Information Quality and Precaution

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Slickspot peppergrass, the age 60 rule, barium, the Northern Goshawk, anthraquinone, and atrazine. One would not normally expect to mention these topics in the same discussion, let alone the same sentence. However, thanks to the Information Quality Act, these subjects are now linked. The Fish and Wildlife Service received a correction request regarding its proposed listing of slickspot peppergrass (a small plant that occurs in sage-brush areas in Idaho) as an endangered species; the Federal Aviation Administration received a correction request about a rule that says pilots are prohibited from flying commercially at age 60 and beyond; the Office of Research and Development, at EPA, received a correction request about the safe level for exposure to barium (a naturally occurring metal); the Forest Service received a correction request regarding habitat management for the Northern Goshawk (a bird from the hawk family that lives in forests); the National Toxicology Program received a correction request about preliminary test results for anthraquinone (a chemical used as an intermediate in the production of dyes, other organics, birdseed, and other areas); and the Office of Pesticides, Pollution and Toxic Substances, at EPA, received a correction request regarding the potential for endocrine disruption of atrazine (a herbicide frequently used by corn growers). These are just a few examples of the breadth of topics that the Information Quality Act has touched upon.

It is my pleasure to be here today to speak with you about the Information Quality Act. The federal agencies have just completed the first year of implementing this new law, and I am happy to share with you what we have learned during this first year.

HISTORY

The story began towards the end of the previous Administration, when Congress enacted a law requiring OMB to develop procedures to improve the quality of information disseminated by federal agencies. The law was enacted as a rider to our appropriations

bill.[1] Informally known as the "Information Quality Act", the law does two main things: (1) it requires the agencies to develop pre-dissemination procedures that will ensure the quality of information disseminated by the agencies. (2) it requires agencies to develop an administrative mechanism whereby affected parties can request that agencies correct poor quality information. If the public is dissatisfied with the initial agency response to a complaint, an appeal opportunity is provided by the Agencies.

The Bush Administration is committed to vigorous implementation of the Information Quality Law. We believe it provides an excellent opportunity to enhance both the competence and accountability of government.

PERCEPTIONS AND REALITIES

OMB has heard many concerns about the Information Quality Law and the implementation process. I would like to share with you some of those concerns, as well as the perceptions and the realities that have come to be associated with them.

Perception:

Agencies will be inundated with requests for corrections.

Reality:

The strong belief that certain agencies would be overwhelmed by the volume of complaints was one of the most common early perceptions. To many peoples' surprise, that has not been the case. In total, the agencies have received about several dozen complaints that appear to be stimulated by the Information Quality Law. There has been a large volume of complaints (almost 5000) to FEMA regarding requests for map correction changes as part of the national flood insurance program, and a large volume of requests (about 100) to the Federal Motor Carrier Safety Administration (FMCSA)

[1] The law is Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001.

regarding the incorrect reporting of individual accidents. However, these kinds of complaints were commonplace prior to the Information Quality Law. Of the approximately 30 distinctive complaints, EPA, HHS, Interior and USDA have received most of the complaints, and a few have gone to Commerce, Education, and OSTP (the White House Office of Science and Technology Policy).

Perception:

The Information Quality correction process is a tool only for industry.

Reality:

I'm pleased to report that the Information Quality Act has been used by virtually all segments of the political spectrum. Complaints have been filed by private citizens, corporations, farm groups, trade organizations, both liberal and conservative non-governmental organizations (for example: the Competitive Enterprise Institute (CEI), Wrestling Coaches Association, Sierra Club, John Muir Society, and Public Employees for Environmental Responsibility), and even other government agencies (an Air Force complaint to Fish and Wildlife). The Information Quality Law has even been used by four U.S Senators (a joint complaint by Senators Boxer, Jeffords, Lautenberg and Sarbanes to EPA).

Perception:

The Information Quality Law will result in slowing down the regulatory process at the agencies.

Reality:

We can also report that to date, neither OMB, nor our engaged stakeholders, has noticed or commented upon any slowdown of the regulatory process. Twice a year the agencies provide OMB and the public with their regulatory agendas. This is a compendium of rules that the agencies intend to take action on within the next 12 months. This acts as a management tool for the agencies and lets OMB and stakeholders know what agencies are planning. Once a rulemaking arrives at OMB, through our tracking mechanisms we

know how quickly the rule moves through the review process. Additionally, on the OIRA website the public can see when a rule arrives, and when it is cleared. To our knowledge, the passing of the Information Quality Law has not affected the pace or length of rulemakings.

Perception:

The appeals process, the public's opportunity to ask for reconsideration of a complaint, will not improve anything.

Reality:

Most of the Information Quality responses to requests for correction that were denied have subsequently been appealed. The majority of the appeals are still in the process of being answered; thus, it is too early to assess the value added. However, this added step appears to have fostered corrections. The appeals process requires independent agency review of the reconsideration request, its justification, and its strength. We recently saw this process play out at HHS where, upon appeal, a complaint to the National Toxicology Program resulted in the discontinuation of the webpage dissemination of a draft abstract that contained results that were flawed (the compound tested contained a contaminant that was believed to have influenced the test results). In this situation, the appeals step was critical in order for the agency to recognize that a correction was needed.

Perception:

The Information Quality Law is aimed primarily at information in federal rulemakings.

Reality:

Most complaints that agencies have received have not been directly related to rulemakings. The correction requests have been directed towards information that is predominantly disseminated to the public as reports, notices, or as a means of sharing agency findings on webpages. These disseminations may eventually lead to regulations at federal, state and local levels, but the disseminations themselves are not rules nor are

they typically contained in rulemaking notices. This is not surprising, as I have been told by the OIRA staff that many of the concerns in the previous administration, which led to the creation of the Information Quality Act, were related to questionable disseminations of agency information on their websites, not necessarily via rulemakings.

Perception:

Colleges and Universities are regulated by the Information Quality Law.

Reality:

OMB has heard claims that college professors and their students, if funded by the federal government, are covered by the Information Quality Law and agency guidelines. OMB believes this is a misreading of the law. The Information Quality Act covers only disseminations by federal agencies, specifically those agencies covered by the Paperwork Reduction Act. The Law does not cover colleges and universities, even when federal research funding is involved. More generally, the law covers only agency disseminations, not disseminations made by third parties (e.g., academics, stakeholders and the public). As a practical matter, it may nonetheless make sense for third parties to consider the quality of information that they disseminate or submit to the federal government. If third-party submissions are to be used and disseminated by federal agencies, it is the responsibility of the federal government, under the Information-Quality Act, to make sure that such information meets relevant information-quality standards. The agency guidelines establish performance goals and procedures to assist in the agency's evaluation of all information for which agency dissemination is under consideration, whether that information was generated by the agency or by third parties.

OMB's LEARNING CURVE

We have learned that passing a statute on information quality is easier than improving the quality of information. Often complaints hinge on the interpretations of science or analyses. When dealing with uncertain scientific issues, it is possible to draw several reasonable inferences depending on the perspective of the reviewer. Thus more than one

plausible answer or methodology may exist. We are learning that it is possible for neither the agency nor the requestor to be incorrect. Thus far, the majority of correction requests have been denied, usually on the basis that a reasonable scientist could interpret the available information in the way that the agency had. Such complaints might have been better focused if they had addressed the inadequate treatment of uncertainty rather than the accuracy of information.

LOOKING FORWARD

Despite all the misperceptions, kinks, and surprises, we feel that we are moving closer to achieving the goals of the Information Quality Act. Agencies are aware that ensuring the high quality of government information disseminations is a high priority of the Bush Administration. The next big step will be to enhance the pre-dissemination procedures making sure that information is valid before it is disseminated. OMB Peer Review Bulletin has undergone 1) public comment, 2) an NAS workshop, and 3) interagency review. We are currently considering all the comments we received and are making appropriate revisions.

The Perils of Precaution

The concept of a universal precautionary principle apparently has its origins in early German and Swedish thinking about environmental policy, particularly the need for policymakers to practice foresight in order to prevent long range environmental problems. The concept was included in the Amsterdam Treaty – an important step toward establishment of the European Union – but the concept was left undefined and was applied only to environmental policy. More recently, the EC extended this concept to consumer protection and public health. Still no formal definition exists and the international legal status is uncertain.

The United States Government believes it is important to understand that, notwithstanding the rhetoric of our European colleagues, there is no such thing as THE precautionary principle. Indeed, the Swedish philosopher Sandin has documented 19 versions of the precautionary principle in various treaties, laws and academic writings. Although these versions are similar in some respects, they have major differences in terms of how uncertain science is evaluated, how the severity of consequences is considered, and how the costs and risks of precautionary measures are considered. The United States Government believes that precaution is a sensible idea but there are multiple approaches to implementing precaution in risk management.

Given the ambiguity about the precautionary principle, it may be useful to start with a dictionary definition. Webster's 2nd Edition of the NEW WORLD DICTIONARY defines precaution as "care taken beforehand" or "a measure taken beforehand against possible danger." Understood in this way, precaution is a well-respected notion that is practiced daily in the stock market, in medicine, on the highway and in the workplace. In both business and politics, decision makers seek the right balance between taking risks and behaving in a precautionary manner.

Before joining OMB, I served for 17 years on the faculty of the Harvard School of Public Health. In that capacity I learned that public health historians have documented the preventable pain and suffering that can occur from insufficient consideration of the need for precaution. In the United States we felt that pain as a result of how we handled

emerging science about tobacco, lead and asbestos. Historians teach us that the major health problems from these substances could have been reduced or prevented altogether if decision makers had reacted to early scientific indications of harm in a precautionary manner.

In each of these examples (tobacco, lead and asbestos), it was epidemiology rather than the experimental sciences that played the most pivotal role in identifying health risks. Ironically, it is epidemiology that is now one of the more controversial contributors to public health science.

There is no question that postulated hazards sometimes prove more serious and/or widespread than originally anticipated. Ralph Nader has previously argued that this is the norm in regulatory science, while the European Commission recently issued a report of case studies where hazards appear to have been underestimated. However, the dynamics of science are not so easily predicted. Sometimes claims of hazard prove to be exaggerated and in fact there are cases of predictions of doom that have simply not materialized.

Consider the "dismal theorem" of the Reverend Thomas Malthus (1798). He hypothesized that population would grow exponentially while sources of sustenance would only grow arithmetically. The result, he predicted, would be that living standards would fail to rise beyond subsistence levels. However, history has shown this theorem to

be incorrect. Malthus did not foresee the technological advances that have allowed both population and standard of living to risk steadily and substantially.

A more recent example in the USA concerns the popular artificial sweetener saccharine. FDA declared the regulatory equivalent of war against this product on the basis of experimental laboratory test results. The finding was that huge doses of saccharine cause bladder cancer in rodents. While FDA attempted to ban saccharine based on this evidence, the US Congress overturned FDA's action. With the benefit of hindsight, it now appears that FDA's attempted ban may have been ill-advised. Just recently, the federal government in the USA removed saccharine from the official list of "carcinogens" for two reasons: experimental biologists have found that saccharin causes bladder tumors in rodents through a mechanism (cell proliferation) that is unlikely to be relevant to low-dose human exposures; and large-scale epidemiological studies of saccharin users have found no evidence that the product is linked to excess rates of bladder cancer in people.

Given that the dynamics of science are not predictable, it is important to consider the dangers of excessive precaution. One of those is the threat to technological innovation. As a thought experiment, Imagine it is 1850 and the following version of the precautionary principle is adopted: no innovation shall be approved for use until it is proven safe, with the burden of proving safety placed on the technologist. Under this system, what would have happened to electricity, the internal combustion engine, plastics, pharmaceuticals, the Internet, the cell phone and so forth? By its very nature,

technological innovation occurs through a process of trial-and-error and refinement, and this process could be disrupted by an inflexible version of the precautionary principle.

Many risk specialists in the USA regret some of the prior policy steps we have taken on the basis of precaution. In US energy policy, for example, the Three Mile Island incident had a large policy impact, though even today there is no evidence of significant public health harm caused by the accident at Three Mile Island. In fact, there has been a de facto moratorium on the construction of new nuclear power plants in the USA. We have become more deeply dependent on fossil fuels for energy, and now precaution is being invoked as a reason to enact stricter rules on use of fossil fuels. Part of the answer may rest with clean coal technologies and renewable energy but we should not foreclose the advanced nuclear option.

Although there are many reasons to be skeptical about Europe's stance on precaution, there are recent signs of progress from Europe. Take the response of Brussels to "mad cow's disease". Once the British government and industry had taken all reasonable steps to address this problem, Brussels instructed Member States of the EU to lift their bans on beef imports from the UK. All member states complied except France, who argued that French beef might still be safer than British beef and that France has the right to invoke the precautionary principle. Brussels took France to the European Court of Justice, where the Court ruled against France, indicating that speculative appeals to the precautionary principle must have some grounding in science.

Much more recently, the EC actually rejected an unauthorized use of the precautionary principle by the provincial government of Upper Austria. In March of this year Austria notified Brussels of its proposed ban of genetically modified seeds that the EC had approved for cultivation under the EC Directive 90/220. Upper Austria appealed to the precautionary principle but Brussels overruled them: "Recourse to the precautionary principle presupposes that potentially dangerous effects . . . have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty." The EC noted that Upper Austria had not made this case and there was certainly nothing unique about the safety of GM seeds in Upper Austria.

While it is fashionable to criticize Europe on the subject of precaution, and much of that criticism is deserved, it should also be noted that the EC's official views on precaution are becoming more nuanced. In the February 2000 Communication, for example, we found the following views that are similar to the perspective of the US government:

1. Precaution is a necessary and useful concept but it is subjective and susceptible to abuse by policy makers for trade purposes.

2. Scientific and procedural safeguards need to be applied to risk management decisions based on precaution.

3. Adoption of precautionary measures should be preceded by objective scientific evaluations, including risk assessment and benefit-cost analysis of alternative measures.

4. There are a broad range of precautionary measures including bans, product restrictions, education, warning labels and market-based approaches. Even targeted research programs to better understand a hazard are a precautionary measure.

5. Opportunities for public participation – to discuss efficiency, fairness and other public values – are critical to sound risk management.

In summary, there are two major perils associated with an extreme approach to precaution. One is that technological innovation will be stifled, and we all recognize that innovation has played a major role in economic progress throughout the world. A second peril, more subtle, is that public health and the environment would be harmed as the energies of regulators and the regulated community would be diverted from known or plausible hazards to speculative and ill-founded ones. For these reasons, please do not be surprised if the US government continues to take a precautionary approach to calls for adoption of a universal precautionary principle in regulatory policy.