



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

MAR | 4 2005

The Honorable Susan B. Hazen  
Acting Assistant Administrator  
Office of Prevention, Pesticides,  
and Toxic Substances  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Dear Ms. Hazen:

On August 8, 2004, the U.S. Environmental Protection Agency (EPA) submitted to the Office of Management and Budget (OMB) for review a draft proposed rule entitled, "Pesticides: Data Requirements for Conventional Chemicals." OMB concluded review on December 8, 2004. The proposed rule would update the *Code of Federal Regulations* (40 CFR Part 158) to reflect current data requirements for registrants of conventional pesticides. The proposal also includes some new data requirements that EPA believes are necessary in carrying out its statutory responsibilities to protect public health and the environment.

The proposed rule represents just the first step toward modernizing pesticide data requirements. Requirements for antimicrobial pesticides and biochemical pesticides will be changed in future rulemakings. In addition, the Agency is in the process of developing a rulemaking proposal governing the required periodic review of existing pesticide registrations.

These regulatory updates raise a timely strategic issue. In the past twenty years, pesticide registration has evolved to reflect new statutory mandates and the increasing complexity and sophistication of scientific considerations. This has given rise to concerns about the cost of data generation and the number of animals tested. Given the increasing amount of resources devoted to pesticide registration<sup>1</sup>, we believe the Agency should identify and consider cost-effective and scientifically sound alternatives to its current data requirements.

In particular, we are concerned about the amount of data required to support a new registration, and we request that the Agency consider improved approaches to toxicity testing that, coupled with other data, would meet its objectives in a more cost-effective manner. We believe the Agency is capable of identifying such alternative approaches given its substantial scientific expertise, long history with the pesticide registration program, and experience with a variety of other chemical testing programs.

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<sup>1</sup> The cost of data generation to support a conventional pesticide has more than doubled over the last twenty years. According to EPA's economic analysis for this draft proposed rule, the 1984 requirements for conventional pesticides are estimated to have cost \$40 million per year (in 2004 \$). Current data requirements for conventional pesticides are estimated to cost nearly \$90 million per year.

During our review of the proposed rule, we learned of an alternative to the current pesticide data requirements being developed under the auspices of the International Life Sciences Institute (ILSI). This project has been developed over the last three years by scientists from industry, academia, and government. It is designed as a conceptual framework for a comprehensive overhaul of the toxicology testing scheme for agricultural pesticides. The goal is to assess the safety of these pesticides more efficiently and with fewer animals. This approach represents a more tiered approach to data generation compared to the current scheme, which relies on a larger "base set" of studies. Papers describing the ILSI alternative are about to undergo peer review, and publication in the scientific literature is targeted for the spring of 2005.

We ask that EPA continue its work with stakeholders to improve testing requirements. We believe the ILSI draft concept, and similar proposals, offer the potential for advances in balancing the essential need for high quality data to make sound scientific decisions, with the pressing demands to be as cost-effective as possible, with the minimum amount of animal testing. We request that EPA assert leadership in achieving these important objectives. Once the ILSI approach is published, EPA should give it, and its elements, priority consideration as an alternative to the proposed data requirements. We recognize that this would necessitate stakeholder participation, inter- and intra-agency review, peer review, efforts to minimize duplicative burdens from inconsistent international requirements, and a determination as to whether the Agency should issue, as appropriate, a supplemental notice of proposed rulemaking or a new proposal. As you evaluate this alternative, keep in mind that Agency adoption of some of its promising elements need not await more extensive consideration of other elements.

At this time, we ask that the Agency provide us with a specific plan for its consideration of improved approaches to toxicity testing, including the ILSI approach. The plan should identify critical actions, target timelines (including the timing of the Part 158 final rule for conventional pesticides), and address how stakeholders will be engaged.

We are available to answer any questions you may have, and we are available to assist the Agency in its deliberations.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald R. Arbuckle". The signature is fluid and cursive, with a large initial "D" and "R".

Donald R. Arbuckle  
Deputy Administrator  
Office of Information  
and Regulatory Affairs