Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17th St., NW
New Exec. Offc. Bldg, Rm. 10201
Washington, DC 20503
Fax to (202) 395-7245
Submitted via e-mail to OMB_RAbulletin@omb.eop.gov

June 15, 2006

Dear Dr. Beck:

CropLife America welcomes the opportunity to provide comments on OMB's Proposed IQA Risk Assessment Bulletin as announced in 71 FR 2600, Jan. 17, 2006. CropLife America (CLA) is a non-profit trade association representing the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management. CLA strongly supports the document's intent of ensuring the "objectivity" and "utility" of federally conducted risk assessments.

CLA considers this bulletin to be an important step in ensuring the objectivity and quality of risk assessments released into the public domain, which will help to increase public confidence in the decisions made by federal agencies. It will enable objective risk/benefit evaluations that will help ensure appropriate use of public resources across disparate sources of potential risk.

We are, however, disappointed in the exemptions included through the statement in Sec. II. Applicability, Pages 10 and 23.

> *2. This Bulletin does not apply to risk assessments performed with respect to:…*
>
> *b. individual agency adjudications or permit proceedings (including a registration, approval, or licensing) unless the agency determines that*
> *i. compliance with this Bulletin is practical and appropriate and*
> *ii. the risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings; and*
> *c. an individual product label, or a risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal agency prior to use.*

CLA recommends that this exemption be removed in light of it's inconsistency with the Information Quality Act, which is stated as a driver for the Bulletin. As stated in Section IV, 4, p14, Standards Related to Objectivity:

"Risk assessments must be scientifically objective, neither minimizing nor exaggerating the nature and magnitude of the risks. On a substantive level, objectivity ensures accurate, reliable and unbiased information."

Within a regulatory context, it is essential that risk assessment methods and policies that support regulatory decisions are transparent to registrants in order to provide certainty in business projections when developing new products and assessing existing products. Under these criteria meeting the objectives of the bulletin should be achievable and appropriate. Furthermore CLA, as representatives of registrants of pesticides and herbicides, notes that the resources required to conduct refined risk assessments beyond a screening level, particularly regarding ecological assessments, is substantial. Under a transparent process with available acceptance and rejection criteria, registrants should be able to submit risk assessments for review by regulatory authorities, without jeopardizing public confidence in the final decision by the regulatory authority.

In Sec. II._Applicability, Page 9:

"A rule of reason should prevail in the appropriate application of the standards in this Bulletin. For example, in a screening-level risk assessment, the analyst may be seeking to define an upper limit on the unknown risk that is not likely to be exceeded. Screening-level assessments, in this situation, would not have to meet the standard of "neither minimizing nor exaggerating the nature and magnitude of risk."

Upper limit risk assessments can indicate a potentially high level of risk that is often shown to be a substantial overestimate in refined assessments. This is often confusing to the public when final regulatory decisions are made. It should be made clear in publicly released screening assessments that large reductions in these potential risks are probable. Screening level assessments should not be interpreted or communicated as realistic estimates of risk.

Thank you for considering these comments.

Sincerely,

Dee Ann Staats, Ph.D.
Environmental Science Policy Leader