.3.6 Influential Risk Assessment

General Risk Assessment

Risk assessment is a process where information is analyzed to determine if an environmental hazard might cause harm to exposed persons and ecosystems (paraphrased from Risk Assessment in the Federal Government, National Research Council, 1983). That is:

$$\text{Risk} = \text{hazard} \times \text{exposure}$$

For a chemical or other stressor to be "risky," it must have both an inherent adverse effect on an

organism, population, or other endpoint and it must be present in the environment at concentrations and locations that an organism, population, or other endpoint is exposed to the stressor. Risk assessment is a tool to determine the likelihood of harm or loss of an organism, population, or other endpoint because of exposure to a chemical or other stressor. To assist those who must make risk management decisions, risk assessments include discussions on uncertainty, variability and the continuum between exposure and adverse effects.

Risk assessments may be performed iteratively, with the first iteration employing protective (conservative) assumptions to identify possible risks. Only if potential risks are identified in a screening level assessment is it necessary to pursue a more refined, data-intensive risk assessment. The screening level assessments may not result in "central estimates" of risk or upper and lower-bounds of risks. Nevertheless, such assessments may be useful in making regulatory decisions, as when the absence of concern from a screening level assessment is used (along with other information) to approve the new use of a pesticide or chemical or to decide whether to remediate very low levels of waste contamination.

OMB Guidelines

In its guidelines OMB stated that, with respect to influential information regarding health, safety or environmental risk assessments, agencies should either adopt or adapt the quality principles in the Safe Drinking Water Act (SDWA) Amendments of 1996.[34,35] In the background section of the OMB guidelines, OMB explains that "the word 'adapt' is intended to provide agencies flexibility in applying these principles to various types of risk assessment."

Guidelines Development Consideration

EPA carefully and practically developed the adaptation of the SDWA quality principles using our considerable experience conducting human health and ecological[36] risk assessments as well as using our existing policies and guidance.

EPA conducts many risk assessments every year. Some of these are screening level assessments based on scientific experts' judgments using conservative assumptions and available data and can involve human health, safety, or environmental risk assessments. Such screening assessments provide useful information that are sufficient for regulatory purposes in instances where more elaborate, quantitative assessments are unnecessary. For example, such assessments could indicate, even with conservative assumption, the level of risk does not warrant further investigation. Other risk assessments are more detailed and quantitative and are based on research and supporting data that are generated outside EPA. For example, pesticide reviews are based on scientific studies conducted by registrants in accordance with our regulations and guidance documents. Our test guidelines and Good Laboratory Practices (GLPs)[37] describe sound scientific practices for conducting studies needed to assess human and environmental hazards and exposures. Such studies are not required to be peer-reviewed. Risk assessments based on these studies can include occupational, dietary, and environmental exposures.

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[34] Safe Drinking Water Act Amendments of 1996, 42 U.S.C. 300g-1(b)(3)(A) & (B).

[35] In section III.3.ii.C. of its guidelines, OMB states that: "With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the equality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g-1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (e.g., imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines".

[36] Because the assessment of "environmental risk" is being distinguished in OMB's adaptation of the SDWA quality principles from "human health risk", the term "environmental risk" as used in these Guidelines does not directly involve human health concerns. In other words, "environmental risk assessment" is, in this case, the equivalent to what EPA commonly refers to as "ecological risk assessment".

[37] 40 CFR part 160 for FIFRA and 40 CFR part 792 for TSCA.

The results of these risk assessments are conducted and presented to policy makers to inform their risk management decisions. EPA currently has numerous policies that provide guidance to internal risk assessors on how to conduct a risk assessment and characterize risk. The *EPA Risk Characterization Policy*[38] and associated guidelines are designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to policy makers.

EPA Existing Policies and Guidance

Current EPA guidance and policies incorporate quality principles. These are designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to policy makers. One example is the *EPA Risk Characterization Policy*[39] which provides a single, centralized body of risk characterization implementation guidance to help EPA risk assessors and risk managers make the risk characterization process transparent and risk characterization products clear, consistent and reasonable (TCCR). These principles have been included in other Agency risk assessment guidance, such as the *Guidelines for Ecological Risk Assessment.*[40] Other examples of major, overarching guidelines for risk assessments include: *Guidelines For Exposure Assessment*[41], *Guidelines For Neurotoxicity Risk Assessment,*[42] and *Guidelines For Reproductive Toxicity Risk Assessment.*[43] Each of these documents has undergone external scientific peer review as well as public comment prior to publication. Additionally, individual EPA offices have developed more specific risk assessment policies to meet the particular needs of the programs and statutes under which they operate.[44] EPA's commitment to sound science is evidenced by our ongoing efforts to develop and continually improve Agency guidance for risk assessment.

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[38] http://www.epa.gov/OSP/spc/rcpolicy.htm

[39] Ibid.

[40] US EPA(1998). Guidelines for ecological risk assessment (Federal Register 63(93):26846-26924). http://www.epa.gov/ncea/raf.

[41] US EPA (1992). *Guidelines For Exposure Assessment.* Federal Register 57(104):22888-22938. http://www.epa.gov/ncea/raf/.

[42] US EPA (1998). *Guidelines For Neurotoxicity Risk Assessment.* Federal Register 63(93):26926-26954. http://www.epa.gov/ncea/raf/.

[43] US EPA (1996). *Guidelines For Reproductive Toxicity Risk Assessment.* Federal Register 61(212):56274-56322. http://www.epa.gov/ncea/raf .

[44] The Office of Solid Waste and Emergency Response has developed Tools for Ecological Risk Assessment for Superfund Risk Assessment. One example is the *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments - Interim Final.*
http://www.epa.gov/oerrpage/superfund/programs/risk/ecorisk/ecorisk.htm
http://www.epa.gov/oerrpage/superfund/programs/risk/tooleco.htm

EPA's Experience Conducting Risk Assessments

The first EPA human health risk assessment guidelines[45] were issued in 1986. In 1992, the Agency produced a *Framework for Ecological Risk Assessment*[46] which was replaced by the 1998 *Ecological Risk Assessment Guidelines*.[47] As emphasized elsewhere in this document, the statutes administered by EPA are diverse. Although the majority of risk assessments conducted within the Agency are for chemical stressors, we also assess risks to biological and physical stressors. In addition to risk assessment guidelines, both the EPA Science Policy Council and the EPA Risk Assessment Forum have coordinated efforts to address the complex issues related to data collection and analysis for hazard and exposure assessments. Thus, the Agency has considerable experience in conducting both screening level and in-depth assessments for a wide array of stressors.

Most environmental statutes obligate EPA to act to prevent adverse environmental and human health impacts. For many of the risks that we must address, data are sparse and consensus about assumptions is rare. In the context of data quality, we seek to strike a balance among fairness, accuracy, and efficient implementation. Refusing to act until data quality improves can result in substantial harm to human health, safety, and the environment.

Public Comments

We received a range of public and stakeholder comments on the adaptation of the SDWA principles for "influential" human health, safety, and environmental risk assessments that are disseminated by EPA. Some commenters stated that we should adopt the SDWA quality principles for human health risk, safety and environmental risk assessments. Many commenters sought clarification on reasons for EPA's adaptation of the SDWA quality principles for human health risk assessments and additional information on how we plan to address this process. Others urged us to adapt the SDWA principles rather than adopt, because of certain elements in the SDWA principles that may not be applicable to all risk assessments such as a "central estimate of human risk for the specific populations affected." Others stated that we should neither adapt nor adopt SDWA principles because the "Data Quality Act" does not authorize importing decisional criteria into statutory provisions where they do not apply. The decisional criteria set forth in SDWA are expressly limited to SDWA. We also received comments at a level of detail that are more appropriate for implementation of the Guidelines than for the formulation of the Guidelines. These include comments regarding the use of clinical human test data, and comments regarding the use of particular types of assumptions in risk assessments. To the extent that an affected person believes that our use of data or assumptions in a particular

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[45] 51 FR 33992-34054, 24 September 1986.

[46] Framework For Ecological Risk Assessment, U.S. EPA, Risk Assessment Forum, 1992, EPA/630/R-92/001.

[47] Guidelines For Ecological Risk Assessment, U.S. EPA, Risk Assessment Forum, 1998, EPA/630/R-95/002F. http://cfpub.epa.gov/ncea/cfm/ecorsk.cfm

dissemination of information is inconsistent with these Guidelines, the issue can be raised at that time.

A few commenters raised a question regarding a conflict between EPA's existing policies and the SDWA principles and asked us to identify the conflicting specific risk assessment standards and make every effort to reconcile the conflicting standards with the SDWA principles. A few commenters stated that EPA should not have two separate standards for risk assessments (i.e., one for influential and one for non-influential), but that all risk assessments should be considered influential. Another stated that if there is a conflict between existing policies and the SDWA principles, EPA should identify the conflicting specific risk assessment standards and make every effort to reconcile the conflicting standards with the SDWA principles. Some commenters have questioned why the "best available, peer reviewed science and supporting studies" language of SDWA was conditioned by terms such as "to the extent practicable" or "as appropriate."

Adaptation of SDWA Quality Principles

Public comments received by the Agency on the draft Guidelines were widely divergent. As no obvious consensus could be drawn, we carefully considered comments and arguments on adoption and adaptation. We also reviewed our experience with the SDWA principles, existing policies, and the applicability and appropriateness of the SDWA language with regard to the variety of risk assessments that we conduct and have determined that, to best meet the statutory obligations of the many statutes EPA implements, it remains most appropriate to adapt the SDWA principles to human health, safety, and environmental risk assessments.

In response to public comments we have removed "as appropriate" from these Guidelines in our SDWA adaptation. EPA agrees that the phrase peer reviewed science "as appropriate" was unclear. We revised this statement in part (A) to "including, when available, peer-reviewed science and supporting studies." EPA introduced such adaptations in order to accommodate the range of real-world situations we address in the implementation of our diverse programs.

Numerous commenters expressed that EPA did not provide adequate clarifications of how we adapted the principles and what our thinking was on each adaptation. In these Guidelines we have provided detailed clarifications regarding each adaptation made to the original SDWA language and other remarks regarding our intent during the implementation of the SDWA adaptation for influential disseminations by EPA. We direct reader to the Guidelines text for such clarifications.

A.3.7 Complaint Resolution

A few commenters noted that EPA should outline how an affected person would rebut the presumption of objectivity afforded by peer review. EPA believes this determination would be made on a case-by-case basis considering the circumstances of a particular peer review and has

decided not to provide specific suggestions for affected persons on how to rebut the presumption of objectivity afforded by a peer review.

OMB and other commenters noted that agencies' guidelines needed to make clear that a request for correction can be filed if an affected person believes that information does not comply with the EPA Guidelines and the OMB guidelines. EPA has added language in the EPA Guidelines to make sure this is more clear to readers.

EPA received numerous comments on the EPA definition of affected persons. In the draft Guidelines, EPA had adopted OMB's definition. EPA agrees with comments suggesting that, instead of elaborating on the definition of "affected person," a more open approach would be to ask complainants to describe how they are an affected person with respect to the information that is the subject of their complaint. EPA is asking that persons submitting requests for correction provide, among other things, such an explanation. EPA has revised the Guidelines accordingly, so that we may consider this information along with other information in the complaint in deciding on how to respond.

Some commenters noted that the EPA Guidelines do not state how the process will work, specifically, for States, municipalities, and EPA. They expressed concern of being "caught in the middle," so to speak, on trying to get their own information corrected. EPA does not believe that the Guidelines needed greater details on how States will work with EPA to address complaints, but intends to work closely with States to better ensure timely correction. EPA does appreciate the frustration of an information owner in seeing what they deem "incorrect" information in a disseminated document or web site. However, EPA notes that this is a very complex issue that cannot be addressed with general language in the Guidelines for all cases.

Several comments indicated that EPA appears to have given itself "carte blanche" authority to "elect not to correct" information. The commenters stated that there was no valid reason why EPA would opt out of correcting information and that all errors should be corrected. To the contrary, EPA like every Federal agency wants to correct wrong information. The issue is not as simple as the correction of an improper zip code or phone number on the EPA web site. Even these simple errors may be very complex if it would involve changing data in an EPA and/or State database. Furthermore, EPA is not certain of the volume of complaints it will receive after October 1 and therefore needed to provide a general provision in the Guidelines to recognize that once EPA approves a request, the corrective action may vary depending on the circumstances. On a case-by-case basis, EPA will determine the appropriate corrective action for each complaint. EPA determined that this was the most reasonable approach. The revision also recognizes practical limitations on corrective action for information from outside sources.

Several commenters noted that EPA needs to establish time frames for the complaint process. Commenters stated that EPA should establish time frames for when affected persons can submit a complaint on an information product, when EPA needs to responds to affected persons with a decision on discrete, factual errors, when EPA would respond to affected persons with a decision on more complex or broader interpretive issues, and when an affected person should submit a

request for reconsideration. One commenter suggested that EPA solicit all complaints at one time during a 6-month window or another time frame. EPA notes that commenters provided helpful examples and well thought out proposals for such a suite of time frames and appreciates the public input.

EPA did not agree on the need to develop two separate time frames for complaints that are more factual in nature versus those that are more complex. One commenter suggests a 15-day time line for discrete factual errors and a 45-day time line for all other complaints. Another commenter recommended 30 days for factual errors and 60 days for all other complaints. Another commenter advised EPA to model this complaint process according to the FOIA process. This commenter also suggested a 3-week time line for more numeric corrections and 60 days for "broader interpretive issues or technical questions." While EPA appreciates the value of these approaches, they might be problematic to implement. However, as EPA learns more about the nature of this complaint process following some period of implementation, these suggested approaches could be revisited.

EPA also agreed with commenters that a window of opportunity for commenters to submit a request for reconsideration made sense. EPA has advised affected persons in these Guidelines to submit a request for reconsideration within 90-days of the initial complaint decision by EPA.

Some commenters asked that EPA establish time lines for when EPA would take corrective action. EPA does not anticipate that there would be any value in applying a specific time frame for this action and prefers to look at each complaint and appropriate corrective action on a case-by-case basis, as discussed above.

Commenters suggested that 45 days was a reasonable time frame for EPA to get back to the affected person with either a decision or a notice that EPA needs more time. One group noted that HHS, SSA, and NRC adopted the 45-day window. EPA disagreed with this approach and instead opted for a 90-day time frame similar to the DOT Guidelines.

EPA received many comments on how EPA should structure its internal processes for the complaint resolution process. Several comments specifically discussed the role that OEI should play in the initial complaint and the requests for reconsideration. EPA does not agree that OEI should be the arbiter on all requests for reconsideration, but does view the role of OEI in the process as an important one. Namely, OEI may work to help ensure consistent responses to complaints and requests for reconsideration. Other comments recommending specific internal implementation processes are being considered as EPA designs the correction and request for reconsideration administrative processes in greater detail.

Many commenters argued that Assistant Administrators and Regional Administrators should not decide requests for reconsideration because they would be biased or would have a conflict of interest when deciding complaints regarding information disseminated by their own Offices or programs, or if they had to reconsider decisions made by their own staffs. EPA does not agree. This type of decision making is within the delegated decision making authority of EPA's

officials, and these decisions should be presumed to be unbiased absent a specific showing that a decision maker is not impartial in a particular case. EPA does agree with commenters who noted that it is important to make consistent decisions on cross-cutting information quality issues. In order to achieve appropriate consistency of response to affected persons on requests for reconsideration and to ensure that cross-cutting information quality issues are considered across the Agency at a senior level, EPA intends for an executive panel to make the final decisions on all requests for reconsideration. Furthermore, we felt it important to add greater detail on the time frame within which EPA would respond to a requestor on their request for reconsideration. We have added that it is EPA's goal to respond to requesters regarding requests for reconsideration within 90 days.

EPA received many recommendations in public comments to include the public in the EPA complaint process. Specifically, commenters requested that EPA notify the public about all pending requests to modify information and one commenter stated that EPA should allow the public to comment on information corrections requests for information that are considered "central to a rulemaking or other Final Agency Action" before EPA accepts or rejects the request. As a general matter, EPA does not intend to solicit public comment on how EPA should respond to requests for correction or reconsideration. EPA also does not intend to post requests for correction and requests for reconsideration on the EPA web site, but we plan to revisit this and many other aspects of the Guidelines within one year of implementation.

EPA also received many comments on how information that is currently being reviewed by EPA in response to a complaint appears to the public on the EPA web site or some other medium. Some commenters recommended the use of flags for all information that has a complaint pending with a note that where appropriate, challenged information will be pulled from dissemination and removed from EPA's web site. Other commenters stated that the information in question should be removed from public access until the resolution process has been completed. Still other commenters requested that EPA not embark on self-censorship. As a general rule, EPA has decided not to flag information that has a complaint pending. EPA believes that information that is the subject of a pending complaint should not necessarily be removed from public access based solely on the receipt of a request for correction.

A.4 Next Steps

EPA is actively developing new policies and procedures, as appropriate, to improve the quality of information disseminated to the public. Some activities specifically support ensuring and maximizing the quality, objectivity, utility, and integrity of information. For instance, we are consulting with the scientific community on the subject of reproducibility. The EPA Science Advisory Board (SAB) is performing an expedited consultation on the subject on October 1, 2002. Based on this initial consultation, EPA and the SAB may consider a full review of reproducibility and related information quality concepts in 2003. Furthermore, as noted earlier, the EPA Science Policy Council has commissioned a workgroup to develop assessment factors for consideration in assessing information that EPA collects or is voluntarily submitted in support of various Agency decisions.

As new processes, policies, and procedures are considered and adopted into Agency operations, we will consider their relationship to the Guidelines and determine the extent to which the Guidelines may need to change to accommodate new activity.