

US EPA ARCHIVE DOCUMENT

TESTIMONY OF  
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RESEARCH  
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Introduction

Good morning, Mr. Chairman and Members of the Committee. Thank you for the opportunity to appear before you today to discuss the Environmental Protection Agency's efforts to harmonize pesticide labeling between the U.S. and Canada as well as our activities to meet our statutory requirements to protect human health and the environment from the potential risks of pesticide use. I assure you that the Agency is committed to working with Congress, our state and federal regulatory partners, and our stakeholders on these important issues.

Pesticide Label Harmonization

I would like to begin my testimony with the issue of pesticide label harmonization with our Canadian regulatory partners. Under the North American Free Trade Agreement (NAFTA)

Technical Working Group on Pesticides (TWG) and other international fora, EPA has been working closely with Canada to address pesticide issues, including those under the NAFTA provisions on Sanitary and Phytosanitary Standards (SPS).

The Working Group's primary objective is to facilitate cost effective pesticide regulation and trade through harmonization and work sharing while at the same time ensuring protection of human health and the environment. Together, we have developed harmonized regulatory and scientific requirements and jointly registered needed products in support of the principles of sustainable pest management. EPA's work on pesticide harmonization with Canada, which began in earnest in 1993, is providing benefits directly to the American farmer. In the long term, the creation and ongoing support of greater harmonization of North American regulatory and scientific requirements for pesticides will ensure a more level playing field across borders while maintaining our high standards of protection.

Under the NAFTA Working Group, the United States and Canada have initiated a stakeholder process including Canadian and U.S. industry, growers, grower representatives, and pesticide distributors to develop and implement strategies to facilitate cross-border movement of pesticide products. The focus of our

work has been to develop both a short- and long-term strategy to facilitate trade in pesticide products across the U.S. and Canadian border. It is important to note that while this work aims at facilitating trade, it will in no way compromise U.S. health and safety standards.

The work group has agreed on the short-term strategy, which involves the re-labeling of existing Canadian product to facilitate import by U.S. growers purchasing it for their own use. While the focus is on developing a viable program for the spring of 2007, a pilot chemical was selected to use as a case study this fall of 2006. The case study of the proposed process has now been completed and we expect actual importation, on a test basis, of the pilot chemical within the next few weeks.

U.S. growers have consolidated and prioritized a list of chemicals that they would like to be able to access through the short-term program. That list will form the basis for selecting chemicals for the import program in the spring of 2007. Registrants have thus far volunteered to participate in the import program for 5 chemicals on the list. We expect that more registrants will volunteer for the program once they have had a chance to analyze the case study.

The long-term strategy focuses on developing joint labels for use in both the U.S. and Canada that will be part of product packaging, facilitating free movement across the border. Two options are currently being considered and registrants have developed draft labels to illustrate these options. EPA, Canada's Pest Management Regulatory Agency (PMRA), and the registrants are working to finalize one of these labels, which will serve as a template for others. Registrants have thus far volunteered three chemicals for development of the joint US/Canada labels and another one is possible, pending resolution of trademark issues. Finally, EPA and PMRA have proposed a process for new joint mechanisms for the label amendments and review. We are very excited about this approach and its potential to address this longstanding issue.

Pesticide Registration Improvement Act (PRIA)

I would now like to discuss EPA's implementation of its statutory requirements, beginning with the 2004 Pesticide Registration Improvement Act (PRIA). PRIA provides for the coupling of registrant fees with specific decision completion timeframes for certain pesticide registration activities. Under PRIA, fees are collected from the pesticide manufacturers for 90 different types of actions, ranging from a request to register a

new food use pesticide to various types of amendments to existing registrations. PRIA also reauthorized maintenance fees, which are providing \$116 million over a five year period for reregistration and tolerance reassessment work at EPA. These fees are critical to ensure stable funding for the review of older pesticides.

In response to the PRIA requirements, we have taken several steps to improve the timeliness of our decisions. For example, we created a stakeholder advisory group to provide advice on program efficiencies. Many actions, such as improving processing and screening of applications, are internal to the Agency. After we receive an application, we bring together appropriate staff to determine what specific work is required and how to most efficiently complete that work. We encourage innovative approaches to streamline reviews and are investigating ways to reduce the time needed for regulatory support work. Work is underway to determine how to enhance work sharing with other regulatory authorities, such as Canada.

Looking forward, the Agency is exploring ways to enhance the use of information technology to facilitate the registration application process and reduce review and decision times. Our goal is to develop an interactive, web-based application system

that would guide an applicant through the application submission process and would help identify mistakes and omissions as they are made. Initially, our focus is on electronic review of labels and review of label changes. It is important to note that, while we are actively seeking ways to improve review times, we will in no way compromise the scientific quality of our assessments.

Since 2004, the Agency has received nearly 3,900 PRIA actions. For those actions we have successfully met or exceeded the deadline 99.8% of the time. In some cases, PRIA calls for decreases in decision timeframes during the life of the legislation. Where this has occurred, we have continued to meet the shorter timeframes.

PRIA implementation has provided new fee revenues, created a performance-based system to improve results, and has increased collaboration between the Agency and stakeholders. EPA will continue to work with the stakeholders to implement PRIA, as well as provide technical assistance on any new or improved fees legislation for pesticide activities at EPA.

The Food Quality Protection Act (FQPA) of 1996

The Agency recently observed the tenth anniversary of the enactment of the Food Quality Protection Act (FQPA). When Congress unanimously passed FQPA in 1996, you presented EPA with the challenge of implementing the most comprehensive overhaul of the nation's pesticide and food safety laws in decades. This was a formidable task that led to a complete transformation in national pesticide regulation. I believe the Agency and its public and private sector partners have been highly successful in carrying out the public health and environmental protections embodied in FQPA.

Tolerance Reassessment

The centerpiece of Congress' challenge was the requirement to review and reassess the tolerances (maximum permitted residues) for all food-use pesticides within a decade. I am proud to report that we have completed reassessments for more than 99 percent of the 9,721 subject tolerances. This complex scientific effort required the detailed review of tens of thousands of studies and test results on toxicity, chemistry, and environmental data. Notably, this work resulted in the revocation or modification of nearly 4,000 food tolerances.

The United States continues to set the bar for pesticide safety and we have raised that bar. EPA's pesticide standards significantly advance food safety, public health, and environmental protection. This 10-year effort, based on sound science and broad public participation, has resulted in more protective measures for all Americans, especially infants and children. We routinely consider the special susceptibility of infants and children to pesticide residues, and we conduct residential, drinking water, and other non-occupational exposure assessments.

#### Reregistration

These enhancements in our risk assessment process were carried out simultaneously and in concert with the effort to make determinations on the reregistration of existing pesticides. That program resulted in the cancellation of nearly 4,400 individual pesticide end-use product registrations while still ensuring that safe pesticides are available to protect Americans, their homes, and their food supply.

The Agency has taken thousands of individual, protective actions, resulting in enormous public health progress. For

instance, the cumulative assessment of organophosphates has resulted in numerous real world benefits. Nearly 1,700 organophosphate tolerances have been reassessed to meet the FQPA safety standards.

Of the 49 organophosphate pesticides (OPs) that were registered at the beginning of the reregistration process, 17 have been voluntarily cancelled or are being phased out. Virtually all residential uses of the remaining 32 OP's have been eliminated. By virtually eliminating use of OPs in residential settings, we have seen reported incidences of unintentional OP poisonings decline by 70 percent. In addition to restricting general organophosphate pesticide use, the amount of these pesticides used on children's foods decreased from approximately 28 million pounds of active ingredient to approximately 12 million pounds between 1994 and 2004 - a 57 percent reduction.

Equally crucial in achieving FQPA goals are the many new products and uses we have registered. Over the past 10 years, EPA has registered 248 new active ingredients and more than 1,600 new uses of existing pesticides. Not only did all of these decisions meet the strict safety standards of FQPA, but these new products provided critical alternatives to many of the

uses restricted or eliminated as part of the tolerance reassessment and reregistration programs. Without these newly registered lower-risk alternatives, America's shift to safer pesticides would not have been possible.

Ensuring Safe and Effective Tools Remain Available for An  
Abundant, Affordable and Healthy Food Supply

Equally important as FQPA's statutory requirements was the innovative approach reflected in EPA's implementation. The Agency's guiding principles have been to ensure that decisions are sound and science-based, that our implementation is open and transparent, that actions are timely, and that public policies are sensible. Our work to upgrade the national pesticide program has been guided by these principles and they are embodied in our everyday work. As a result, we have ensured that safe and effective pest management tools are always available to support production of an abundant, affordable, and healthy food supply.

There were many critics who believed that implementation of FQPA would result in the loss of long relied-upon pest control tools without viable alternatives. Instead, the Agency has made a reasonable transition for pesticide users a cornerstone of its

implementation activities. Throughout the regulatory process, we communicate with the user community to gather information on the benefits of pesticides and which pesticides or pesticide uses are most critical - information that we consider when making our regulatory decisions.

We have made tremendous progress in the registration of newer, safer chemistries which have enabled growers to move away from older chemicals. We work closely with our colleagues at the U.S. Department of Agriculture, university researchers, and pesticide users to facilitate transition. Finally, activities such as the Pesticide Environmental Stewardship Program and the Strategic Agricultural Initiative help pesticide users interact with Agency personnel and work together to promote sustainable pesticide practices. We look forward to building on this sound foundation to meet the remaining challenges in protecting human health and the natural environment and carrying out additional FQPA mandates.

#### Registration Review

Notable among the remaining challenges in implementing FQPA is establishing the Registration Review program, which Congress envisioned as the means to guarantee the ongoing stewardship of

existing pesticides. Registration review is intended to ensure that all pesticide registrations are systematically reviewed to determine whether they continue to meet the statutory standard for registration. Our goal is to have a seamless transition between reregistration and registration review.

To implement the program, EPA will announce a schedule for pesticides to be reviewed during the current year and at least the two subsequent years. We will assemble information we intend to consider in our review and provide that information for public review and comment. We will review the information and comments to determine what has changed since the last regulatory action and how significant those changes are.

Following that review, the Agency may decide there is no cause to amend the original registration or reregistration decision or that a new risk assessment is needed. If necessary, we will ask for additional data to conduct the new assessment. At the end of the process, a decision document will be published indicating whether a pesticide meets the requirements for registration and, if not, what steps must be taken to ensure that it does.

As with reregistration and tolerance reassessment, the registration review program will be conducted in a manner that is based on sound science and provides for public participation, transparency, and efficiency to protect public health and the environment.

### Conclusion

EPA continues to seek and create effective mechanisms for safeguarding our health and environment while ensuring the continued availability of pest management tools. We continue to work to harmonize the availability of pesticide products between the U.S. and Canada through the NAFTA pesticide working group. We are striving to improve our regulatory decision-making so that we continue to meet the stringent PRIA deadlines. Finally, while EPA is proud of our accomplishments in implementing FQPA, we realize that we must continue that momentum through registration review.

While the Agency pursues these activities, we are ever mindful of our responsibility to protect human health and the environment. Our challenge is to continue meeting this responsibility in a manner that uses the best available science,

that is open and transparent, and that recognizes the need to make sensible, timely decisions.

Thank you for the opportunity to discuss these matters. I look forward to working with you, other Members of Congress, and other affected stakeholders on these important issues.