

Center for Regulatory Effectiveness

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November 16, 2006

Via e-mail, emantus@nas.edu

Ellen Mantus
Board on Environmental Studies and Toxicology
Division on Earth and Life Studies
The National Academies
500 Fifth St., NW
Washington, DC 20001

Re: Project BEST-K-06-02-A, Review of the OMB Proposed Risk
Assessment Bulletin

Dear Ms. Mantus:

In July, the NRC committee for this project sent to federal agencies a series of questions, with some questions for specific agencies. One of the questions to EPA concerned interpretation of the exemptions provision in the subject proposal as it might apply to pesticide risk assessments. EPA responded, and four other agencies also commented on the exemptions provision.

The exemptions provision has also received widespread attention in the public comments to OMB, and is a matter of concern to CRE. We believe it is one of the most important issues in the OMB proposal. Accordingly, we have prepared the attached paper that examines in detail how the exemptions provision has evolved through the various OMB data quality guidance documents, the issues it raises, and our recommendations for addressing those issues. Our basic conclusion is that there is no supportable rationale and legal justification for the proposed exemptions, nor for the EPA interpretation regarding pesticide risk assessments.

We request that you distribute the attached paper on the exemptions issues to the committee members for this project. We are providing a copy to OIRA.

Thank you.

Sincerely,

/s/

William G. Kelly, Jr.
Western Representative
Center for Regulatory Effectiveness

Attachment

cc w. att.: Dr. Nancy Beck, OMB/OIRA

**LACK OF JUSTIFICATION AND EXPLANATION FOR
THE EXEMPTIONS IN OMB’S PROPOSED
DATA QUALITY RISK ASSESSMENT GUIDANCE**

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I. Executive Summary

The Data Quality Act (“DQA”)¹ guidelines on risk assessment currently proposed by OMB contain broad exemptions that can be interpreted to go far beyond the exemptions in the original general government-wide DQA guidelines of 2001 and 2002. A recent response by EPA to the National Research Council committee reviewing the OMB risk assessment proposal demonstrates this. OMB has not provided any cogent or consistent rationale – legal or policy – for these apparently expanded exemptions, as it must. The currently proposed exemptions language, as well as the previously used language, has generated widespread concern and uncertainty. Before broad new exemptions become firmly embedded as interpretations of the DQA, it is becoming increasingly important to examine how the exemptions could be interpreted, whether they have been explained and justified, and whether they could be justified if their limits were carefully clarified.

This paper examines in detail the evolution of the exemptions provisions, rationales given or not given, their implications, and makes recommendations for clarification.

The exemptions began in the original DQA guidelines of 2001 and 2002 as a qualification to the definition of the statutory term “dissemination”: Information would not be regarded as disseminated and subject to the guidance if its distribution was “limited to”

¹ The DQA is the legislation enacted in 2000 to mandate implementation of the information dissemination and quality guideline provisions of the Paperwork Reduction Act of 1995 (“PRA”, 44 U.S.C. § 3501 *et seq.*). See 44 U.S.C. § 3516, note. The 2000 legislation did not contain a formal title, but it has been popularly referred to as either the Data Quality Act or the Information Quality Act. The DQA specifically incorporates by reference the provisions of the PRA. In this paper, when we refer to the “DQA” we are referencing both the 2000 legislation and the PRA.

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adjudicatory processes. This qualification/exemption thus appeared to state that the guidance would not apply to information that was not intended to be distributed to the public – *i.e.*, outside a specific adjudicatory proceeding and its individual parties. The rationale given for this limitation also indicated that it was intended to apply only to adjudicatory proceedings that provided the individual parties with a formal evidentiary hearing.

Subsequently, in the peer review guidance and the current risk assessment proposal, the original definition of “dissemination” with this limitation has been retained, but a new section on “exemptions” has been added. Each time this new exemptions provision has been proposed or finalized, the language in the preamble and in the substantive portion of the guidelines has changed, and without any explanation or rationale, and not framed as a response to public comments. The language used in the peer review guidelines and proposed for the risk assessment guidelines appears capable of being interpreted to apply to any risk information used in support of an adjudication (including permitting, licensing, registration, approvals, labeling, or site-specific determination) or inspections. Such an exemption could affect a vast number of proceedings under multiple environmental, health, and safety statutes, or non-environmental statutes requiring an environmental review. EPA has argued for this interpretation in the context of pesticide registrations, and several other federal agencies have supported the exemptions or requested that they be made broader, while others have opposed or questioned them. A wide array of nonprofit, industry, and other governmental entities have opposed the exemptions, called for clarification, or questioned whether they are justified, demonstrating the need for further review of this matter.

Our central conclusion and recommendation is that the only justifiable exemption is the one in the original guidelines, which remains in effect, and is the only one, if any, that should remain in effect. That exemption is a simple qualification to the definition of “dissemination” to make it clear that “dissemination” to the public does not occur when a distribution of information is “limited to” an adjudicatory proceeding that provides a formal evidentiary hearing. Subsequent changes have not been explained or justified, and therefore violate fundamental Administrative Procedure Act principles and are contrary to the DQA.

II. Legislative Background

The Paperwork Reduction Act of 1995 (“PRA”) directed OMB to “develop and oversee the implementation of policies, principles, standards and guidelines to – (1) apply to Federal agency dissemination of public information regardless of the form or format in which such information is disseminated.” 44 U.S.C. § 3404(d)(1). This PRA provision is explicitly incorporated by reference into the 2000 DQA legislation. The “Purposes” provisions of the PRA are also incorporated. One purpose is to “ensure the greatest possible public benefit from and maximize the utility of information created . . . and disseminated by or for the Federal Government”. Another is to “improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society.” 44 U.S.C. § 3501(2) and (4). The 2000 legislation directs OMB to issue guidelines to fulfil the stated purposes of the PRA. The PRA also defines “public information” to mean “any information, regardless of form or format, that the agency discloses, disseminates, or makes available to the public.” 44 U.S.C. §

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3502(12) (emphasis added). The term “any” is regarded as all-encompassing, absent some other indication or presumption regarding Congressional intent.²

The DQA does not indicate any exemptions whatever to its coverage of “dissemination of public information.” Neither does its legislative history. On the other hand, the information collection provisions of PRA do provide specific exemptions. 44 U.S.C. §§ 3502(3)(B) and 3518(c)(1). The statutory construction maxim of *inclusio unius est exclusio alterius* (to include one is to exclude the other) indicates strongly that Congress, when it set out very explicit exceptions to the definition of a “collection of information”, but did not set out any for information dissemination, did not intend to allow any exemptions for information dissemination.³ The kind of exemptions specified for information collection, but not for information dissemination, are also pertinent to the legislative intent regarding information dissemination, since they indicate that Congress considered inclusion of exemptions of the kind under discussion here for PRA directives. One of the exemptions for information collections specified in the PRA encompasses some types of proceedings that the OMB guidelines exempt from information dissemination. That information collection exemption in the statute is for information collected “during the conduct of . . . an administrative action . . . against specific individuals or entities.” 44 U.S.C. § 3518(c)(1)(B). This is a description of an adversarial adjudicatory proceeding, and OMB has provided exemptions in its DQA guidelines for just such types of proceedings even though they were not specified as exemptions to the PRA information dissemination provisions.

The legislative history of the PRA confirms that Congress gave careful consideration to the appropriateness of exemptions for information collections:

[S]ection 3518(c)(1) creates certain exemptions for civil and criminal law enforcement that apply to collection of evidence pursuant to investigations whether before or after initiation of formal charges. These exemptions are not limited to formal discovery or analogous stages in administrative processing and include interrogatories, depositions and subpoenas. . . . The language in this subsection regarding ‘an administrative action or investigation involving an agency against specific individuals or entities’ is intended to preserve a well-settled exception for subpoenas and similar forms of compulsory process used for the collection of evidence or other information in an adjudication or investigation

² *United States v. Gonzales*, 520 U.S. 1, 5 (1997) (holding that “any other term of imprisonment” includes terms of imprisonment imposed by State as well as federal courts). *Cf. Small v. United States*, 544 U.S. 385, 388-91 (The expansive interpretation of “any” in *United States v. Gonzales* does not apply to foreign convictions due to the commonsense presumption that Congress generally legislates with domestic concerns in mind.”).

³ *See, e.g., Russello v. United States*, 464 U.S. 16, 23 (1983) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”).

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for law enforcement purposes. See 4 C.F.R. Section 10.6 (c)(5), (c)(8). Section 3518(c)(1)(B) [the subsection quoted in the above paragraph] is not limited to agency proceedings of a prosecutorial nature but also includes any agency proceeding **involving specific adversary parties**. Similar to the collection of information in litigation, **an agency’s intended use of investigatory and adjudicative process is sufficiently safeguarded through judicial superintendence to render unnecessary the administrative clearance process of this Act.**”

S. Rep. No. 930, 96th Cong., 2d Sess. at 2980, reprinted in 1980 USCCAN 6241, 6295-96 (emphasis added). The “administrative clearance process” of the PRA referred to above in the report involves agency and OMB review of the utility/necessity of the information collection, the burden it imposes, and opportunity for, and review of, public comments. During formal administrative proceedings – *i.e.*, those overseen by an administrative law judge or hearing examiner – discovery to collect evidence/information from an opposing party is subject to similar review under rules and principles for determining relevance/necessity and burden, with opportunity for the parties to object to discovery on such bases.⁴ More importantly, discovery, and the associated judicial superintendence, of information collection is unnecessary if the information has been, or is being, publicly disseminated, thereby making discovery unnecessary. Similarly, there is a degree of “judicial superintendence” of information introduced as evidence (as opposed to information collected/discovered) in a formal administrative proceeding; but there is no such superintendence of public dissemination of the information.⁵ Thus, there is no “judicial superintendence” of the public dissemination of agency information, although there might be limited superintendence of its use within the confines of the proceeding. It should also be noted that the exemption for information collections in administrative adjudicatory proceedings pertains only to collection of information “during the conduct of” the proceeding; it does not pertain to collections outside the conduct of such proceedings, even though the collection might then later be used in the proceedings. The same distinction between information introduced “during the conduct” of adjudicatory proceedings and information disseminated to the public but also used in administrative proceedings appears to be appropriate.

⁴ See, e.g., 5 U.S.C. §§ 554, 556, 558 (APA provisions regarding adjudications/licensing requiring hearings and procedures for hearings); 40 CFR Part 22, (EPA’s “Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits”); *Federal Maritime Comm’n v. South Carolina State Ports Authority*, 535 U.S. 743, 756-59 (2002).

⁵ In addition, even in the case of information introduced as evidence in a formal administrative/adjudicative proceeding, and particularly in the case of risk assessment information, there do not appear to be any quasi-judicial superintendence constraints on the quality of the information in terms of whether it meets the DQA quality standards; and it is doubtful that an administrative law judge or other presiding official could exclude an agency risk assessment on grounds, for example, that a scientific assessment of risk was biased by agency policy, since such officials do not have the authority to override agency policy.

Information disseminated to the public outside formal administrative adjudicatory proceedings is not subject to oversight similar to "judicial superintendence."⁶

In view of the apparent Congressional intent not to provide for exemptions to the information dissemination provisions of the IQA, and the inapplicability of the rationale for the information collection exemptions to public information disseminations, there is a heavy burden on OMB to explain and justify any exemptions to public information dissemination under the DQA, and to delineate any such exemptions with care and precision.

III. History of Changes in the Exemptions Language in the OMB Guidelines

In each case, the potentially significant new or changed wording discussed below is underlined. Unfortunately, this historical "summary" is unavoidably complex due to the many changes in language and explanation (or lack of explanation).

The Initial OMB Government-Wide Guidelines

The first DQA guidelines proposed and promulgated by OMB were the government-wide guidelines of September 2001 and February 2002. 66 FR 49718, Sept. 28, 2001; 67 FR 8452, Feb. 22, 2002. They were first promulgated as "interim final" guidelines in 2001, and then as "supplemental final" guidelines in 2002.

When both of those government-wide guidelines were proposed, they included a definition of "dissemination" that stated that the term "means government initiated distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use of sharing of government information, and responses to requests for agency records under the Freedom of Information Act . . . or Privacy Act. This definition also does not include distribution limited to replies to correspondence and subpoenas or judicial process." 66 FR 34489, 34492-93, June 28, 2001 (substantive portion) (emphasis added). The preamble to the proposal stated that the draft definition of "dissemination" was "modeled . . . on the longstanding definitions . . . in OMB Circular A-130, but tailored . . . to fit into the context of these guidelines." *Id.* at 34491 1st col. No further explanation was given. The version of OMB Circular A-130 in effect at that time⁷, however, contained a definition of "dissemination" that did not include an exemption for "judicial process".

⁶ The American Bar Association's comments on the proposed assessment risk Bulletin suggest that the Bulletin should not be applied to adjudications because, among other reasons, the PRA does not apply to adjudications, citing § 3518(c)(1)(B)(ii). At 8. The ABA reference to the PRA in support of a broad exemption for dissemination of agency risk information is mistaken, since the PRA section the ABA section cited applies only to information collection in formal adversarial administrative proceedings.

⁷ Revision No. 3, Feb. 1996.

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The interim final government-wide OMB guidelines of September 28, 2001 included an altered definition of “dissemination” that stated that the term “does not include distribution limited to . . . adjudicative processes.” 66 FR at 49725 1st col. (substantive portion) (emphasis added). The term “adjudicative processes” was not defined.

The preamble portion of the interim final 2001 guidelines did, however, again state that “OMB modeled the definitions of ‘information,’ ‘government information,’ ‘information dissemination product,’ and ‘dissemination’ on the longstanding definition of those terms in OMB Circular A-130, but tailored them to fit into the context of these guidelines.” 66 FR 49720 1st col., 49722 3d col., and see 49718 2d and 3d col. The definition of “dissemination” in Circular A-130 is “the government initiated distribution of information to the public.” The only exception in the definition is “distribution limited to government employees or agency contractors or grantees, intra- or inter-agency use or sharing of government information, and responses to requests for agency records under the Freedom of Information Act (5 U.S.C. 552) or Privacy Act.” The terms “government information,” “information,” and “information dissemination product” in the Circular encompass any type of “communication or representation of knowledge” without exception. The Circular A-130 definitions did not (and still do not⁸) include an exemption for either “judicial process” or “adjudicative processes.”

The September 2001 preamble did not articulate an explanation or justification for the “adjudicative process” exemption; rather, it simply stated that “in the definition of ‘dissemination,’ we changed the exclusion for ‘judicial process’ to adjudicative process’ to make it clear that these guidelines do not apply to the issuance of agency adjudicative decisions.” 66 FR at 49723 1st col. (emphasis added). There also was no indication of what public comments, if any, had provided the impetus for this change.⁹

In its supplemental final government-wide guidelines of February 22, 2002, OMB provided some explanation of its intent behind the exemption for “adjudicative processes”. The explanation stated:

The exemption from the definition of “dissemination for “adjudicative processes” is intended to exclude, from the scope of these guidelines, the findings and determinations that an agency makes in the course of adjudication involving specific parties. There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide

⁸ Rev. No. 4, Nov. 28, 2000, is still in effect.

⁹ OMB received almost 100 public comments on the proposed rule, including comments from most federal agencies that would be affected. Those comments are available at <http://www.thecre.com/quality/comments/DQGuidanceComments.html>. OMB also convened an inter-agency working group to assist in developing the guidelines. 66 FR 49720 2d col. Thus, it is not clear that the substance of all agency comments was made publicly available.

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parties to such adjudicative proceedings any additional rights of challenge or appeal. [Emphasis added]

67 FR 8452, 8454 2d col.¹⁰ The wording of the exemption for “adjudicative processes” in the definition of “dissemination” in the substantive portion of the rule remained the same as it had been in the September 2001 interim final guidelines. 67 FR 8460 3d col. It should be noted that this preamble explanation is ambiguous with regard to what is exempted. The previous guideline and explanation stated that the exemption applied to “adjudicative processes,” and then “adjudicative decisions”. This explanation does not refer to either “adjudicative processes” or “adjudicative decisions” and could be read as exempting any information (“findings and determinations”) introduced by the agency as a party to the proceedings, rather than “findings and determinations” made by an administrative law judge or other official presiding over the adjudicatory proceedings. The validity and implications of this supplemental explanation of the exemption are examined later in this paper in the Discussion section.

The OMB Government-Wide Peer Review Guidelines

There were two proposals for DQA peer review guidelines. In OMB’s initial proposed peer-review guidelines of September 15, 2003, OMB simply referenced its definition of “dissemination” in the February 22, 2002 guidelines. 68 FR 54023, 54027 2d col.

On April 28, 2004, OMB issued a revised proposal for peer review guidelines. The preamble of the proposal used the previous definition of dissemination exempting “distribution limited to . . . adjudicative processes.” 69 FR 23230, 23233 2d col. Another portion of the revised proposal, however, contained a new section on “Exemptions” with an expanded explanation of the “adjudicative processes” exclusion:

This Bulletin does not cover official **disseminations that arise in adjudications and permit proceedings**, unless the agency determines that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) and likely to have precedent setting influence on future adjudications or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration process for specific products and development activities, as well as site specific disseminations such as those made under Superfund or the National Environmental Policy Act (NEPA).

69 FR at 23238 3d col. The proposal did not explain the source of this new language or its supporting rationale or legal justification.

¹⁰ In its interim final government-wide guidelines of Sept. 28, 2001, OMB requested additional comment on the standard of “capable of being substantially reproduced” and the definition of “influential scientific or statistical information.” It did not request additional public comment on other aspects of the rule. Thus, it is not clear where the impetus came from for this explanation of the exemption for “adjudicative processes.”

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The substantive portion of the revised proposal contained the following exemptions language:

Agencies need not have peer review conducted on information that is . . . 3. **Disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination)** unless the agency determines that the influential dissemination is scientifically or technically novel and likely to have precedent-setting influence on future adjudications and/or permit proceedings.

69 FR at 23241-42. It is noteworthy that the above language incorporated the term “dissemination” that was already defined as excluding information the distribution of which was “limited to” adjudicative processes. Thus, this language might be viewed as incorporating the “dissemination” definition.

On December 16, 2004, OMB issued its final guidance on peer review (published in the *Federal Register* on January 14, 2005, 70 FR 2664).

In the final guidance, the definition of dissemination remained the same as previously, with its exclusion for “distribution limited to . . . adjudicative processes.” 70 FR 2667 1st col., 2674 3d col. The “exemptions” language also remained the same, except that the words “practical and appropriate” were added to the portion regarding agency discretion.

The substantive portion of the final peer review guidance stated:

Agencies need not have peer review conducted on information that is: . . . 2. **Disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination)** unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings. [Emphasis added to indicate new language.]

The preamble explanation remained the same in substance, but eliminated the reference to Superfund or NEPA as examples of exempt site-specific disseminations. However, the preamble contained a new qualifying paragraph:

If information is disseminated pursuant to an exemption to this Bulletin, subsequent disseminations are not automatically exempted. For example, if influential scientific information is first disseminated in the course of an exempt agency adjudication, but is later disseminated in the context of a non-exempt rulemaking, the subsequent dissemination will be subject to the [peer review] requirements of this Bulletin even though the first dissemination was not.

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70 FR at 2674 2d col. Note again that the term “dissemination”, that has already been defined as excluding distribution “limited to” adjudicative processes, is employed in the exemptions language, possibly indicating that the changes were made with the intent of defining an “adjudication”, not the changing the definition of “dissemination”.

The reference to “influential scientific information” is also interesting, because it indicates that the exemptions could apply to information that would have a substantial impact on important public policies or private sector decisions (67 FR 8460 3d col.), and it is unclear how this could be the case if its distribution were “limited to” the adjudicatory process. Perhaps the intent was to explain that the exemption did not apply if the information used in the adjudicatory proceeding (or the adjudicatory “decision”?) later became “influential” due to being distributed to the public.

Despite its request for additional comment when it published the revised peer review proposal in April 2004, the final guidance did not contain a response to comments section, and in particular did not address any comments on the new “exemptions” section added to the revised proposal.

Although the addition of the words “practical and appropriate” is not explained in the rulemaking notice, it appears from that wording that the new exemptions section might have been the result of comments submitted by the American Bar Association’s Section of Administrative Law and Regulatory Practice (“ABA”).¹¹ The ABA comments supported the proposed exemptions for peer review and cautioned against the proposed proviso that the exemption for an individual adjudication or permit proceeding would not apply if “the agency determines that the influential dissemination is scientifically or technically novel and likely to have precedent-setting influence on future adjudications and/or permit proceedings.” The ABA comments observed that “the mere attempt to apply peer review to an adjudication also raises practical concerns” and that peer review in an adjudicatory context “raises procedural complexities not present in other forms of agency dissemination.” This, it explained, is because “[t]raditionally in an administrative adjudication, the validity of scientific information submitted by a party is assessed by the administrative law judge both as to admissibility and as to the weight it should be afforded.” If the ALJ is to invoke peer review, the comments asked, how would that be done? Thus, the ABA section made out a case for exempting scientific and technical information presented in adjudicatory and permit proceedings from peer review requirements that would have to be conducted during the course of the proceedings.¹²

¹¹ Letter from William Funk, Section Chair, to Dr. Margo Schwab of OIRA, dated May 28, 2004. Available at www.abanet.org/adminlaw/policy_letters/policyletters.html.

¹² See also the ABA comments (May 22, 2006) on the proposed risk assessment Bulletin at 8. Available at http://www.whitehouse.gov/omb/inforeg/comments_rab/aba.pdf.

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The OMB Proposed Guidance on Risk Assessment¹³

The OMB proposal appears to adopt uncritically in large part the exemptions language from the peer review guidance of 2005¹⁴ rather than the language from the original broad guidance of February 2002, and then extends it even further to encompass product labeling and inspections..

The preamble to the proposed risk assessment guidance states:

The Bulletin does not apply to risk assessments that arise in the course of individual agency adjudications or permit proceedings, unless the agency determines that: (1) compliance with the Bulletin is practical and appropriate and (2) the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities. This Bulletin also shall not apply to risk assessments performed with respect to inspections relating to health, safety, or environment.

This Bulletin also does not apply to any risk assessment performed with respect to an individual product label, or any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use. An example of this type of risk assessment includes risk assessments performed for labeling of individual pharmaceutical products. This Bulletin does apply to risk assessments performed with respect to classes of products. An example of this type of risk assessment is the risk assessment performed by FDA in their evaluation of the labeling for products containing trans-fatty acids. [Emphasis added]

The preamble does not provide any further explanation or any justification for these exemptions. However, the portion of the preamble discussing the scope of the term “influential risk assessment” raises questions concerning the intended scope of the exemptions. On that subject, the preamble gives as examples of “influential risk assessments” covered by the guidance “assessments that determine the level of risk regarding health . . . safety and

¹³ A notice of availability for the proposed guidelines was published in the *Federal Register* on January 17, 2006. The notice announced a comment period until June 15. The text of the proposal is available at http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf. The notice also announced that the proposed bulletin would be peer reviewed by the National Academy of Sciences (actually the National Research Council of the National Academies) Links to the proposal, the NRC review webpage, and public comments are also available at <http://www.whitehouse.gov/omb/inforeg/infopoltech.html#iq>.

¹⁴ However, the reference to “site-specific” determinations is notably absent, although many such determinations would be covered by licensing or permitting.

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environment,” and gives as examples “reference doses, reference concentrations, and minimal risk levels.” Other examples given include “margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles, NIOSH current intelligence bulletins and criteria documents, and risk assessments performed as part of economically significant rulemakings.” The problem with reading this explanation in conjunction with the exemptions language is that many of these types of risk assessments are used in individual adjudicative or permit proceedings (*e.g.*, IRIS RfDs, margin of exposure estimates, food tolerances, and NAAQS standards) and therefore might be considered to be risk assessments that “arise in the course” of, or are “performed with respect to”, individual adjudicative or permit proceedings.

The substantive portion of the guidance Bulletin states the exemptions described in the preamble in different language in a section titled “Applicability”, dispensing with the “arise in the course of” wording:

2. This Bulletin does not apply to risk assessments performed with respect to:
 - a. inspections relating to health, safety, or environment;
 - b. individual agency adjudications or permit proceedings (including a registration, approval, or licensing) unless the agency determines that
 - i. compliance with this Bulletin is practical and appropriate, and
 - ii. the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings; and
 - c. an individual product label, or a risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use. [Emphasis added]

Note that these provisions do not use the term “disseminated”, which was defined and used in both the original final guidance (both interim and supplemental) and the peer review guidance, although presumably that definition remains in effect with regard to all types of information. Note also that the exemptions for adjudications or permitting are not modified by “for specific product development activities” as in the preamble explanation.

Summary of the Changes

The exemptions language in the OMB guidance – from the original IQA guidance to the currently proposed risk assessment guidance – has changed in what appear to be substantial respects. The import of these changes is not clear, since little or no explanation has been provided. In summary, here are the different substantive descriptions of the exemptions and any explanation provided by OMB in its three final guidance documents and its current proposed risk assessment guidance:

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The original interim final government wide guidance (Sept. 2001)

Substantive portion: The term “dissemination” “does not include distribution limited to . . . adjudicative processes.” (Emphasis added)

Preamble: No explanation given other than the statement that “the guidelines do not apply to the issuance of agency adjudicative decisions.” (Emphasis added)

The supplemental final government-wide guidance (Feb. 2002)

Substantive portion: No change from substance of previous guidance (the definition of “dissemination”).

Preamble: Explanation added: “The exemption from the definition of ‘dissemination’ for “adjudicative processes” is intended to exclude, from the scope of these guidelines, the findings and determinations that an agency makes in the course of adjudication involving specific parties. There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal.” (Emphasis added)

The final peer review guidance (Dec. 2004)

Substantive portion: The definition of “dissemination” remained the same as in previous guidance, but a new section on “Exemptions” was added, stating that agencies do not have to conduct peer review on information “[d]isseminated in the course of an individual adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination) unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent setting influence on future adjudications and/or permit proceedings.” (Emphasis added)

Preamble: No rationale or justification for the new language was given, but it was explained that the exemption does not necessarily cover information that was initially exempt if it is later disseminated in the course of a non-exempt rulemaking.

The current proposed risk assessment guidance

Substantive portion: The proposal would provide an exemption for risk assessments “performed with respect to” inspections and individual “adjudications or permit proceedings (including a registration, approval, or licensing)” unless the agency determines that compliance with the guidance is “practical and appropriate” and scientifically or technically novel or likely to be precedent-setting with regard to future adjudications or permit proceedings. Risk assessments “performed with respect to”

product labeling approved by a Federal agency are exempt without regard to the agency discretion applicable to inspections, adjudications, and permit proceedings. (Emphasis added)

Preamble: No explanation has been given. EPA and some other agency comments indicate a desire for a broad interpretation. The preamble description of examples of “influential risk assessments” subject to the guidance includes types of risk assessments likely to be used in support of, or in the course of, adjudications and permit proceedings, and which might be considered to be “performed with respect to” adjudications, permit proceedings, labeling, or inspections.

IV. EPA’s Interpretation of the Exemptions and its Implications

On July 5, 2006, the National Research Council committee reviewing the proposed OMB guidance sent a series of questions to the agencies, through OMB, that included a question directed specifically to EPA about how it interpreted the exemptions language with regard to pesticides.¹⁵ The committee asked EPA: “Regarding pesticides specifically, what risk assessment activities will be covered by the Bulletin and what risk assessment activities will be exempted?”¹⁶ EPA responded --

The Agency agrees with the OMB bulletin that risk assessments for permitting or licensing **programs** should be exempt. **Thus, pesticide risk assessments or actions under FIFRA would be excluded** given that pesticide registration/re-registration program is a licensing program. However, the proposed Bulletin did indicate that actions that involve assessment/reassessment of tolerances for pesticide residues on food would be subject to the Bulletin (page 10, par. 2). EPA’s Office of Pesticide Programs conducts risk assessments **in support of** the establishment of tolerances under [sic] Federal Food Drug and Cosmetic Act (FFDCA). **Because pesticide risk assessments supporting tolerances are tied to the pesticide registration-re-registration program (i.e., licensing), such risk assessments should also be exempted from the OMB bulletin.** Furthermore, all new food tolerances are impacted by the short PRIA (Pesticide Registration Improvement Act) time frames (2 years and less). Although **pesticide risk assessment tied to the registration/re-registration program (licensing) should be exempted**, we agree with OMB that certain pesticide risk assessments that have significant science issues that are debated by the scientific community and

¹⁵ It is strange that the NRC committee requested EPA to interpret the OMB proposal, rather than OMB. It is also strange that EPA was the only agency questioned with regard to its view on the impact of the exemption language, and only with regard to pesticides, since the proposed OMB exemptions language does not refer to pesticides, and it obviously encompasses far more than pesticides and applies to agencies other than EPA.

¹⁶ Memorandum to agencies from Steven D. Aitken, Acting OIRA Administrator, dated July 5, 2006, attaching the NRC committee’s questions.

that have intra- and inter-agency impact on regulatory decisions of broad consequences (e.g., arsenicals) should be subject to the Bulletin."¹⁷

Pesticide risk assessments “supporting” tolerances and “tied to” pesticide registration or re-registration, would apparently exempt risk “reference levels” (RfDs and RfCs) included in the EPA IRIS¹⁸ database and disseminated broadly to the public and often relied on by State governments and affected persons. The preamble to the OMB proposal also specifies, in the portion referenced above by EPA, that “reference levels” and IRIS information are to be regarded as “influential” risk information covered by the guidance. Reference levels are risk assessments “supporting tolerances” and “tied to” pesticide registrations because they determine the size of the “risk cup” used to determine the allowable levels of pesticide food tolerances. Nevertheless, EPA’s response to the NRC committee does not specifically refer to reference levels or IRIS, perhaps because it is aware that any such reference would be a tipoff to the extraordinary breadth and implications of the exemption interpretation it wishes to have adopted.

V. Potential Impact of the Proposed Exemptions

The EPA response regarding pesticide risk assessments raises the question of whether EPA could adopt the interpretation it proposes based on the existing language in the proposed guidance and without any changes by OMB. It appears that EPA could arguably take the position that the statements regarding what is included in the term “influential risk assessments” (e.g., IRIS values) must be read together with the exemptions section, so that even “influential” risk assessments such as those described are exempt if they support an exempt activity. Moreover, if a similar interpretation were adopted by, or with regard to, other agencies, a great number of influential risk assessments would be exempted.

If EPA’s reasoning in responding to the NRC committee were adopted, by EPA, by OMB, or by other agencies, and applied to programs other than pesticide registration – *i.e.*, that the “Applicability” “exemptions” should include (or be interpreted to include) all risk assessments underlying and used “for”, “in support of”, and “tied to” adjudication and permit/licensing proceedings – a huge number of federal permit proceedings, adjudications, and inspections would be excluded. Below is a list of federal statutes involving permit or petition (and often inspection or labeling) actions that appear to be encompassed by the exemptions. The risk assessments underlying and used in these proceedings are often widely disseminated to the public -- either apart from the adjudicatory proceedings or through notice and comment opportunities during such proceedings -- and are often matters of keen public interest and

¹⁷ At 16.

¹⁸ IRIS stands for “Integrated Risk Information System”. Despite the title and obvious purpose of this database, some commenters have argued that IRIS information should not be subject to the OMB guidance because it is “hazard” information rather than “risk” information.

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influence public perceptions and State and local governmental legislative and regulatory actions.¹⁹

- Atomic Energy Act licensing and permitting
- CERCLA (Superfund) adjudications and permitting
- Clean Air Act permits (NSR and PSD)
- Clean Water Act permits (sec. 404, NPDES, and TMDLs)
- Consumer Product Safety Act labeling and rulings on petitions
- Endangered Species Act incidental take permits
- Federal Food, Drug and Cosmetic Act labeling and approvals
- Federal Hazardous Substances Act adjudications
- Federal Insecticide, Fungicide and Rodenticide Act registrations and labeling
- Federal Land Policy and Management Act permits (rights-of-way, grazing, timber harvesting)
- Federal Power Act permits/licenses
- Hazardous Materials Transportation Act registration, licensing, labeling
- Magnuson-Stevens Fishery Conservation and Management Act permits
- Marine Mammal Protection Act permits
- Marine Protection, Research, and Sanctuaries Act permits
- Occupational Safety and Health Act inspections, labeling, adjudication
- Outer Continental Shelf Lands Act oil/gas/mining permits/leasing
- Resource Conservation and Recovery Act corrective action proceedings and Part B permitting
- Rivers and Harbors Act permits
- Safe Drinking Water Act permits for underground injection
- Solid Waste Disposal Act permits
- Surface Mining Control and Reclamation Act permits
- Toxic Substances Control Act labeling

VI. Organizations Opposing or Questioning the Proposed Exemptions

Attesting to the importance of the exemptions issue, twenty-four public comments filed with OMB on its proposed bulletin and five federal agency responses to questions addressed to federal agencies by the National Research Council have either opposed or questioned the basis for, or meaning of, the exemptions:

Non-profits, Professional Associations, Governmental Entities, and Think Tanks

American Bar Association (At 8-9)²⁰

¹⁹ See, *e.g.*, EPA's guide to "Public Involvement in Environmental Permitting", particularly section 3, available at <http://www.epa.gov/permits/publicguide.pdf>.

²⁰ The ABA comments, while supporting some exemptions for adjudicatory proceedings, as in the original OMB guidance, recommended that OMB consider carefully how to distinguish between use of risk assessments in adjudicatory proceedings that might pose legal/procedural or practical issues from

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American Water Works Association (attached comments of Dr. Crawford-Brown on product labeling, sec. 7: explanation and justification for exemption of product labeling should be clarified)

Iowa State University, Biosafety Institute for Genetically Modified Agricultural Products (At 2, questions whether there is a justification for the exemptions)

Center for Regulatory Effectiveness (At 6-7, questions legal validity of exemptions)

Environmental Working Group (At 3, questions whether there is a rationale for exemptions)

Leech Lake Band of Ojibwe (Comment 4, requests that OMB provide the rationale for the exemptions)

Minnesota Chippewa Tribe (supports Ojibwe request for clarification, *supra*)

Lorenz Rhomberg (At 10, applicability/exemptions need to be clarified)

Natural Resources Defense Council (At 7-8, opposing exemptions)

OMB Watch and Public Citizen (At 13, opposing exemptions for product labeling)

Pamela Williams, ScD.(At 2, sec. 3, requests clarification of coverage)

Policy Navigation Group (At 6, opposes exemptions as they would apply to site-specific assessments)

Regulatory Checkbook (At 18-19, discusses, suggests changes)

Society of Toxicology, Risk Assessment Specialty Section (identified as an issue by multiple section members)

Swinomish Tribal Community (At 2, sec. 4, OMB fails to explain and justify exemptions)

Federal Agencies

Department of Defense (At 9 in responses to NRC questions, regarding need for clarification of exemptions)

Department of Health and Human Services (At 8, in responses to NRC questions, seeks broadening of exemptions to include risk assessments for classes of products)

Department of Energy (At 7-8, seeks expansion of exemptions to include “influential” risk assessments)

Department of Housing and Urban Development (At 2, in responses to NRC questions, suggests clarification of exemption for inspections)

Environmental Protection Agency (At 16, requests extension of exemptions, or clarification, to include pesticide risk assessments supporting registration tolerances)

Industry

Aerospace Industries Association (At 4-5,7-8, opposes exemptions for site-specific assessments under, e.g., CERCLA, RCRA, and CWA, and requests clarification of exemption for inspections)

American Chemistry Council (At 10-11 of 6/15/06 comments, opposes exemptions)

adjudicatory situations that do not pose such problems. At 8-9. Available at http://www.whitehouse.gov/omb/inforeg/comments_rab/aba.pdf.

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Animal Health Institute (At 2, questions exemption for product development activities and labeling)
CropLife America (At 1-2, opposes exemptions)
Edison Electric Institute (At 2, opposes exemptions)
General Electric Co. (At 4, opposes exemptions for CERCLA, RCRA, and NPDES proceedings and permitting)
National Association of Manufacturers (At 4-5, opposes exemptions)
National Federation of Independent Businesses (At 4-5, appears to oppose, but not completely clear)
Rio Tinto Minerals (At 2-3, opposes, questions exemptions)

It is clear that there is widespread concern and confusion over the meaning of, and the policy rationale and legal justification for, the exemptions. Concerns are not being expressed predominantly by any one interest group.

VII. Discussion

The wording of the exemptions in the three final guidelines and the currently proposed risk assessment guidelines has been constantly changing, with either different rationales or no rationale given for the changes. The original government-wide guidelines contained a simple limitation on the definition of “dissemination”; the peer review guidelines and the risk assessment proposal contain a new section on “exemptions” with different wording from the original guidance and from each other.

Under the Administrative Procedure Act, and case law, an agency change in policy must be adequately explained. If the change is a change in the agency’s interpretation of law (such as the IQA), it must be justified under the principles of *Chevron*.²¹ It is clear that OMB has not to date provided a reasoned explanation and justification for the changes in exemptions, nor has it addressed public comments.

The changes in wording from the original guidance to the current risk assessment guidance proposal are mainly of two types.²² First, the kind of proceedings to which the limitations and/or exemptions apply has changed. The term “adjudicatory processes” in the original guidance has been altered and expanded to “individual adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination)” in the peer review guidance, and similar language in the proposed risk assessment guidance, but with the reference to “site-specific determination” removed and inspections and product labeling added. Second, the description of how the information is involved in those kind of proceedings has

²¹ *National Cable & Telecommunications Ass’n v. Brand X Internet Serv.*, 545 U.S. 967, 125 S.Ct. 2688, 2699-2700 (2005); *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Insur. Co.*, 463 U.S. 29, 103 S.Ct. 2856, 2866 (1983).

²² We do not consider here the language giving the agency discretion to ignore an exemption that is in the peer review guidance and the risk assessment proposal..

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changed. In the original guidance, the limitation on the definition of “dissemination” stated that “dissemination” did not include “distribution limited to” the adjudicative proceeding. The new section on “exemptions” added to the peer review guidance states that the guidance does not apply to information “disseminated in the course of” an individual adjudicative proceeding. We address these two types of changes separately.

The expansion of the term “adjudicatory process” is puzzling because, on the one hand it appears to be in part simply a reference to the definitions of “adjudication” and “licensing” in the Administrative Procedure Act, since those are the only broadly applicable statutory definitions of those terms. The APA defines an “adjudication” as encompassing “licensing”, which in turn is defined to include permitting, registration, or other forms of approval or permission. 5 U.S.C. § 551(6), (7), (8), (9). However, neither the peer review guidance nor the proposed risk assessment guidance indicate that the intent of the added wording is simply to reflect the APA definitions. Instead, the guidance and proposed guidance refer to an individual adjudication “or” a permit proceeding, with a permit proceeding including a licensing, registration, or approval. Moreover, references to inspections and product labeling have been added. The APA does not define a permit proceeding as a type of proceeding different from an adjudication, and it does not refer to either inspections or product labeling. Product labeling can be considered a type of adjudication, since it involves an “approval”; however, an “inspection” does not come within any of the descriptions of an adjudication.²³ Thus, the changes in wording regarding the types of proceeding that an exemption applies to are inconsistent with each other and with the APA, and no explanation has been provided.

The changes in wording regarding the way in which information must be involved in the specified types of proceedings in order to support an exemption are also puzzling. The original guidance used the definition of “dissemination” to exempt information when distribution of the information was “limited to” adjudicatory processes. This appeared to have some possible justification, although it was not stated. The term “dissemination” and the phrase “dissemination of public information” in the legislation can clearly be interpreted to require that the OMB guidance address only information that is distributed to the public. If the distribution of information is “limited to” an adjudicatory proceeding, there is arguably no public dissemination, as implied by including the exemption in the definition of “dissemination”. However, this sensible limitation has not been clearly retained. The new exemptions provision in the peer review guidance applies to information “disseminated in the course of” an individual adjudication, and the current risk assessment proposal would provide an exemption for risk assessments “performed with respect to” inspections and adjudications. No explanation is

²³ An inspection could be considered an “investigation” involving the collection of information that would be exempt under the information collection provision of the PRA (44 U.S.C. § 3518(c)(1)(B)(ii)). However, the proposed exemption does not apply to “inspections” and information collected during an inspection; rather, it applies to risk assessments “performed with respect to” inspections. A risk assessment would not be considered “disseminated” to the public under the existing definition of “dissemination” if its distribution is “limited to” the proceeding; however, since an inspection is not a type of adjudication (although it might be considered part of an “adjudicatory process”) it might not be covered by the exemption in the “dissemination” definition.

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provided for these changes, as is also the case with the first type of change discussed above. It is possible that those involved in drafting the various guidance documents realized that the “limited to” language did not provide much of an exemption, since many adjudicatory proceedings involve public notice and comment, responses to public comments, and dissemination of final decision information to the public, so that distribution of risk assessment information could not be said to be “limited to” the proceeding. If so, the changes in wording with regard to the risk assessment guidance represent an attempt to greatly broaden the original exemption without explanation or justification.

And what cogent rationale could be given for the broad exemption of various adjudicatory proceedings and inspections? One possible rationale is mentioned above: Distribution of information that is “limited to” the adjudicatory proceedings and not publicly disseminated is not a “dissemination of public information” covered by the legislation. While that is the rationale implied by the original definition of “dissemination”, it is not the rationale given in the supplemental government-wide guidance of February 2002. That rationale was that adjudicative proceedings provide “well-established procedural safeguards and rights to address the quality of adjudicatory decisions.”

However, not all adjudications involve formal evidentiary hearings under the APA that will provide any “well-established safeguard” and rights to challenge the quality of adjudicatory process information. For example, NPDES (National Pollutant Discharge Elimination System) permits under the Clean Water Act and incidental take permits under the Endangered Species Act do not involve formal evidentiary hearings. In the absence of a formal evidentiary hearing, the rationale for the exception of “adjudicatory process” from the definition of “dissemination” in the original final OMB guidelines of February 2002 is mistaken.

More importantly, even if an adjudicatory proceeding involves a formal evidentiary hearing, the “well-established procedural safeguard and rights to address the quality of adjudicatory decisions” do not include the right to invoke the data quality standards. Therefore, the suggestion in the stated rationale for the original “dissemination” exemption that application of the data quality standards would serve no purpose because they would be redundant to existing “safeguards” and “rights” in formal adjudicatory hearings is not accurate. Such rights are likely to be substantially inferior to a right to be able to invoke the data quality standards. This is especially true with regard to risk assessments, since they have often involved substantial agency policy bias, and an administrative law judge or hearing examiner is not free to question or override agency policy absent some new authority to do so.²⁴

²⁴ It has been suggested by some (see the Regulatory Checkbook comments) that the impetus for the proposed exemptions is derived from a “cultural” heritage within OIRA, since many “adjudicatory” proceedings have long been exempted from application of the regulatory review Executive orders administered by OIRA. A reluctance to become involved in the substance of individual adjudicatory decisions is perhaps understandable on political grounds; however, the promulgation of government-wide guidelines, or the interpretation of those guidelines, is not the same as intervention in the merits of individual adjudicative decisions. Moreover, the data quality guidelines, unlike regulatory review, are governed by legislative mandates, and OMB does not need to intervene to enforce data quality standards because Congress has made a formal petition mechanism available to obtain corrections.

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When the new section on “exemptions” was added to the peer review guidelines, no explanation was given. The unstated rationale might have been that an administrative law judge or hearing examiner would face practical procedural difficulties in requesting or overseeing a peer review on information presented during an adjudicatory proceeding; however, such a rationale was not given. Furthermore, such a rationale would not cover a situation in which the information presented was developed outside of the adjudicative proceedings and could have been peer reviewed before being presented. In such a case the information should be subject to objection that it does not meet the peer review quality standards. This issue should be revisited, since no explanation was given for expanding the exemption contained in the definition of “dissemination” contained in the original government-wide guidance.

The general intent behind the IQA is to ensure and maximize the quality of information disseminated to the public. If risk information is disseminated to the public, it must be covered by the quality standards. Also, the definition of “influential” assumes that “influential” risk information is disseminated to the public, because otherwise it could not have a significant impact on private sector and non-federal public sector decisions.

VIII. Principal Conclusions

1. The DQA covers all disseminations of public information. It does not authorize exemptions for adjudicatory proceedings if they involve the dissemination of public information, or if information used in the proceedings was disseminated to the public outside the adjudicatory process.. The information collection provisions of the PRA authorize exemptions for adversarial adjudicative proceedings; the information dissemination proceedings do not. There is no indication that Congress intended to confer discretion on OMB to exempt certain types of information disseminated to the public; unlike the information collection provisions of the PRA, the Congressional mandates on information dissemination are unqualified. OMB undoubtedly has significant discretion in the crafting of guidance on the quality of information disseminated to the public; however, it does not have discretion with regard to what types of public information the guidance will apply to.

2. The original exemption of information the distribution of which was "limited to" adjudicatory processes from the definition of “dissemination” can arguably be justified under the DQA. Information that is not distributed to the public and is not of significant public interest might be considered not to be public information. However, the explanation/rationale actually given for that exemption (well-established safeguards and rights to challenge) is not supportable because the well-established safeguards and rights to challenge (1) do not incorporate the quality standards, and (2) many adjudicatory proceedings do not provide for a formal evidentiary hearing.

3. The provision for exemptions in the various guidance rules issued and now proposed has changed in ways that appear significant but are not explained and have given rise to widespread concern and uncertainty, as demonstrated by the large number of comments on this issue in the

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risk assessment proposal. It also appears that the changes and failures to explain have substantially impaired the ability of the public to comment on the issue.

4. The interpretation of the proposed exemptions in the risk assessment guidance advanced by EPA in its responses to the NRC committee – that information (in this case, risk assessment information) is exempt if it “supports” and is “tied to” an adjudicative proceeding – has the potential, if upheld, to exempt huge amounts of risk information under a great variety of environmental, health, and safety laws. The proposed interpretation cannot be justified.

5. The proposed exemptions language and the EPA interpretation would represent a significant change in interpretation of the DQA and policy, and therefore would have to be supported by a “reasoned explanation” that provides a permissible rationale for such an interpretation of the DQA. Such an explanation and justification have not yet been provided.

6. The apparent changes to exemptions have not been explained by OMB. There is an obvious need, and legal requirement, for explanation and justification of the exemptions, particularly in their expanded form. Since it appears doubtful that a reasoned explanation and legal justification can be provided, the current exemptions proposal must be reconsidered.

7. It does not appear to make sense to have one set of standards for some risk assessments, and then exempt broad categories of other risk assessments.

8. “Influential” risk assessments cannot, by definition, be considered exempt.

9. There is no need to define or expand on the term "adjudications" or "adjudicatory" , since "adjudication" is already defined in the APA. The reference to "adjudicatory processes" in the original guidance is sufficient and clear, but subsequent expansions of the term are inconsistent, inaccurate, confusing, and unnecessary.

IX. Recommendations

1. Only the original qualified definition of “dissemination” has a basis for being retained. The “exemptions” provision from the peer review guidelines, or anything resembling it, should not be included in the risk assessment guidance. And the EPA interpretation of the exemptions provision with regard to influential pesticide risk assessments is untenable and cannot be adopted.
2. Any exemptions provision that represents a change in policy and DQA interpretation from the provisions of the original government-wide guidance (i.e., the qualified definition of "dissemination") must be explained and justified on both policy and legal/statutory grounds.
3. At a minimum, the risk assessment guidance should be issued as “interim final guidance” as in September 2001, with a request for further comment on the exemptions issue. This interim final guidance would utilize the definition of “dissemination” already in use and

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leave out any additional exemptions language pending review of the comments and any further action.

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