UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Wendelyn Jones, Ph.D.
Senior Director, Human Health Policy
CropLife America
1156 15th St. N.W.
Washington, DC 20005

Re: Petition For Rulemaking To Establish Criteria For Acceptance Of Epidemiological Evidence Into the Pesticide Risk Assessment Process For Human Health Effects

Dear Dr. Jones:

In a letter dated December 28, 2010, you transmitted to EPA a petition from CropLife America (CLA) requesting that EPA promulgate a regulation establishing criteria for evaluating whether epidemiological evidence will be accepted for use in pesticide risk assessments. For the reasons detailed below, CLA's request is denied.

EPA is in the process of preparing guidelines regarding use of epidemiological data in pesticide risk assessments. On January 7, 2010, EPA released a draft guideline on this matter entitled "Draft Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment" ("Draft Framework"). This document proposes "a framework to describe the scientific considerations that EPA will weigh in evaluating how such studies and scientific information can be integrated into risk assessments of pesticide chemicals."[1] In February 2010, EPA sought review of the Draft Framework from the Scientific Advisory Panel (SAP) created under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. The SAP issued a report on the Draft Framework on April 22, 2010.[2] SAP review is a public process. CLA as well as other representatives of the pesticide industry filed written comments on that review and also appeared before the Panel to present oral remarks. EPA is currently reviewing the SAP's report on the Draft Framework and plans to release a revised version of the Framework for public comment this year.

[1] Draft Framework at 6.

[2] See Memorandum, Myrta R. Christian, Designated Federal Official, FIFRA Scientific Advisory Panel, to Steven Bradbury, Acting Director, Office of Pesticide Programs, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting on the Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment (April 22, 2010) (hereinafter cited as "SAP Meeting Minutes").

In its petition, CLA argues that a guidance document on the use of epidemiological data in pesticide risk assessment would be inadequate. Instead, CLA requests that EPA establish by rule "firm criteria for quality assessment of epidemiological studies to be used in risk assessment" and not use any epidemiological studies in risk assessments prior to promulgation of that rule. CLA claims that a rule is necessary to address this issue because epidemiological data are "important" to pesticide risk assessment, the transparency of the rulemaking process is needed to produce defensible criteria on the acceptability of epidemiological studies, and criteria designated by a guidance document would be a "de facto rule" and thus invalid.

EPA's general practice is to address science issues through non-binding guidance documents rather than by mandatory regulations. There are several reasons for this approach. First, and probably most important, science questions usually cannot be reduced to a rigid decisional framework; rather, science questions invariably involve the weighing of multiple considerations and the use of scientific judgment. As the SAP report on EPA's Draft Framework noted in its recommendations on criteria to be used in EPA decision-making: "Inevitably, it will be necessary to exercise some degree of scientific judgment in this assessment."[3] Second, encasing science decision-making in a rigid rule structure is inconsistent with the fluid and developing nature of science. Thus, EPA is concerned that writing science decision-making rules will stultify or freeze the science underlying the rule making scientific advances less likely. Finally, the nature of science issues is not easily compatible with the timeframes associated with formal rulemaking. Given the extended time often required to promulgate or amend a rule, the science underlying science-based criteria may well have significantly advanced between the time of the proposal and the time of the final rule. EPA may then be forced into restarting the rulemaking process or may end up being locked into outdated science decision-making until a rule can be amended. There are numerous examples of EPA appropriately addressing important science questions through guidance, not rules, at both the Agency level and the program-specific (pesticide) level.[4]

CLA has offered no compelling reason to follow a different course with regard to epidemiological data. Epidemiological data are no more "important" to pesticide risk assessments than many other data inputs or science-related issues. Yet, as explained above, EPA invariably addresses pesticide risk assessment issues through guidance documents. For example, the Office of Pesticide Programs has issued almost two dozen science guidance documents on

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[3] SAP Meeting Minutes at 9.

[4]. See, e.g., U.S. EPA, Framework for Metals Risk Assessment, (March 2007) (EPA 120/R-07/001); U.S. EPA, Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants (November 2005) (EPA/630/P-03/003F); U.S. EPA, Guidelines for Carcinogen Risk Assessment (March 2005) (EPA/630/P-03/001F); Office of Pesticide Programs, U.S. EPA, Office of Pesticide Programs' Policy on the Determination of the Appropriate FQPA Safety Factor(s) For Use in the Tolerance Setting Process (February 28, 2002); Office of Pesticide Programs, U.S. EPA, The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorous and Carbamate Pesticides (August 18, 2000).

issues critical to pesticide risk assessment in the wake of the passage of the Food Quality Protection Act of 1996.[5] Further, as evidenced by the process followed to date with EPA's Draft Framework, there are many ways to insure a transparent process for science decision-making guidelines other than through rulemaking. Finally, there is nothing unique about evaluating epidemiological data that would indicate that EPA could not craft non-binding guidelines for incorporating epidemiological data in risk assessments, including non-binding guidance on specific criteria to be considered in weighing the value of particular epidemiological data.

EPA agrees that transparency is a critical part of its science decision making. Our decisions on important policies and guidance documents always follow a transparent process with numerous opportunities for public comment. Such a process was followed in the review of the Draft Framework by the SAP and will be followed as we further revise the guidance. EPA welcomes CLA's interest in its Draft Framework. As noted above, EPA plans to hold further public dialogue on the issues presented by the Draft Framework as it moves forward.

Sincerely,

Steven P. Bradbury, Ph.D., Director
Office of Pesticide Programs

[5] See U.S. EPA, Pesticides: Science and Policy, Science Policy Issues and Guidance Documents, available at http://www.epa.gov/oppfead1/trac/science/