An Attack on Cancer Research

Industry's Obstruction of the National Toxicology Program

OMB Watch

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OMB Watch is a nonprofit research and advocacy organization whose core mission is increasing government accountability and improving citizen participation. Public access to government information has been an important part of our work for more than 20 years, and we have both practical and policy experience with disseminating such information. OMB Watch also actively engages in agency regulatory processes, encouraging sensible, effective agency rules that are more responsive to public needs.

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OMB Watch
1742 Connecticut Ave., NW
Washington, DC 20009
202-234-8494
www.ombwatch.org

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Contents

Abbreviations

ACC: American Chemistry Council

CPC: Chemical Products Corporation

CRE: Center for Regulatory Effectiveness

DQA: Data Quality Act

EPA: U.S. Environmental Protection Agency

HHS: Department of Health and Human Services

IQA: Information Quality Act

NIEHS: National Institute of Environmental Health Sciences

NIH: National Institutes of Health

NTP: National Toxicology Program

OEHHA: California Office of Environmental Health Hazard Assessment

OMB: Office of Management and Budget

OSHA: Occupational Safety and Health Administration

RoC: Report on Carcinogens

Executive Summary

The National Toxicology Program (NTP) is a federal interagency program that collects, organizes and disseminates information on toxic chemicals. It is housed at the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). NTP produces the biennial Report on Carcinogens (RoC), which identifies chemicals shown by scientific research to be carcinogenic. The RoC and other NTP reports are used by public health professionals and state and federal governments to identify public health threats and target protective measures.

The Information Quality Act (IQA), also known as the Data Quality Act (DQA), has been used by the chemical and manufacturing industry to obstruct NTP's research on cancer-causing agents. DQA is a two-paragraph provision that slipped through Congress in late 2000 without debate and has grown into a mountain of controversy, pitting industry against the public interest. It has been used to lodge frivolous information quality challenges, which slow regulatory action and pressure agencies to remove or revise information.

As of August 2007, industries have filed ten information quality challenges with NTP. DQA challenges delayed the review of the latest RoC for over a year and eventually resulted in an unnecessary complication in the RoC review process in April 2007. In other challenges, companies sought to remove chemicals from the RoC and delay the study of potentially hazardous substances. As a result, government agencies and public health officials have been denied access to the latest information on the most dangerous toxic chemicals.

While most DQA challenges have not significantly weakened NTP information because the program has either rejected or only instituted temporary or minor changes, these challenges have wasted NTP resources that would have otherwise been devoted to studying cancer-causing chemicals. An NIH spokesperson stated, "NIH devotes considerable time and resources of senior level staff and experts in responding to requests for corrections. Responses to information quality complaints generally take months to develop."[1] In the meantime, delays in the release of information can have a profound impact.

As industries succeed in slowing down NTP procedures, others may be emboldened to misuse the law by promoting delay. The DQA process has the potential to drain federal funds and divert resources away from the important work of protecting public health. Dr. Christopher Portier, former Director of the Environmental Toxicology Program and Associate Director of NTP, stated that NTP procedures "have been delayed while issues related to IQA have been resolved. We have used senior level staffing time and resources to address IQA issues."[2]

Problems with the Data Quality Act

Delay Slows down government studies and implementation of protective regulations.

Wasted Resources Forces high-level government employees to spend time issuing detailed responses to often-frivolous complaints.

Reducing Uncertainty Imposes standard of certainty which is impossible for scientific studies to achieve, thereby creating uncertainty in government decisions.

Duplicative Creates an unnecessary bureaucratic layer because agency information quality procedures already exist.

Questions of Policy Does not question and attempt to revise facts but questions and attempts to revise policy decisions.

[1] NIH spokesperson. E-mail interview. December 2005.

[2] Portier, James. E-mail interview. December 2005.

Solutions for Implementing the Data Quality Act

- Dismiss DQA challenges covered by existing information quality procedures.
- Only consider challenges of substantive information.
- Distinguish between fact and policy.
- Dismiss challenges that would result in significant delays in agency action.

An Attack on Cancer Research reviews the NTP challenges, identifies commonalities and trends, and provides a series of recommendations to restore and protect NTP operations against the hindrances imposed by industry's use of DQA. OMB Watch believes that NTP should continue its successful mission of protecting public health by guiding regulatory agencies in notifying the public of carcinogenic chemicals and should not allow DQA to encumber this mission.

This report is divided into four sections:

Section I presents an overview of NTP's founding and purpose as well as the program's existing information quality procedures.

Section II reviews industry's use of vague DQA language in attempts to derail NTP's review and recommendation procedures.

Section III details the problems that arise when industry misuses DQA.

Section IV offers recommendations to preserve the information quality controls in place while preventing industry from misusing the DQA process.

Though this report focuses on the DQA challenges received by NTP, the problems discussed are not unique to that program. Most federal agencies face similar problems, as most operate under information quality guidelines. *An Attack on Cancer Research* identifies five problems with the use of DQA at NTP (see "Problems with the Data Quality Act" on page 1).

OMB Watch has also identified solutions that agencies can implement to resolve these problems (see "Solutions for Implementing the Data Quality Act"). These solutions aim to improve the legitimate use of DQA procedures, reduce the burden of responding to frivolous and time-consuming challenges, and allow agencies to act in a timely and efficient manner. Congress needs to conduct oversight on the use of DQA and limit its scope to curtail its abuse. In the meantime, agencies should implement these recommendations to protect the health and safety of the American public.

I. The National Toxicology Program: Purpose and Procedure

In the 1960s, the American public health community became increasingly aware of the negative health consequences of the presence of thousands of chemicals in the environment. Public awareness and pressure resulted in a number of efforts in the federal government, including the founding of NIEHS in 1966, which was later brought under the aegis of NIH.

In 1978, NTP was founded at NIEHS to study and raise awareness about toxic chemicals that may pose a health risk to the American public. NTP information and research methods are used to help advance the study of how environmental toxins affect public health involving respiratory ailments, cancer, hereditary diseases, birth defects, and other areas of research. "NTP has had a profound effect on how toxicology is being practiced outside of government in industry, the scientific community and society in general. The approaches [NTP has] taken in review of data and peer review systems are now very common everywhere," stated Dr. James Popp, President of the Society of Toxicology, a 6,000-member scientific organization focused on promoting and advancing toxicology research. According to Dr. Popp, toxicity information from NTP is "utilized by academic and government research programs around the world."[3]

The biennial RoC is one of the most effective tools developed by NTP to inform health professionals and guide regulatory action. Mandated by Congress, the RoC identifies toxic chemicals that can cause cancer (carcinogens) or genetic mutations (genotoxins), analyzes the potential for human exposure to these substances and assesses federal regulations that limit public exposures. The intent of the RoC is to list chemicals for which there is scientific consensus regarding carcinogenicity or genotoxicity. NTP published the first RoC in 1980 with 26 hazardous chemicals. In 2005, the 11th RoC was released and listed over 1,700 toxic substances.[4]

Use of NTP Research

While not a regulatory agency, NTP produces valuable information, which is used by agencies at the state, federal and international levels to issue regulations and monitor the effectiveness of public health and pollution prevention programs. According to the California Office of Environmental Health Hazard Assessment (OEHHA), NTP research is used to:

- Conduct chemical assessments to establish the state's ambient air quality standards, drinking water standards and other regulatory requirements;
- Develop "safe harbor numbers" that identify levels of exposure to toxic chemicals that trigger warning requirements;
- Assess health risks to the public from air pollution, pesticide and other chemical contamination of food, seafood, drinking water, and consumer products;
- Provide guidance to local health departments and other agencies, including appropriate actions to take in chemical emergencies; and
- Obtain current and historical information on U.S. production and imports of a chemical.

"The RoC is an exceptionally comprehensive, well-researched and accurate source of information on important chemical compounds and other substances. OEHHA uses the RoC to obtain summaries of the carcinogenicity, chemical properties, uses, and exposure for specific agents," stated Allan Hirsch, deputy director at OEHHA. "Any state that has environmental regulations essentially uses the NTP information directly or indirectly. NTP information is also used extensively by federal and international agencies for regulatory and other purposes."[5]

[3] Popp, James. Telephone Interview. June 2006.

[4] See Report on Carcinogens, Eleventh Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program.

[5] Hirsch, Allan. E-mail Interview. October 2006.

NTP Nomination and Review Procedures

In the RoC, NTP classifies carcinogenic chemicals into two main categories:

1) *Known to Be Human Carcinogens*: There is sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture and human cancer.

2) *Reasonably Anticipated to be Human Carcinogens*: There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded.[6]

To determine whether or not a chemical is carcinogenic or anticipated to be carcinogenic, there is a thorough nomination and review process before the release of each new RoC. Dr. Popp, who served on NTP's external peer review panel, stated that "the RoC has had a very extensive process for the identification of chemicals and preparation of material to support a nomination, opportunity for public input, review from within government agencies and from an external peer review panel."[7]

Data Quality Act Process

DQA requires agencies to establish procedures for receiving, responding to and appealing information

quality challenges. This allows complainants to file information quality challenges to NTP and request the correction of disseminated information. According to the NIH guidelines, the complainant must present:

- A detailed description of the specific material that is proposed for correction, including where the material is located;
- The specific reasons for believing that the information disseminated does not comply with Office of Management and Budget (OMB), Department of Health and Human Services (HHS), or NIH guidelines and the supporting documentation, if any;
- Suggested recommendations for what corrective action(s) should be taken; and
- A description of how the person requesting the correction is affected by the information error.[8]

The information challenged must be NIH information that is "substantive (i.e., reports, studies, summaries) rather than pertaining to basic agency operations." Once the challenge has been made, the agency then has 60 days to respond. After the response is issued, the complainant then has 30 days to appeal the decision.

[6] Or, there is sufficient evidence of carcinogenicity from studies in experimental animals, which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset. Or, there is less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans (Report on Carcinogens, Eleventh Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program).

[7] Popp, James. Telephone Interview. June 2006.

[8] National Institutes of Health Guidelines for Ensuring the Quality of Information Disseminated to the Public. Page 21 of 27. <http://aspe.hhs.gov/infoquality/Guidelines/NIHinfo2.shtml>

NTP Nomination Process

1. Receipt of Nominations: Nominations derive from three sources – the public's response to a published request for nominations; the NTP Executive Committee, a consortium of experts from federal agencies; and an NTP review of science/medical journals and pertinent work of agencies.

2. Approval of Nominations: The RoC Review Committee, composed of NIEHS scientists, decides if sufficient information supports a review of the proposed chemical. If not, additional justifying information is requested from the nominator. The Review Committee's nomination approvals are forwarded to the NTP Director for final decision.

3. Announcement of Nominations: After NTP Director approval, nomination announcements are published with a request for public comments. Based on an NTP review of scientific and medical journals and public comments, NTP compiles a background document for each nomination.

NTP Review Process*

Three committees review nominations: RoC Review Committee, Executive Interagency Working Group for the RoC, and the non-governmental Board of Scientific Counselors. Committee recommendations go to the NTP Executive Committee and the NTP Director.

Step 1: RoC Review Committee – The Committee approves the background document for each nomination, then proceeds with formal recommendations to the NTP Director regarding acceptance or rejection of each nominated chemical.

Step 2: Executive Interagency Working Group – Composed of scientists from various executive agencies, the Working Group performs the same review and also makes formal recommendations to the NTP Director.

Step 3: Board of Scientific Counselors – The Board conducts a public meeting to collect further input. Based on the meeting record, background documents, previous public comments and recommendations from two previous committees, the Board makes recommendations to the NTP Director.

Step 4: Executive Committee – Recommendations from the three committees are published and another round of public comments is solicited. The Executive Committee makes final recommendations based on the work of the three committees and final round of public comments.

Step 5: Final Recommendations – Based on all previous committee work and recommendations, the NTP Director submits final recommendations to the HHS Secretary.

Step 6: Approval and Publication – After reviewing and approving the NTP Director's recommendations, the Secretary sends a final RoC document to Congress, and the official RoC is published and made available to the public.

* This procedure was revised on April 16, 2007. The two major changes are that the background document will be peer reviewed by scientific expert panels and draft substance profiles will be peer reviewed by the Board of Scientific Counselors. See 72 Fed. Res. 18999 (April 16, 2007).

II. Challenges: Industry's Use of DQA

The RoC has prompted more DQA challenges than any other single set of government information. A review of these challenges offers insight into industry's use of DQA to slow scientific research and obstruct efforts to protect public health. All ten NTP challenges were made by companies or industry-affiliated organizations, even though the audience for NTP's information is considerably broader, including environmental groups, the research community and public health agencies. NTP has an extremely thorough review process, but industries have, nevertheless, attempted to use DQA to challenge the quality of the program's information.

Based on industry's systematic attack on the RoC, OMB's Office of Information and Regulatory Affairs former administrator John D. Graham issued a prompt letter to NIH Director Elias Zerhouni regarding the information quality procedures at NTP. The 2004 letter stated that Graham was motivated to recommend revisions to NTP's "already rigorous process of scientific deliberation" because of the "six distinct information quality correction requests related to either the NTP Report on Carcinogens or to the NTP review process for individual substances."[9] In August 2006, NTP proposed a revision in RoC review procedures, incorporating many of Graham's recommendations. This resulted in the delay of the review of the 12th RoC for over a year and a revision in the review procedures, which were finalized in April 2007.[10]

It appears industry challenges fall into two strategic categories: delay of agency activity and elimination of information. First, as noted by the former associate director of NTP, responses to information quality challenges take a great deal of time to prepare. Industries have used this to delay the process of developing and releasing information. Resolving technical matters pertaining to some DQA challenges may be a lengthy process due to review and approval procedures. With only three full-time staff members assigned to the RoC and 75 total NTP staff members, agency resources are limited, and DQA challenges can often result in significant delays in agency practices.[11]

Second, industries have submitted information quality challenges in an attempt to restrict the public release of scientific findings. The scientific process requires openness and access to information to move forward. Information, even if flawed or problematic, helps guide and inform future studies. Efforts to use DQA to retract reports, prevent distribution of drafts, and restrict or rescind press releases and public notices are particularly disturbing, as they can block disclosure of research, which is of great value in protecting public health.

More Concerned about Profits than Data

The RoC is often viewed as a significant threat to companies' bottom lines. Listing a chemical as carcinogenic or even announcing plans to study a chemical can have large financial impacts in several respects.

First, companies selling chemicals listed in the RoC or products containing these chemicals will likely face regulations. As previously noted, products

[9] Letter from Dr. John Graham, Administrator, OIRA to Dr. Elias Zerhouni, Director, NIH (November 16, 2004), available at: http://www.ombwatch.org/info/OMB_NTP_prompt_letter.pdf.

[10] 72 Fed. Reg. 18999 (April 16, 2007).

[11] Factual information from: Mackar, Robin (News Director, National Institute of Environmental Health Sciences, NIH). E-mail Interview. June 2006.

Data Quality Challenges of NTP*						
Complainant	Request	Response to Request	Appeal	Response to Appeal	Challenge	Resolution
Chemical Products Corporation (CPC)	11/15/02	3/19/03	3/27/03	9/8/03	Abstract of a Draft NTP Report	Abstract removed from NTP website
Nickel Development Institute	4/9/03	10/24/03	11/17/03	10/27/04	RoC classification of nickel as a carcinogen	Denied with slight revisions to RoC
Styrene Information and Research Center	6/10/03	8/14/03	NA	NA	NTP press release and fact sheet	Changes made to press release and fact sheet
CPC	2/24/04	7/16/04	7/29/04	1/31/05	Same Draft Report challenged in November 2002	Denied as outside the scope DQA
American Chemistry Council (ACC)	4/1/04	1/18/05	2/18/05	11/2/05	RoC background document in its evaluation of naphthalene and the findings of RoC Subcommittee meeting	Denied
Center for Regulatory Effectiveness (CRE)	6/28/04	2/16/05	NA	NA	NTP notice to study the chemical atrazine	Denied
ACC	7/1/04	1/18/05	NA	NA	Current and former RoC classifications of vinyl chloride as a carcinogen	Denied, stating the the issue is addressed in RoC process
CRE	7/16/04	5/25/05	6/24/05	Withdrawn by CRE	NTP notice on the RoC procedure	Denied; NTP later revises review procedure
Airepel	1/18/05	4/21/05	NA	NA	Draft NTP technical report on anthraquinone (same report challenged by CPC)	Denied as outside the scope of DQA
CPC	6/6/06	12/22/06	1/5/07	NA	Same report (no longer in draft form) on anthraquinone challenged by CPC in November 2002 and February 2004 and by Aierepel in January 2005.	Denied, stating that the information in the report is accurate. NTP has yet to respond to the appeal.

* For the full Data Quality docket at the Department of Health and Human Services, see http://aspe.hhs.gov/infoquality/requests.shtml.

sold in California have to be properly identified as containing a carcinogenic chemical. The listing can also encourage the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and a variety of state and other federal agencies to closely monitor the chemical and potentially regulate its use. OSHA's Hazard Communication Standard, for instance, requires chemicals listed in the RoC to be identified in material safety data sheets.

Second, a listed chemical and its potentially harmful effects may become publicized by news media and public interest groups, creating the potential for decreased sales. The chemical may also become the target of efforts to reduce its consumption or use. Moreover, the producers may be seen as liable for health problems and be besieged by lawsuits. The American Chemistry Council (ACC) likens being listed in the RoC to a "stigma [that] can and often does lead to product liability claims, diminished sales, product substitution by downstream users of the substance, and related commercial damage."[12]

A Systematic Attack on the RoC

Because having a chemical listed in the RoC can result in significant financial consequences, industries often attempt to avoid RoC listings. In recent years, they have found DQA to be a useful tool to prevent and delay the study of chemicals. Almost every aspect of the review and nomination process has been attacked by industry, and NTP staff time has been squandered rebutting frivolous challenges. What follows is an overview of some of the aspects of the RoC that have been attacked by industry groups.

Notice to Review Challenged

When NTP begins investigating a chemical for possible inclusion in the RoC, a notice is published to inform the public and interested parties about the agency's intentions and encourage those with relevant information to submit it to NTP. In June 2004, the Center for Regulatory Effectiveness (CRE), an industry advocacy group, decided to challenge such a notice when NTP announced its intention to study the carcinogenicity of atrazine, an herbicide widely used on major crops like corn.[13]

CRE claimed that NTP's notice was misleading and incomplete because it failed to clarify that a particular study on rats cited in the notice was irrelevant to human cancer. However, such a complaint is not an information quality challenge. First, a public notice announcing the intention to investigate a chemical is not the "substantive" type of information that may be challenged under the agency's DQA guidelines. The notice offered no conclusion or official position on atrazine's possible carcinogenic effect. Rather,

it merely stated that the agency would investigate the chemical and referenced the study as one supporting factor in the agency's decision. Second,

[12] American Chemistry Council. "Request for Correction of Information," submitted to the National Institutes of Health, April 1, 2003, p. 3. <http://aspe.hhs.gov/infoquality/request&response/14a.pdf>

[13] Center for Regulatory Effectiveness. "Request for Correction of Information," submitted to the National Institutes of Health, June 28, 2004. <http://aspe.hhs.gov/infoquality/request&response/16a.shtml>

a DQA challenge is not the appropriate forum for the complaints contained in the CRE petition. Such arguments and information are properly presented during the investigation of atrazine, for which there are multiple opportunities such as public hearings and comment periods. By submitting a challenge on the notice of intent to investigate, CRE was essentially challenging NTP's decision to gather more information on atrazine. In providing a thorough response to the challenge, NTP used valuable resources that could have been used more appropriately.

Background Document Challenged

Several challenges have attacked the background document, which is made public after approval by the RoC Review Committee, as being biased and subjective. The background document is used to inform decisions regarding the listing or de-listing of chemicals from the RoC. Given its use as a reference document, the background document should not be challengeable because it does not contain an agency position.

Challengers of the background document commonly claim that a study supporting industry's position (usually industry-sponsored) is given insufficient consideration or that a study contradicting industry's position should be given less or no consideration. The Nickel Institute, for instance, argued the latter. The Institute claimed that the background document for the 10th RoC (released Dec. 11, 2002) was biased because it failed to mention studies which found that nickel does not cause cancer when it is not inhaled.[14] While such claims may be worth raising and considering, they are not matters of information quality. CRE actually sued HHS in another case involving the listing of dioxin as a known human carcinogen because the agency's decision relied in part on studies involving animals. NTP's decision was upheld as not arbitrary and capricious.[15] Such complaints about emphasis or reliance on certain studies over others are disagreements with agency choices and as such are matters of policy. In the nickel case, how one is exposed to nickel is not the issue. The fact that inhaling nickel can cause cancer is enough to list nickel in the RoC. NTP took over 15 pages to refute the Nickel Institute's challenge and appeal, using resources that could have been spent doing research. In the end, NTP agreed to make a few minor changes to the document.

Public Meetings Challenged

At several points in the nomination and review process, NTP provides opportunities for public comment, including the public meeting held by the NTP Board of Scientific Counselors. The ACC challenged this meeting as failing to meet the requirements of objectivity.[16] Once again, the focus of the petition clearly falls outside the intended scope of the DQA process. A meeting is not a public dissemination and should not be challengeable under DQA. The ACC claimed that the chairman marred the meeting by presenting findings allegedly not previously disclosed by the committee. Additionally, the industry group challenged a claim made by the chairman. The ACC argued that the vote of the NTP Executive Committee should be rescinded and that another meeting needed to occur immediately. Rejecting both claims, respondents at NTP stated

[14] Nickel Development Institute, Nickel Producers Environmental Research Association, and Inco, Inc. "Request for Correction," April 9, 2003. <http://aspe.hhs.gov/infoquality/request&response/7a.pdf>

[15] *Tozzi v. U.S. Department of Health and Human Services*, 00-5364 (D.C. Cir. 2001).

[16] American Chemistry Council. "Request for Correction," April 1, 2004. <http://aspe.hhs.gov/infoquality/request&response/14a.pdf>

that they "do not agree that your request under the information quality guidelines for new processes, in the form of new meetings and new votes, is appropriate."[17] Responding to a challenge of the Executive Committee required the involvement of high-level NTP officials. While this particular challenge was rejected, the mere consideration of a challenge of a meeting could have a chilling effect on free and frank discussion at future meetings.

Review Procedure Challenged

Even NTP's extremely thorough review procedure, involving comment periods and committee reviews to ensure high information quality, has been attacked under DQA. CRE requested that NTP delay publication of the 12th RoC and that notices regarding its release be removed because the description of the review procedure did not meet the requirement of objectivity. Due to inconsistencies in descriptions of the review process, CRE requested that "NTP withdraw its Notice and not publish any other Notice regarding the 12th RoC until and unless NTP decides what procedures apply to the 12th RoC nomination, selection and review process."[18] NTP agreed to clarify the procedure in a subsequent *Federal Register* notice, though the announcements regarding the 12th RoC were not removed. In part due to this challenge, the 12th RoC review procedure was delayed for over one year. NTP revised its review procedure to accomodate complaints such as those raised by CRE. While inconsistencies or even inaccuracies of the review process description should be resolved, the complaint did not include any problems with the quality of the data within the RoC, nor did it claim that the review process used was insufficient. This issue would best be handled outside of the DQA process, without demands that release of important cancer research materials be delayed because of minor issues about the description of procedures.

Conclusion

Though NTP frequently responded appropriately and rejected most of the frivolous DQA challenges, these repeated complaints had several negative impacts on the program's cancer research. The work of NTP was continually delayed as high-level employees were pulled off important health and safety projects to review and respond in detail to these challenges. Moreover, industry, at some points, has been successful in removing important information from the public and severely delaying the release of information. The DQA challenges and responses at NTP demonstrate how industry continues to test the limits of the DQA process by seeking yet another opportunity to influence agency activities.

Five of the ten information quality challenges to NTP offered no scientific data, expert testimony or conclusive evidence that would warrant change. The scope of the requests often grossly overreached the parameters of DQA, seeking to challenge agency choices in methodology, and in one instance, requesting the rescission of agency guidelines and policies. Instead of creating a process by which information is corrected for public benefit, DQA has given industry an opportunity to make veiled attempts at circumventing NTP's existing procedures. DQA has thereby hindered NTP in its efforts to produce timely reports which inform the public health community about exposures to carcinogens.

[17] National Toxicology Program. "Response to Request for Correction," January 18, 2005, p. 8. <http://aspe.hhs.gov/infoquality/request&response/14b4.pdf>

[18] Center for Regulatory Effectiveness. "Request for Correction," June 28, 2004. <http://aspe.hhs.gov/infoquality/request&response/16a.shtml>

III. Problems: How Industry is Misusing DQA

The challenges of NTP cancer information expose five specific information quality guideline problems that are shared by most agencies implementing this relatively new requirement. These problems include: delay, wasted resources, reducing certainty, duplicative process, and questioning of policy decisions.

Problem 1: Delay – DQA challenges often delay agency action, slowing down both the study of issues and implementation of regulations. Several NTP challenges targeted early stages of the research process including the basic announcement that research will be performed. Taking advantage of the bureaucratic steps in the DQA process, the earlier obstacles are raised in the process, the longer the delay. A common strategy appears to be to challenge the draft of a report in order to delay the final report and consequently any action that might be taken on the basis of the final report. For instance, a report on the carcinogenicity of anthraquinone had a four-year delay, in part due to data quality challenges. CPC has filed three separate data quality challenges against the different iterations of the same report over a five-year period, and it is still under review by NTP. As demonstrated above, industries have slowed down the RoC review by challenging almost every aspect of the process. These delays in essential information regarding the carcinogenicity of chemical products translate into delayed action to protect public health and safety.

Problem 2: Wasted Resources – Another serious problem with DQA challenges is that they force high-level government employees to spend time giving detailed responses to often-frivolous complaints. Unlike other agency processes, such as agency rulemakings or Freedom of Information Act requests, DQA challenges often cannot be handled by ordinary agency staff dedicated to this program. DQA challenges often target complex and highly technical data, thereby requiring the response from expert personnel – policy makers, scientists, researchers, economists and others. For instance, 75 people work at NTP, three of whom are scientists directly responsible for the publication of the RoC, but only those three individuals are able to handle the information quality requests.[19] As a result, DQA challenges often divert time and resources away from the work of studying carcinogenic chemicals. The same likely holds true in other agencies, where challenges divert the time and resources of scientists, economists, statisticians and other experts who work to protect public health and safety.

Problem 3: Reducing Certainty – DQA challenges repeatedly focus on the lack of absolute certainty or conclusions in scientific research, even though such a standard would be an unreasonable expectation and

impossible for scientific studies to achieve. Industry DQA challenges prey on the uncertainty of scientific findings, attempting to cast doubt on agency reasoning and action. Demanding certainty, DQA challenges often attack a policy or finding based on research which is inherently based on probability. Increased uncertainty makes it more difficult for agencies to take action, even when that action is based on the reasonable application of scientific research.

Problem 4: Duplicative of Existing Processes Another notable problem is that information procedures already exist to handle many of the complaints raised under DQA. As demonstrated in Section I, NTP has an extremely thorough data review

[19] Factual information from: Mackar, Robin (News Director, National Institute of Environmental Health Sciences, NIH). E-mail Interview. June 2006.

process, which includes numerous opportunities for input and discussion (e.g., public comment, peer review and transparency) to ensure the necessary information quality. The DQA mechanism of challenging information creates an unnecessary bureaucratic layer to existing agency processes. Instead of handling information quality complaints with the pre-existing processes, agencies are forced to comply with the formalistic requirements of DQA. All of the issues and concerns raised in the NTP challenges could have been handled more easily and more efficiently within the program's existing process. In fact, many of the issues were raised through these pre-existing avenues, but DQA gives industry another bite at the apple. If existing information quality processes miss certain items, then such procedures should be revised. It is easier and smarter to fix the current system than to add a new set of procedures on top of it.

Problem 5: Questions of Policy – The final problem exemplified by NTP challenges is that most information quality challenges do not question or attempt to correct facts but, rather, question and attempt to revise policy decisions. Even though such challenges are beyond the scope of DQA, agencies repeatedly accept and respond to these overreaching complaints. Almost all of the NTP information quality challenges are disagreements with policy. Deciding whether or not to investigate or list a chemical as carcinogenic is a policy decision, informed by scientific evidence. Agencies utilize objective expertise to make decisions and take actions. While those decisions and actions are and should be challengeable, they should not be challengeable under DQA because they are not issues of information quality.

IV. Recommendations: Lessons Learned from NTP

NTP challenges reveal that DQA has resulted in a number of problems for federal agencies. This section outlines four recommendations to alleviate the identified problems and may assist NTP and federal agencies with future implementation of DQA. While larger changes are needed at the legislative level to fix the DQA statute by restricting its use and clarifying its scope, immediate steps can be taken at the agency level to minimize misuse of DQA. OMB Watch advises agencies to consider utilizing the following four recommendations in responding to information quality challenges.

Recommendation 1: Dismiss DQA challenges covered by existing information quality procedures.

Information quality guidelines should play the role of a gap-filler and should prohibit challenging information which is handled by existing information quality procedures. Unfortunately, industry has used the DQA process as an opportunity for another bite at the apple in opposing the use of certain studies and research. Agencies should promptly dismiss such challenges without expending resources and time to develop detailed responses to these repetitive challenges.

Most agencies have "[e]xisting public comment procedures for rule-making and other formal agency actions [that] already provide well established procedural safeguards that allow affected persons to raise information quality issues on a timely basis. Accordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process," according to the HHS DQA Guidelines.[20] Information already subject to information quality mechanisms, especially those that include opportunities to provide input or additional information, like the RoC process, should not also be subject to DQA. The necessary mechanisms for ensuring information quality are already in place, and adding another layer of procedures will only slow the operations of government agencies.

Recommendation 2: Only consider challenges of substantive information.

Agencies should restrict DQA challenges to substantive information and reject all DQA challenges which are beyond this scope. Industry has used DQA to challenge various types of information, from abstracts of draft reports to background research documents to press releases. Among the challenges received thus far by NTP, the program often failed to take a strong stance on limiting the scope of challengeable information. Even in cases where NTP recognized that a challenge exceeded the scope of DQA, the agency still responded with a thorough defense of the information.

According to the HHS and NIH Information Quality Guidelines, DQA applies to "substantive information (i.e., reports, studies, summaries) rather than information pertaining to basic agency operations."[21] It explicitly states that "receipt and review materials (e.g., summary statements, information for advisory councils or advisory committee members) [are not subject to DQA nor are] [p]ress releases that support the announcement or give public notice of information that NIH has disseminated elsewhere."[22] Many federal agencies have similar language limiting the information covered by the DQA process. However, most of these agencies also fail to properly defend these limits. Agencies should strictly apply their existing guidelines regarding challenges of non-substantive information and dismiss such challenges with minimal discussion and expenditure of agency resources.

[20] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, "Scope and Applicability of the Guidelines." <http://aspe.hhs.gov/infoquality/Guidelines/part1.shtml>

[21] Ibid.

[22] Ibid.

Recommendation 3: Distinguish between fact and policy.

DQA complaints should be limited to clear questions about facts and data. Federal agencies should make a greater effort to distinguish between challenges that attempt to correct facts and challenges that disagree with policy decisions. Challenges that fall into the latter category of attempting to couch policy debates as an information quality challenge should be rejected as outside the scope of DQA.

Many DQA challenges do not dispute specific facts, but, rather, dispute agency policy decisions. When challenges contend that a particular study was not given enough consideration, it is not an information quality issue. The distinction between fact and policy is critical in managing information quality challenges. While NTP often made this distinction in answering information quality challenges, the program still expended resources to respond in great detail. Instead, agencies should simply dismiss information quality challenges that do not seek a correction of fact.

Recommendation 4: Challenges should not delay agency action.

Challenges of information should not be allowed to unduly delay agency action or the production of information. If the timing of an information quality challenge would unduly burden an agency process or activity, the agency should refrain from responding to the challenge until its action is complete. Information quality is an open-ended process that should not trump an agency's primary responsibilities. While agencies should make concerted efforts to maximize data quality, this should be within the broader considerations of timeliness, resource limitations and the primary mission of the agency. It is unreasonable to demand that agencies only release or act on perfect information.

Most agency information quality guidelines include a provision which states that agencies may not respond to an information quality challenge if responding would "unduly delay issuance of the agency action or information product."[23] However, similar to the provisions allowing agencies to reject challenges of non-substantive information, agencies neglect to exercise this option when such challenges are filed. Responses to information quality challenges should be delayed if responding would slow down agency actions, such as completion of an important regulation or the timely distribution of a needed report.

Implementation of these recommendations should improve the legitimate use of the DQA procedures, reduce the burden of responding to frivolous and time-consuming challenges, and allow agencies to act in a timely manner. As noted, Congress needs to conduct oversight on the use of the law and clarify and limit the scope of DQA to curtail its abuse. In the meantime, agencies have the flexibility to address these problems. Agencies should implement these recommendations to prevent the diversion of resources from protecting the health and safety of the American public.

[23] Ibid.

OMB WATCH
1742 Connecticut Ave., NW
Washington, DC 20009
202-234-8494
www.ombwatch.org