State of New Jersey
DEPARTMENT OF ENVIRONMENTAL PROTECTION
Policy, Planning and Science
401 East State Street, 7th Floor
P. O. Box 402
Trenton, New Jersey 08625
Tel. #(609) 341-5311
Fax. #(609) 292-3268

JON S. CORZINE
Governor

LISA P. JACKSON
Acting Commissioner

FAX TRANSMITTAL COVER SHEET

DATE: June 9, 2006

TO: Dr. Nancy Beck

FAX #: 202-395-7245

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FROM: Commissioner Jackson, N.J. DEP

COMMENTS: Comments on Risk Assessment

State of New Jersey
DEPARTMENT OF ENVIRONMENTAL PROTECTION
PO BOX 402
TRENTON, NJ 08625-0402
TEL. # (609) 292-2885
FAX # (609) 292-7695

JON S. CORZINE
Governor

LISA P. JACKSON
Commissioner

June 9, 2006

Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building, Room 10201
Washington DC 20503

Dear Dr. Beck:

I am pleased to submit the attached comments on behalf of the New Jersey Department of Environmental Protection. These comments detail my grave concern with the OMB's proposed Risk Assessment Bulletin. This bulletin outlines a process for the use of risk assessment in the regulatory process that marks a dramatic turn from the approach that has been in place and has functioned well in the protection of public health and the improvement of environmental quality. The proposed approach will make it virtually impossible for federal regulatory agencies, including the U.S.EPA, to continue to use risk assessment approaches based on the current public health protective default assumptions. Instead, the proposed approach will turn the focus of risk assessment in the regulatory process from public health protection to an endless debate about uncertainty and alternative assumptions from which neither the public health, nor the environment will benefit. The proposed change will affect not only the federal government, but given the close links that have developed between the regulatory processes in the federal and state governments, will also greatly and aversely impact the attempts by states to protect their publics and environments.

I urge you to carefully consider the attached comments and to revise the proposed Risk Assessment Bulletin accordingly in keeping with the mandate of the federal regulatory agencies to protect public health and the environment.

Sincerely yours,

Lisa P. Jackson
Commissioner

Comments on OMB Risk Bulletin 1/9/06

General Comments

While risk assessments can be conducted to provide a description of the risk at a given location or under a specific set of well described circumstances, risk assessments carried out by both the federal government as well as states (including New Jersey) are, for the most part, ultimately concerned not with simple description of risks but rather with settings standards and guidelines for the protection of public health. The goal of such risk assessments is not to provide a strictly accurate estimate of risk. The inherent and largely unavoidable uncertainty in the risk assessment process makes such a goal impossible. Rather, the goal of such risk assessments as currently envisioned by the federal government and by states is to provide a reasonable estimate of risk or safety that protect against significant adverse outcomes.

Consistent with this goal, risk-based standards and guidelines have been based on a standard of plausibility rather than likelihood. This overarching goal is not necessarily concerned with in-depth treatment of uncertainty or context. Instead it is, rightly, concerned with public health protection. Within that mandate, the risk assessment approach should strive to achieve that protection with the least amount of overprotection, but clearly, the priority has been and should be given to the reasonable maximization of protection as opposed to the minimization of overprotection. This means that the application of risk assessment to the derivation of such standards and guidelines must account for the impact of uncertainty by applying conservative (i.e., protective) assumptions to the various aspects of uncertainty. At both the federal and state levels, this has been accomplished by the selection of default models, scenarios, mechanistic assumptions, and default treatment of uncertainties that are both scientifically reasonable and intentionally conservative. The use of these default approaches, properly acknowledged and discussed within the risk assessment, has allowed risk managers and policy makers to extract clear guidance from the risk assessment process and to make comparisons among risk assessments on a consistent and equal footing.

The draft OMB bulletin on the other hand, proposes a broad approach to risk assessment that doesn't merely acknowledge the uncertainties and assumptions in the risk assessment process but unfocuses the goal of providing guidance to risk managers by concentrating on the uncertainties themselves and on the range of competing risk estimates that would result. It seems clear that the approach set forth in the bulletin will hinder rather than aid the risk management process. The result will, without doubt, be to devalue the risk assessment process by making it an excuse for inaction rather than a tool to guide action. Multiple guidance and competing estimates constitute no guidance at all. By opening up risk assessment intended to support regulation to the consideration of all possible assumptions and contexts, the bulletin invites manipulation and obfuscation of the process, and thus sets up a clear opportunity for pettifogging intended to delay and eviscerate risk-based regulation. Despite the bulletin's couching of its goals in terms of scientific honesty and transparency, it is difficult to see the intent of the bulletin as anything but an attempt to dismantle risk-based regulation at the expense of public health.

Specific Comments

pg. 12 - *1. Standards Relating to Informational Needs and Objectives*

For example, an explicit statement of the ranges of chemical doses for which the assessment is relevant will inform other users as to whether or not the assessment is relevant their purposes.
Risk assessments are not necessarily undertaken to describe a specific set of circumstances or a particular exposure scenario. Often, risk assessments are carried out to describe the potential health impacts of exposure to the chemical that can occur over a broad range of exposure conditions. Furthermore, the available data do not often allow a precise assessment of the range of exposure or doses over which adverse effects can occur with chronic exposure, especially to the most sensitive members of the population. In such cases, in order to ensure that guidance resulting from the assessments are protective, it is necessary to apply assumptions and defaults regarding the range of doses over which effects can reasonably occur. Such assumptions include default cancer dose-response models, and uncertainty factors in RfD/RfC derivations. A requirement to provide an explicit statement about the range of doses over which the assessment is relevant cannot necessarily be made if the intended level of protectiveness is to be ensured.

Once the affected entities are defined, the assessment should define the exposure or event scenarios relevant to the purpose of the assessment as well as the type of event-consequence or dose-response relationship for the exposure or event ranges that are relevant to the objectives of the risk assessment.
This is a reasonable requirement when a descriptive risk assessment is being carried out (e.g., a site assessment, a contaminated drinking water supply), however, when the assessment is a more generic assessment evaluating the potential health effects associated with a chemical and/or setting generic guidelines for acceptable exposure (e.g., a cancer slope factor, an RfD), it is not appropriate to identify specific exposure scenarios. Not only are such guidelines intended to apply across all exposure scenarios, including unanticipated scenarios, but the limitations on the characteristics of exposure (e.g., frequency, duration) that determine the potential for adverse health effects are generally not known with any certainty. Risk assessment guidance should always be applied with careful consideration to the applicability of the guidance to any given situation, but such considerations should operate on a case-by-case basis, not *a priori* when the generic guidance is developed.

pg. 13- 2. *Standards Relating to Scope*
When agencies ask whether a particular chemical or technology causes or contributes to a particular disease, completeness in a scientific sense may entail consideration of evidence regarding the causative role of other factors in producing the disease of interest.
Risk assessments intended to address a specific exposure or a specific exposure scenario may need to describe the full range of exposures relevant to an adverse health outcome that may be associated with an exposure to a specific agent. However, the use of such a

contextual approach to risk assessment is an issue that needs to be addressed on a case-by-case basis. In most cases, it is important that both the independent risk from the specific agent and the combined risk from total exposures be known so that reasonable risk management decision can be made. Such decision may or may not require or benefit from a contextual approach. On the other hand, risk assessments designed to provide guidance for a specific chemical that can be applied generically, should not be constructed on the basis of potential co-exposures. Not only are such exposures unknown in advance for any given application, but the appropriateness of a contextual approach in the risk management decision is unknown in advance. Known or likely synergistic or additive exposures should, of course be noted as part of the generic assessment, but should not be factored into the quantitative generic guidance for the specific agent.

pg. 13 - 3. Standards Related to Characterization of Risk

Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided.

At this point in the proposed risk assessment bulletin, OMB quotes a NRC report (Science and Judgment in Risk Assessment – footnote #26) in support of the notion that all risk assessments should present a range of estimates arising from the inherent uncertainty in the risk assessment process. However, in the same passage, the NRC also notes that "EPA should make uncertainties explicit and present them as accurately and fully as feasible as needed for risk management decision-making" (emphasis added). The NRC is clearly pointing out that the treatment of uncertainty in a given risk assessment should be dictated by the requirements and needs of the risk management decision. Uncertainty analysis is a means to an end, not the end itself. OMB's proposed guidance leans toward making it a fetish without concern for its feasibility or need. The document also cites the Risk Commission Report (1997), but fails to acknowledge that the report tends to be skeptical about the value of quantification of uncertainty for decision-makers. Although the bulletin does suggest some flexibility in application of its rules to a few cases, overall it fails to take into account the varying value of uncertainty analysis in its quantified form. The outcome of this attempt at standardization for the implied sake of quality control is likely to be, instead, the proliferation of often unneeded, and possibly counter-productive, calculations that do not contribute to the understanding of either decision-makers or of their various constituencies.

These SDWA quality standards should be met, where feasible, in all risk assessments which address adverse health effects.

With respect to the SDWA requirement that *"...specify, to the extent practicable... (ii) the expected risk or central estimate of risk for the specific populations [affected..."* If applied to issues of exposure assessment, it is generally clear what is meant by central estimates of risk since (within a given scenario) exposure can generally be described in terms of the mean, median, and percentiles of exposure based on empirical data. However, these estimates are, nonetheless, uncertain, and the implications of such uncertainty must be addressed. However, if such requirements are applied to dose response, the meaning of "central estimate" is not clear. Because of uncertainties in the

basic toxicology, in cross-species extrapolation, and in the nature of sensitive populations, determinations of dose-response are generally not driven entirely by empirical data, but are, of necessity, highly influenced by assumptions about dose-response models. As discussed above, such models are chosen as defaults based on consideration of providing adequate and intended levels of public health protection in the face of the inherent uncertainty. Thus any application of the term "central estimate" to dose-response will generally be vague and often meaningless. Furthermore, for these reasons, the central tendency estimate of a given dose-response model will not necessarily be the best estimate of the risk as this is an unknown quantity and is furthermore, only definable in the context of the specific population and exposure scenario. When describing the fit of a specific dose-response model to empirical data, it is appropriate to describe the best estimate of the fit as well as the confidence bounds of the fit. However, for the reasons described above, the best fit is not necessarily synonymous with the best estimate of the risk. Providing information on the central tendency estimate for a given application of a given exposure or dose-response model (as directed in the SDWA regulations) should be seen as necessary, but should not be seen as a requirement that the risk-based guidance be based on that estimate.

Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided. Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates.

A full discussion of the uncertainty of any risk assessment is a well accepted and mandatory part of a formal risk assessment. However, to the extent that risk assessments are carried out to provide guidance for regulators and the public, or to serve as the basis for regulation, the provision of multiple and contradictory quantitative estimates of risk defeats such purposes. In the end, governmental agencies must provide guidance that is based on their policies designed to adequately protect public health. These are almost always based on plausible, but conservative (i.e., protective) assumptions. The nature and uncertainty of those assumptions must be acknowledged and discussed, however, multiple guidance is, in fact, no guidance.

pg. 14 - 4. *Standards Related to Objectivity*
When determining whether a potential hazard exists, weight should be given to both positive and negative studies, in light of each study's technical quality.

All studies providing health effects information on a chemical of concern from human, animals, or *in vitro* studies should be discussed in a risk assessment. However, the current approach used by regulatory agencies is to base the risk assessment on the most sensitive study, species, and endpoint, unless 1) it is known through mechanistic studies that the endpoint is not relevant to humans due to differences in physiology, metabolic activation or deactivation, or other factors or 2) the study is scientifically flawed. Risk assessments carried out for the purpose of deriving public health protective standards and guidelines are, by definition, intended to address reasonably plausible risks of adverse

effects and to derive standards and guidelines that are protective against such effects. Such risk assessments are not necessarily intended to present a proof or even a strong likelihood of the occurrence of such effects. This is in keeping with the notion of public health protection. Therefore, the statement cited above appears to direct a change in this current approach to risk assessment towards an approach that is less protective of public health. This is because the bulletin appears to move away from a protective standard of reasonable plausibility to one of weighting positive and negative studies in some sort of risk accounting exercise. Risk assessments should, of course, consider negative studies and should consider the quality of both positive and negative studies, but these should be considered and discussed in the context of the overall evidence for the plausibility of health risk, and not in terms of a balance sheet.

pg. 15 - 6. *Standards Related to the Executive Summary*
The executive summary should also place the estimates of risk in context/perspective with other risks familiar to the target audience.
By policy and by legislation, environmental risks are generally not managed in a global context. Often, by the same policies and legislation, they are not even managed within an overall environmental context. Furthermore, risk assessments are not necessarily carried out for the purpose of comparing risks. Rather, they are often carried out to describe the risk from a given substance in absolute terms. Thus, providing risk comparisons as a matter of policy and without consideration of the context of the assessment can easily be misleading. Such comparisons can easily be manipulated to make a given risk appear either excessive or trivial, neither of which is necessarily true for a given context. Furthermore, the suggestion that agencies "consult the risk communication literature" will do little to foster the goal of putting risks into context, and may make things worse. The bulk of that literature on risk comparisons is based neither on theory nor on empirical data, but rather on hunch and misleading personal "experience." The few empirical published studies do not provide guidance specific to a given risk assessment or even risk topic. Rather, they reveal more general issues that are not easily translated into practical advice for what comparisons agencies should use. For example:
--experts' and officials' assumptions about the kind of risk comparisons that put risks "in context/perspective" are often wrong
--people in the aggregate may report that <u>any</u> risk comparison they are offered is "useful"
--there is little agreement among citizens on which kinds of comparisons rank as better or worse (e.g., in terms of helping put risks into context)
--any effects of risk comparisons on perception of risk and acceptability may be fragile, easily revised under criticism of the comparison's validity or relevance.
Where the intended purpose of a risk assessment is to help the audience choose among specific alternative options, comparison of the risks (and other attributes) of those particular options--e.g., tap water versus bottled water for drinking; smoking cessation versus radon remediation for lung cancer--can be valuable. However, given the lack of agreement on appropriate generic comparisons, and the easily manipulated nature of these comparisons, the value of such comparisons to the risk assessment process is likely to be far more polemical than either scientific or objective. The provision of risk comparisons should be limited to those instances where the explicit purpose of the risk

assessment is to provide such comparisons, or where such comparisons will aid the public in choosing among several alternative risk management strategies.

Section V: Special Standards for Influential Risk Assessments

pg. 16 – *1. Standard for Reproducibility*
Influential risk assessments should be capable of being substantially reproduced. ...independent reanalysis of the original or supporting data using the same methods would generate similar analytical results.....
There is no question that the actual calculations presented in a risk assessment should be reproducible by anyone reviewing them. However, it is not correct to assume that a risk assessment is valid only if another scientist starting with the same primary scientific literature would arrive at the same final conclusion. The development of a risk assessment involves scientific judgment at many steps in the process, and different scientists can make different, but equally defensible, choices in developing a risk assessment. Furthermore, the outcome of a risk assessment will depend on the mandate and responsibility of the individual risk assessor. Given the leeway provided by the uncertainties inherent in the risk assessment process, it is naïve to expect that a risk assessor employed by a governmental agency that is charged with the protection of public health will develop a risk assessment with the same purposes and mandates as a risk assessor employed by a regulated entity who is charged explicitly or implicitly with finding a basis in the scientific evidence for minimizing the regulatory burden.

pg. 17 - 3. *Standard for Presentation of Numerical Estimates*
When there is uncertainty in estimates of risk, presentation of single estimates of risk is misleading and provides a false sense of precision. Presenting the range of plausible risk estimates, along with a central estimate, conveys a more objective characterization of the magnitude of the risks.
As discussed previously, because of uncertainty in toxicological mechanisms, and model specification, such approaches, especially for dose-response assessment, are generally meaningful only in the context of a given model and set of assumptions. Often, numerous models and assumptions may be possible, and in such cases, the notion of providing a range of plausible risk estimates, particularly central tendency estimates is likely to be meaningless and/or to result in a vague and useless cloud of amorphous information. In the (common) case of such multiple uncertainties, guidance should be provided within the context of specific default assumptions selected as a matter of policy to provide reasonable and plausible protection of public health and the environment. The uncertainties associated with such selection should be adequately discussed in the context of the formal discussion of uncertainty that should be a critical part of any formal risk assessment. Risk assessments intended to provide guidance and/or support regulation should provide such guidance and support and not provide a miasma of competing risk estimates.

4. Standard for Characterizing Uncertainty
Influential risk assessments should characterize uncertainty with a sensitivity analysis and, where feasible, through use of a numeric distribution (e.g., likelihood distribution of risk for a given individual, exposure/event scenario, population, or subpopulation).
The development and characterization of risks in terms of distributions (derived through use of Monte Carlo or other probabilistic approaches) has definite utility and place in risk assessment. However, while the variability portion of uncertainty can generally be described in empirical and objective terms, the portion of uncertainty that is based on "true uncertainty" (i.e., lack of knowledge) cannot be described in purely objective terms due to the inherent limitations arising from lack of knowledge. That is, the description of a given (true) uncertain parameter in objective quantitative terms, itself, requires a degree of knowledge that, by definition, does not exist. Such true uncertainty is often a major element in risk assessments. The characterization of such uncertainty in apparently objective terms through the presentation of quantitative probability distributions of risk is both misleading and highly subject to manipulation through the underlying and necessary subjective judgments required by analysis of true uncertainty. Furthermore, contrary to the intent of this bulletin, such descriptions are often based on highly complex and unique manipulations of information that are not transparent and not reproducible. This is not to say that true uncertainty should not be addressed in risk assessments. However, there are much less arbitrary and less misleading approaches for this including propagation of semi-quantitative descriptors of uncertainty (e.g., high, medium, low) that will not convey the impression of more knowledge and more precision than actually exists. In summary, undue pursuit of "multiple estimates of risk" (p. 13), "alternative theories, data, studies and assessments that suggest different or contrary results" (p. 19), and associated uncertainties can confuse the real issues of the weight of evidence of risk estimates relative to the relevant risk management decision, and the degree of protectiveness sought in the face of the uncertainty (which is a policy judgment, not a technical one).

pg. 18 - *When risk assessors face model uncertainty, they need to document and disclose the nature and degree of model uncertainty. This can be done by performing multiple assessments with different models and reporting the extent of the differences in results.*
As discussed previously, the description and treatment of model uncertainty is often open-ended and highly subject to arbitrary manipulation. Model uncertainty should be addressed in the formal discussion of uncertainty, but guidance based on the outcomes of multiple models and (as described in the bulletin) the attempt to weight different models in the face of model uncertainty will result in no useful guidance at all. In the presence of model uncertainty, the use of default models selected so as to provide a desired and policy-based level of public health protection should be continued.

pg. 19 - 5. *Standard for Characterizing Results*
Authors of the assessment have a special obligation to evaluate and discuss alternative theories, data, studies and assessments that suggest different or contrary results than are contained in the risk assessment

The standard for considering alternatives puts no bounds at all on what alternatives must be considered versus those that are discretionary. What qualifies an "alternative theory" as worthy for consideration against standard approaches? How would such a standard be applied without opening the door to "junk science" intended to foster obfuscation and delay?

pg. 20 – 7. *Standard for Characterizing Human Health Effects*
Even the measurement of a biological event in the human body resulting from exposure to a specific chemical may not be a demonstration of an adverse effect. Adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges.
The goal of risk assessments intended to support standards and guidelines for the protection of public health is the identification of a level of exposure that will not result in adverse effects. However, given the uncertainty inherent in the risk assessment process, standards and guidelines based directly on exposures that produce a frank adverse effect may not offer sufficient protection against that adverse effect, or against more subtle, yet significant adverse effects, or the production of a different frank adverse effect in humans than that observed in a species of test animal. This is particularly the case for steep-dose response curves where the uncertainties in the identification of the effective dose or in the appropriate inter-species extrapolation can blur the threshold between non-frank effects and severe effects. This is also the case for pre-cancerous changes and lesions that may not, themselves, be considered adverse, but that are predictive of the production of tumors. In such cases, risk assessment approaches that seek to move away from the traditional cancer potency extrapolation procedure should not be based on exposures that cause irreversible tumors. Rather, they should properly be based on exposures that cause pre-cancerous effects that can progress to tumors, even if those effects are not themselves adverse. This is quite analogous to the responsible practice of medicine where the physician's goal is to lower elevated blood cholesterol levels in preference to providing clinical care for a myocardial infarction. The requirement as stated in the bulletin would confine the critical effects addressed by risk assessments only to those that effect functional performance or adaptive ability, and would preclude basing risk assessment on "upstream" effects. For the reasons stated above, such an approach cannot provide an adequate degree of public health protection.

pg. 20 - 9. *Standard for Addressing Significant Comments*
An agency is expected to consider all of the significant comments received on a draft influential risk assessment report. Scientific comments shall be presumed to be significant.
This requirement places no limitation or restriction on the definition of "scientific comments." What qualifies a comment as scientific, and worthy of a detailed response? The term could simply refer to comments on a draft influential risk assessment that are made in technical language but without any true scientific merit. Certainly there are those with an interest in delaying risk-based regulations who will submit a myriad of comments to a draft influential risk assessment all of which can be couched in scientific language, but whose true scientific value is minimal or non-existent. Such comments can

be used not only to delay governmental acceptance of the conclusions of a risk assessment, but also to establish a basis for litigation that will then force the courts to attempt to sort issues of scientific merit from mere obfuscation. These tactics using "junk science" are well known and are used effectively to hamper regulation. This requirement in the draft bulletin will only serve to open the door wider to such abuses and make it almost impossible to promulgate regulations based even on risk assessments of the highest quality.