Policy Navigation Group supports the efforts of the Office of Management and Budget (OMB) and the Office of Science and Technology Policy (OSTP) to establish minimum standards for government risk assessment. Of course, it is unlikely that anyone will stand against improving the utility, objectivity, and integrity of the documents that form the basis of important policy decisions. In fact, the bulletin contains no revolutionary ideas in risk assessment; it would be revolutionary if agencies placed these ideas into routine practice.

As for agency implementation, the bulletin recognizes that risk assessment can be complex and risk assessors are forced to make compromises to meet competing purposes served by their analyses. The bulletin relies, wisely, on the rule of reason and professional judgment to resolve such conflicts; the bulletin thus has solid aspirational goals that can still be implemented by the mortals called on to perform and to use these assessments.

Addressing risk assessment before risk management decisions are made or risk communication occurs is important for good public policy. First, providing risk managers with comprehensive, objective, understandable analysis is the primary purpose of risk assessment -- the better the information, hopefully, the better the decision. Second, providing the public with risk information that is incomplete or exaggerated can make it more difficult for risk managers to make sound decisions when better information becomes available. Third, since the public faces more risk than has resources to respond, the government needs accurate data to balance competing threats. Moreover, states and sometimes federal regional offices will sometimes take risk assessments (even preliminary ones) and begin implementing them as if they were themselves standards. The preamble to the bulletin alludes to the economic and behavioral impacts that risk assessments can have, even when not part of a regulation.

One needs look no further than our experience with saccharin to see the effect that a risk assessment can have on an industry and consumers. Saccharin warning labels based on a rat study (later discredited) caused great disruption in the food industry as well as with the manufacturers of saccharin. After years of primate, human, and epidemiological studies, the FDA finally removed the warning label. Ironically, American manufacturers of saccharin were required to file an anti-dumping petition with the Department of Commerce because Chinese produced saccharin had become so cheap in the intervening years.

So if it is worth doing, it is worth doing well. This bulletin is an encouraging first step to bring a set of minimum standards to these documents that influence so much of our lives.

Policy Navigation Group is not submitting these comments on behalf of any organization or client. Our interest is to support OMB and the government's effort to improve risk assessment and to give the public more insight and knowledge of Federal government risk management decisions. As former participants in the OMB regulatory and paperwork processes, and continued users of federal risk assessment – particularly

in a regulatory context – we are intimately familiar with what can happen when risk assessments are poorly done. We are glad that OMB and OSTP are taking this step to provide guidance on how to do such assessments correctly.

A Balancing Act

The bulletin sets out three general goals for improving the risk assessment process, making risk assessment documents:

1. more understandable;
2. more objective; and
3. more transparent.

Of course, these goals can be, at times, mutually exclusive. For example, the use of simplifying assumptions or single point estimates can make risk assessments easier to understand at the expense of objectivity (and sometimes transparency).

The bulletin, therefore, seeks to guide agencies in balancing these three goals. The bulletin seems to favor transparency and objectivity at the expense of simplicity – crediting decision makers and other users of risk assessments with the intelligence to understand any additional complexity the additional information might add. As highly exposed risk assessment consumers, we believe OMB strikes the right balance.

The Bulletin Proposes Needed Improvements in Risk Assessment Practice

OMB is to be commended on its clear distillation of federal risk assessment issues and of the steps necessary to improve these assessments. Yet, as mentioned above, these steps are laid out in a way that provides agencies with the flexibility to respond to real world constraints as they seek to improve the basis for their decision making.

One of the more encouraging requirements of the bulletin is that the design and problem formation for risk assessments be the result of an iterative process between the risk assessor and risk manager (public involvement would be even better). In addition to improving the utility of the analysis for the risk manager, this arrangement implies that the risk assessment – like economic analysis – should precede the risk management decision. We applaud this realization.

Part of this iterative discussion should lead to better matching of the analysis to the question at hand. Often analysis performed for one reason (say risk screening) is used for some other risk management purpose (such as standard setting). While the conservative assumptions used in screening analysis may be appropriate for evaluating which risks are require additional consideration, considerable further work needs to be done to use this information for meaningful risk reduction. Further, use of screening-level analysis for standard setting, or as the sole basis for risk communication, undermines the utility of screening-level analysis by rendering every risk a top priority. Making meaningful resource choices regarding which risks to address first becomes impossible. Unfortunately, screening-level risk values too often become the enforceable standard. Hopefully, the requirements of this bulletin relating to both problem formation and transparency will lessen the prevalence of this practice.

The bulletin also encourages better matching of the analysis to the population of concern. This has profound implications for risk communication. Hopefully, clarification of the populations to whom risks apply will end the occurrence of grown men avoiding fish consumption due to concerns over mercury in the fish (scientific data associates mercury exposure at low levels with fetal development issues that, as yet, do not affect adult males of the species).

The preamble to the bulletin refers to risk information (usually hazard information) obtained through clinical or, more often animal bioassays. It cannot be stressed enough how important the requirements of this bulletin are to the extrapolation from such studies. Scientists are getting better at discerning those modes of action that are applicable to humans from those that are peculiar to the species tested. Unfortunately, government scientists can be slow to accept this new body of knowledge into their risk assessments and, by extension, their risk management decisions.

For example, in 2000, the Office of Pesticide Programs at the Environmental Protection Agency sought to classify the herbicide atrazine as a "likely human carcinogen" – one step below a known carcinogen on EPA's cancer risk classification scale. This determination was based on a rat bioassay showing evidence of tumors in one sex of one species of rodent, despite evidence that this mode of action was unique to the rat and evidence provided by the registrant that human data did not support a carcinogenicity determination. Not until the issue was brought before a peer review did the agency staff move off of its determination. The peer review committee voted unanimously that atrazine should be classified as "not likely to be carcinogenic in humans[1]."

One of the ways that the bulletin recognizes the realities faced by agencies performing, or commissioning, risk assessments is by requiring that the level of effort and resources devoted to a risk assessment be commensurate with the value of the information. However, use of this informational benefit-cost analysis must work in both directions. While the agencies should be encouraged not to waste resources on analysis that will not impact the correct risk management decision in a meaningful way, neither should the agency claim resource constraints as an excuse to avoid performing analysis that would reduce uncertainty in a way that may result in a less stringent standard.

For both general risk assessments and influential risk assessments, the bulletin contains a number of standards, for that pertain to understandability and transparency. Failure of risk assessors to clearly state critical assumptions, explain their terms, or take other steps to make their work understood by lay audiences (often including managers charged to decide policy issues) can lead to perverse public reactions and policy responses. For example, in Massachusetts, public health officials closed a school cafeteria's dishwasher when low levels of perchlorate were discovered in the water supply and officials became concerned with potential leftover dishwater condensate on school lunch trays. In this case, again, the health endpoint that justifies

[1] Hawks, Roger, PhD., Memorandum on Atrazine: Cancer Peer Review Meetings – Provisional Conclusions, November 1, 2000, EPA.

the reference dose on this chemical is fetal neurodevelopment. The food on the trays probably contains chemicals with a much stronger effect on thyroid health than the perchlorate that caused the panicked reaction. It also seems doubtful that students would drink a lot of water of a wet tray or a fork. This may have been a case where local officials did not understand the risk assessment rather than a failure of the assessment itself. However, the clearer risk assessments become, the less likely such reactions will be.

Another area that demands greater clarity is in the combination of multiple assumptions. This is particularly the case when a risk assessment fails to recognize the assumptions already built into a value from another risk assessment.

Take, for example, a typical drinking water Maximum Contaminant Limit Goal (MCLG) for a pollutant with a threshold health effect. Recently, these standards have been set using a "relative source contribution factor" to account for exposures to the chemical that an individual may receive from other sources. The logic behind this factor is that an individual may be exposed to the same chemical from alternative routes such as breathing or eating food with the same chemical. The default factor is 0.2 – indicating that the individual will receive 80 percent of her exposure through non-drinking-water routes of exposure. The drinking water exposure limit is, in this case, set at one fifth of the "safe" level in drinking water. This ensures that individuals do not receive an "unsafe" dose of the pollutant irrespective of where they might otherwise encounter the pollutant in their daily lives.

But wait, the "safe" level in drinking water is based on a reference dose, which the EPA defines as "an estimate, with uncertainty spanning perhaps an order of magnitude, of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." This definition refers only to the level at which there is no risk of deleterious effect. It does not say anything about what the effect might be if such a level is exceeded. In other words, it defines "safe" without making any judgment about what is "unsafe."

The reference dose, in turn, is often based on an animal study, which in turn has been adjusted to reflect interspecies variation, intra-species variation, and as many as three other factors. This can result in a reference dose that is one-one hundred thousandth of the level at which effects were observed in the animal study.

So, if a site specific risk assessment shows that groundwater under a sight exceeds an MCLG, what does that mean for public health? If we have a single study that shows an adverse effect in a rat at 1000 mg/kg/day we may translate this result into a reference dose as follows:

Assumption	Hazard Level
Lowest Observed Adverse Effect	1000 mg/kg/day
No Observed Adverse Effect is lower	100 mg/kg/day
Some rats are more sensitive	10 mg/kg/day
Humans are more sensitive than rats	1 mg/kg/day
One study doesn't tell us much	0.1 mg/kg/day
Chronic exposures are less safe than acute exposures	0.01 mg/kg/day

Taking this example further, the MCLG would be set at a level roughly equivalent to a dose of 0.002 mg/kg/day, a level so far from the single data point that we do have that meaningful interpretation is difficult if not impossible. Yet the public, and local risk managers will interpret this level as health – if not life – threatening. Moreover, this example does not deal with the assumptions associated with describing how ground water contamination at the site reaches a water supply.

If there is one idea in the bulletin that stretches common practice – at least in the regulatory community – it is that appropriate weight should be given to negative studies. As demonstrated above, there is no way for the simple math of the risk assessor to translate a study that shows no effect into a convenient risk number for regulatory purposes. As a result, risk assessors tend to ignore the studies with negative results entirely and concentrate only on studies where an effect is demonstrated – often the study with the lowest concentration at which an effect is observed. This is a pure policy driven call that not only has no scientific content, but is actually bad science. Good science would involve seeking an explanation for why a particular study showed an effect in the face of conflicting evidence.

Neither risk assessors, risk managers, OMB, nor OSTP staff can be expected to police all of these issues on every risk assessment. Probably the best way to improve risk assessments is to significantly expand the level of meaningful peer review and public involvement at all stages of their development. However, care must be taken to ensure that preliminary risk assessments are not used for regulatory, communication, or other purposes while this review is ongoing. Too often, preliminary risk assessments are used by states and even federal regional offices as the basis for risk management decisions. If peer review and public comment are to be worthwhile uses of time and effort for the peers and members of the public, implementation of risk management and communication must wait for the process to be complete.

Scope

The definition of risk assessment in the bulletin refers only to human health, safety, and the environment. We are assuming that, for definitional purposes, safety includes the type of fault tree and other analyses associated with construction standards. While this represents a significant portion of the risk assessment performed by and for the government, it does seem to leave out some important types of risk assessment. Notably, financial risk assessment performed by agencies such as the Office of the Comptroller of the Currency and its sister agencies. Given that these agencies are covered by the requirements of the Paperwork Reduction Act and other statutes

administered by the Office of Information and Regulatory Affairs, their absence from the coverage of this bulletin seems curious.

In addition, the exposure side of the risk equation, most notably, fate and transport modeling seems to receive little attention in the bulletin or its preamble. Without equal attention paid to the assumptions and analysis behind exposure analysis, the potential improvements in measures of hazard will do little to lead to better risk management decisions. In fact, the bulletin refers to EPA reference doses and reference concentrations as measures of risk. In fact these are conservative measures of hazard that contain little to no information about risk.

While it is clear that each and every site-specific risk assessment cannot be expected to meet all of the standards set forth in the bulletin, nor can OMB or OSTP be expected to review all such documents, completely exempting these documents undermines the entire purpose of the bulletin for a significant number of important policy decisions. Many programs specifically dealing with human health and environmental risk – RCRA permitting, Superfund – are administered through the use of site-specific risk assessments performed by regional officials or delegated state authorities. These documents should, to the extent possible, embody the principles set forth in the bulletin. Otherwise, the bulletin will cause hew and cry here in Washington, with no improvement in risk assessments – and the subsequent analysis or communication – in the real world.

Implementation

OMB stated that it has not yet determined, or made public how the provisions of this bulletin are to be implemented. In the interest of being helpful, we offer the following suggestions.

Centralized implementation of this bulletin through the Office of Information and Regulatory Affairs makes sense. OIRA already has authorities under Executive Order 12866 (as amended) to disapprove draft regulatory actions that fail to comply with minimum standards. As the preamble to the bulletin makes clear, risk assessments can have real affects on individual behavior and the economy. It makes no sense to treat a risk document and a draft regulation differently if they are expected to have the same economic impact. Otherwise, OIRA will foster an incentive for agencies to dispense with regulatory actions through the release of risk assessments.

Since it is unlikely that any risk assessment will meet all of the standards set forth in this bulletin, the certification requirement should include a provision for the agency to discuss where the risk assessment differs from the standards established in the bulletin.

To facilitate the updates in Section VI, a public nomination process should be created to allow the public to make agencies aware of relevant scientific information. This process would apply to all existing agency risk assessments, not just those originally covered by this bulletin. This notification process would be analogous to the call for "regulatory reform" nominations that OMB has made under the "Regulatory Right to Know Act."

Agencies should also be encouraged to make influential risk assessments – or major risk assessments to be used for regulatory purposes – part of their regulatory agenda submission, so that the public has notice that the risk assessment is underway. The public's ability to contribute to the scientific dialog is severely limited if they only become aware of these influential assessments at the end of the process. Industry is often called on to provide information or resources to inform these assessments, and they could do a better job if given more notice. In addition, some agencies require that interested parties supply their own peer reviewed science to refute or clarify any portion of an agency risk assessment. Such studies take time, and prior notice would allow interested parties to prepare this research.

The inclusion of risk assessment schedules in the Unified Regulatory Agenda is not new. The Occupational Safety and Health Agency, for example, currently lists the completion of its peer review of the risk assessment for crystalline silica as the next step in the development of that standard.

Major site-specific risk management decisions should be subject to the bulletin when they involve new chemicals, models, or risk assessment information. Otherwise, site-specific risk-based decisions would be allowed to continue without further interference under this bulletin. However, guidance from headquarters to risk assessors in the field should be modified to include the principles and standards included in this bulletin. A similar approach could be taken with respect to the financial models used by bank regulators, and weather models used as the basis for risk communication such as storm warnings.

Fate and Transport Modeling

The preamble to the bulletin discusses extensively the issues related to hazard assessment of risks to human health. It discusses issues of exposure somewhat less. However, it is nearly silent on the issue of fate and transport modeling. We recommend that the final Bulletin emphasize that it applies to agency's contaminant fate and transport modeling. While toxicology and hazard assessment estimates the potential adverse health effects once a person is exposed to a contaminant, the fate and transport component of a risk assessment calculates the probability, amount, and timescale of contaminants movement from point of release to potential human exposure.

Risk management decisions imbedded into models either by design, by scientific uncertainty, or by necessity due to the fundamental need to simplify in order to compute solutions in a useful timeframe. Some of the assumptions that occur throughout the fate and transport modeling are the following:

- the boundary conditions;
- the phenomena considered;
- the transport mechanisms modeled; and
- the interactions between compounds and between transport mechanisms.

While it has always been an important component of risk assessment, the imbedded conservatisms or assumptions in fate and transport modeling have not been discussed as much as toxicology assumptions. The draft Bulletin is similarly unbalanced.

This unbalance is particularly unfortunate since fate and transport models are increasingly important in risk assessments and regulatory policy. Since the earliest days on environmental regulation, EPA has relied on fate and transport model to support risk-based decisions. EPA applied early air and surface water fate and transport models in the 1970s. Groundwater fate and transport models grew into routine use with the emphasis on hazardous waste management regulation and contaminated site cleanup in the 1980s. With the expansion of the Clean Air Act in 1990, EPA has adopted fate and transport models to measure the fate and transport of air toxics. In the current decade, the United States signed international treaties and participated in discussions on the global fate and transport of certain persistent and bioaccumulative compounds and of greenhouse gases.

While EPA's regulatory reach –and attendant modeling needs – has grown in the scale of space to the nation if not the globe – a scale of 10^9 meters. At the same time, EPA is trying to model interactions 21 orders of magnitude smaller – interactions between engineered nanomaterials and the natural environment.

Concerns Raised at the National Academies of Science Panel Public

On May 22nd, 2006 the National Academies of Science held the first public meeting associated with their review of the bulletin. This meeting provided an opportunity for federal agencies and other stakeholders to raise issues related to the bulletin to the panel.

A number of common themes were raised by presenters at this meeting. In most cases, these issues are already addressed by the bulletin or its preamble, or it is clear that the public policy benefits of the bulletin outweigh the costs associated with the concerns. In a few cases, minor changes to the bulletin may be required to match the letter of the bulletin to its spirit.

The issues raised by commenters at this meeting include the following:

Scope is too broad

A number of commenters raised concerns that the scope of the bulletin was too broad and would include a number of risk communication or other activities where full compliance would fundamentally damage the underlying federal purpose of the information dissemination.

The preamble to the bulletin is clear that risk communication documents are not directly subject to these standards. However, a change in the definition may be required to make this clearer. In addition, the bulletin, like other authorities implemented through OIRA, relies on the rule of reason to determine when and with what level of rigor to apply its principles. Clearly information that is required to avoid an imminent threat or that is otherwise time sensitive could receive special attention under the bulletin.

Some of the risk communication information that is currently covered would fall into the category discussed above with respect to the models used in site-specific risk

assessment. In these cases, the models – or the risk communication system – would only be covered by the bulletin when undergoing fundamental change to the model or system. Individual actions under the system would not be covered.

The bulletin is unnecessary because we are doing this anyway

A number of agencies raised this as a concern, suggesting that additional resources would be required with no commensurate improvement in risk assessment. As a frequent "consumer" of risk assessments, allow us to assure you that risk assessments are not universally done to the standards set forth in the bulletin. In addition, if risk assessments are being done to this standard, there should be no additional cost to the agencies.

Moreover, the bulletin explicitly requires agencies to match the level of effort and resources devoted to risk assessment to the importance of the information. Therefore, additional resources will be required only where they are justified.

It is also likely to be cheaper for agencies in the long term to do risk assessment once correctly than it would be to fight endlessly over methodology and interpretation after the assessment is completed.

Most importantly, it is duplicitous of agencies to complain about having to expend additional resources to use the best practices and best available science on a risk assessment that is likely to be used as the basis for regulations costing citizens millions or billions of dollars per year. This would seem to be an instance where the dividends for getting the facts straight would be enormous.

NASA comments

NASA raised concerns that the definition of risk assessment was inconsistent with the risk assessment they are already doing to even higher standards. This is potentially a concern. However, NASA's work is based on probabilistic risk assessment, a methodology that OIRA has supported in the past. It would be odd if the bulletin intentionally interfered with its use by any agency. We urge OIRA, OSTP, and NASA to resolve this issue before finalizing the bulletin.

Fruit of the Poisoned Tree

Perhaps the strangest concern was raised by the National Resources Defense Council. They expressed concern that research funded by industry must also be considered by risk assessors. Leaving aside the fact that most product specific research is funded, directly or indirectly by industry, where the money for a study comes from has nothing to do with the scientific credibility or the research. Judging scientific credibility of individual studies is one of the reasons transparency and peer review is so important to improving risk assessment.

Conclusion

This bulletin represents an important first step in improving risk assessments – and, by extension, risk management and risk communication. However, without strong

centralized implementation, it is just so many words. As we stated at the beginning of these comments, there is nothing revolutionary in this bulletin. What would be revolutionary would be for the agencies to embrace these goals and standards and actually implement them.