

June 15, 2006

VIA ELECTRONIC MAIL

Mr. Steven D. Aitken
Acting Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building, Room 262
17th Street and Pennsylvania Avenue, NW
Washington, DC 20503
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Re: Comments on OMB's Proposed Risk Assessment Bulletin

Dear Mr. Aitken:

We represent members of the agricultural community and are pleased to submit the attached comments in support of OMB's proposed Risk Assessment Bulletin. We believe that the proposed bulletin would raise the quality, objectivity and transparency of agency risk assessments. This should improve the quality of important government decisions and promote the public's right to know about them.

We applaud this proposal, and we look forward to its timely issuance in final form when OMB concludes its deliberations.

Sincerely,

The American Farm Bureau Federation
The National Pork Producers Council
The United Egg Producers
The National Cattlemen's Beef Association

COMMENTS ON RISK ASSESSMENT BULLETIN PROPOSED BY
THE OFFICE OF MANAGEMENT AND BUDGET

Submitted by the American Farm Bureau Federation, the National Pork Producers Council, the United Egg Producers and the National Cattlemen's Beef Association

We represent members of the agricultural community on a wide range of issues and are pleased to submit these comments in support of OMB's proposed Risk Assessment Bulletin. The bulletin would establish government-wide standards to improve the technical quality and transparency of agency risk assessments. We believe this is an important and long-overdue initiative.

Risk assessments are important analytic tools to estimate the likelihood and severity of environmental, health and safety risks and for informing decisions on how to manage those risks. Risk assessments can serve as a foundation for a wide range of decisions impacting agriculture, from environmental regulations to food safety standards and food import and export decisions. Wise risk-management decisions and reliable risk communication depend on accurate, unbiased and transparent risk assessments.

The goals at stake, and the consequences of government decisions, are too important to rely on low quality and opaque information and analysis. The regulated community – as well as the public as a whole – benefit most when regulations are based on sound science and objective risk assessments. In the absence of such standards, the ultimate fairness and integrity of the process are called into question and undermine public confidence in the regulatory system. Articulating comprehensible, reliable guidelines, as OMB is attempting to do in this notice, is entirely appropriate and should further the goal we all share to make sure that regulations are appropriate to the needs of the public.

Inaccurate risk assessments can lead to wasteful and counterproductive allocations of scarce societal resources. We cannot afford to spend those resources – either public or private – unwisely. Accordingly, we recognize the importance of setting basic quality standards for agency risk assessments.

The proposed bulletin concisely distills about 25 years of recommendations from the National Academy of Sciences' National Research Council, the Presidential/Congressional Commission on Risk Assessment and Risk Management, and other leading authorities. The bulletin sets laudable goals for the agencies, as well as: (1) general risk assessment standards, (2) particular standards for risk assessments that will be incorporated into regulatory analyses, and (3) more exacting standards for influential risk assessments likely to have a clear and substantial impact on important public policies or private sector decisions.

www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf.

The general risk assessment standards reflect both good analytics and common sense. We agree that a good risk assessment should clearly state the objectives, summarize its scope, have a high degree of transparency, explain the basis for critical assumptions, and include a clear executive summary. The risk assessment also should be quantitative when possible and provide a plausible range of risk estimates. The assessment should be scientifically objective, neither minimizing nor exaggerating the risk. It should give weight to both positive and negative studies, describe how changing critical assumptions may change the assessment, and put the risk in a context that is useful and relevant for the intended audience.

Where a risk assessment will be used for regulatory analysis, the bulletin directs that the assessment should comply with OMB's benefit-cost analysis guidelines in Circular A-4 and include a quantitative uncertainty analysis if the annual effects exceed \$1 billion. The risk assessment also should evaluate alternative options, clearly establish the baseline risk, compare the baseline with alternative risk mitigation options, consider the timing of exposure and the onset of effects, provide estimates of population risk as well as individual risk estimates, and provide central estimates of risk when possible.

For those risk assessments that rise to the level of being influential, the proposed bulletin requires that, to the extent appropriate, the assessment needs to be substantially reproducible, characterize variability with a distribution, discuss its limitations, and, in the face of uncertainty, provide central estimates of risk as well as high-end and low-end estimates. The bulletin also requires agencies to characterize uncertainty with a sensitivity analysis and a quantitative distribution, where feasible, to evaluate alternative endpoints and studies and how they may affect the outcome, to consult with clinicians and appropriate experts before determining whether an effect is adverse, and to respond to significant comments received.

Some of these provisions merit special attention. For example, we think that it is critical that risk assessments be "scientifically objective . . . neither minimizing nor exaggerating the nature and magnitude of risks." We also think that, if a risk assessor has been tasked with determining whether an effect is adverse, the effect should be specifically identified and the determination should be justified based on the best available scientific information. Dramatic advances in methods of detection (such as biomonitoring) have meant that it is possible to detect substances at levels that may not be of concern. It is important to distinguish between an observed phenomenon or biomarker that leads to an adverse effect and one that does not.

In some respects, the bulletin could be strengthened. For example, while the bulletin and the accompanying preamble require agencies to consider and respond to significant public comments when conducting influential risk assessments, OMB

could enhance the bulletin by specifying public participation requirements at the outset so that agencies take them seriously. Risk assessments should be conducted in a manner that not only promotes rational and informed risk management decisions but that also promotes informed public input into and understanding of the process of making agency decisions. Though it may be appropriate to allow agencies some flexibility in conducting risk assessments, OMB's prefatory catchall "to the extent appropriate" raises concerns about the extent to which agencies might feel free to ignore either the letter or the spirit of the bulletin. If the bulletin is to have the intended effect of improving federal regulations and the role risk assessments play in those regulations, OMB should do all it can to assure that those goals are met. That leads to the more fundamental question of how OMB will enforce the bulletin. Because the bulletin states that it is intended to improve the internal management of the executive branch and disclaims any judicial role in enforcing it, OMB has a particular responsibility to ensure that agencies comply with the bulletin.

OMB also should clarify the relationship of the bulletin to its other reforms. For example, OMB should explain that the bulletin is a supplement to its government-wide information quality guidelines. Accordingly, OMB should make clear that when an agency disseminates a risk assessment that does not comply with the bulletin, an affected party may file an information quality petition to obtain correction of the assessment. OMB also should clarify that when an agency initiates or sponsors a risk assessment prepared by a third-party – whether from the private sector, another agency or another governmental entity – the risk assessment must comply with the bulletin. Finally, OMB should clarify how the bulletin dovetails with its benefit-cost analysis guidelines in Circular A-4, and explain how it fits hand-in-glove with its Peer Review bulletin.

Having raised these points, we note that the objectives of the bulletin are necessary to develop rational regulations and programs. Objective and unbiased analysis is necessary for benefit-cost analysis that is so important for wise regulatory decisions. Simply put, benefit-cost analysis requires an apples-to-apples comparison, and there should be symmetry between benefits and costs. As OMB stated in its benefit-cost analysis guidelines, Circular A-4: "the risk assessment methodology must allow for the determination of the expected benefits in order to be comparable to expected costs. . . . [C]onservative assumptions and defaults (whether motivated by science policy or by precautionary instincts) will be incompatible with benefit analyses as they will result in benefit estimates that exceed the expected value" (p. 40). Agencies should maintain the distinction between risk assessment and risk management, and objective and unbiased risk reduction estimates should be produced regardless of whether benefit-cost balancing is a substantive requirement, such as under the Federal Insecticide, Fungicide and Rodenticide Act or the Toxic Substances Control Act, or is done purely for informational purposes under Executive Order 12866, OMB Circular A-4 or the Regulatory Right-to-Know

Act. We observe that the bulletin does not bind risk managers to consider only central estimates of risk. The bulletin promotes more, not less, information disclosure to risk managers – and to the public.

At its annual meeting in January 2006, Farm Bureau delegates adopted policies relating to Federal issues, and in numerous instances these representatives called for the kind of reforms contemplated in this bulletin. Among other things, the delegates stated that regulations should be “based on sound scientific data which has been subject to replication and peer review” and that “a risk assessment analysis should be conducted prior to the promulgation of a regulation.” We believe strongly that sound science must be a component of the Federal regulatory structure, and we commend OMB for furthering this important effort.

It also is important to note that we are unaware of any irreconcilable conflict between the risk assessment standards in the bulletin and statutory requirements for regulatory programs. The bulletin addresses risk assessment, not risk management. The preamble specifically states that it does not encompass how agencies should manage risk (p. 3). Accordingly, the bulletin does not conflict with statutory risk management standards, such as the requirement in the Food Quality Protection Act that, in the absence of reliable data on the safety of a lower margin, EPA should use a safety factor of ten for children when establishing pesticide tolerances. Regardless of whether or not a statute contains a precautionary approach to risk management, it is essential that agencies maintain a distinction between risk assessment and risk management and that risk assessments be scientifically objective and unbiased.

We also are unaware of any statutory requirements for risk assessment that conflict with the bulletin. Substantive regulatory statutes generally do not prescribe specific risk assessment methods. In the case of the Safe Drinking Water Act, which does contain some basic risk assessment requirements, the bulletin is actually grounded in those requirements – including use of best available science conducted in accordance with sound and objective scientific practices; comprehensive, informative and understandable presentation of risk information, including the expected risk or central estimate of risk; and specifying scientific studies that support or fail to support any risk estimate and the methodology used to reconcile any inconsistencies in the data. See 42 U.S.C. § 300g-1(b)(3).

Furthermore, the risk assessment standards in the bulletin are fully consistent with statutory directives to OMB, as well as other authorities. The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. § 3501 et seq., required OMB to “develop and oversee implementation of policies, principles, standards and guidelines to . . . apply to Federal agency dissemination of public information.” The Information Quality Act of 2000, which amended the PRA, further required OMB to “provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality,

objectivity and integrity of information” disseminated by Federal agencies. See Pub. L. No. 106-554, § 515(a). The “Regulatory Right-to-Know Act” specifically required OMB to “issue guidelines to agencies to standardize . . . measures of costs and benefits of Federal rules.” Pub. L. 106-554, 31 U.S.C. § 1105 note. All of these statutory directives are satisfied by the bulletin. In addition, the bulletin fulfills OMB’s responsibilities under Executive Order 12866 to provide guidance to the agencies on regulatory planning and priority-setting. Finally, OMB’s general authorities support the bulletin.

In sum, a risk assessment should accurately assess the risk. OMB’s proposal would raise the quality, objectivity and transparency of these important analyses. More accurate and transparent information will improve the quality of important government decisions. It also will promote the public’s right to know about important risk communications and risk management decisions by its government. This is laudatory, and we respectfully request that, after receiving input from the public and peer reviewers, the administration move forward in a timely fashion and issue final risk assessment guidelines.