

Those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug and Cosmetics Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

B. How can I get copies of this document and other related information?

1. *Docket.* EPA has established a docket for this action under docket ID number EPA-HQ-OPP-2010-0001. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the **Federal Register** listings at <http://www.epa.gov/fedrgstr>.

II. Background

1. SFIREG/EQI letter re: environmental and human health benchmarks.

2. EPA use of monitoring data vs. use of modeling outputs in registration review process.

3. Endangered Species—bulletins update, possible rulemaking procedure, new biological opinions.

4. Bed bugs: “One State’s Experience”, EPA taskforce update, misuse of pesticide products, proposed next steps.

5. Water quality Pesticide Regulatory Education Program (PREP) update.

6. Water quality PREP—National Pollution Discharge Elimination System (NPDES) discussions.

7. NPDES permit update—rollout, feedback and comments, EPA responses, NPDES/FIFRA Workgroup meeting, next steps.

8. Pesticide Of Interest Tracking System (POINTS) database—reporting and use update.

9. OPP and OECA updates.

10. Office of Water updates—Drinking water strategy.

11. Status of deleted and under-review pesticides (endosulfan, atrazine), pyrethroids and pyrethrins reevaluation, chlorpyrifos lawsuit, and usefulness to the states of Study Profile Templates for pesticide registration applications?

12. Canary software—detect intentional or unintentional contamination in drinking water systems.

II. How can I request to participate in this meeting?

This meeting is open for the public to attend. You may attend the meeting without further notification. Non EPA attendees will need to be signed in at lobby security and escorted to the fourth floor meeting room.

List of Subjects

Environmental protection.

Dated: September 17, 2010.

Kevin Keaney,

Acting Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 2010-24435 Filed 9-28-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2008-0935; FRL-8804-7]

Pesticide Science Policy; Notice of Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA announces the withdrawal of the pesticide science policy document “Use of the Pesticide Data Program (PDP) in Acute Risk Assessment.” In estimating dietary exposure to pesticides, the Agency uses a variety of data and different models. This science policy document was developed to explain a particular statistical methodology, known as decomposition, for using information from the U.S. Department of Agriculture’s (USDA) Pesticide Data Program (PDP) in risk assessments of acute exposure to pesticide residues in food. EPA is withdrawing this policy because EPA has been using a less resource-intensive and generally comparable method of analyzing data on pesticide residues. This action is in response to the recommendations made by EPA’s Office of Inspector General during its review of EPA’s implementation of the Food Quality and Protection Act (FQPA). In its report “Opportunities to Improve Data Quality and Children’s Health through the FQPA” issued January 10, 2006, the Office of Inspector General recommended that EPA should update the status of its Science Policy issue papers. This **Federal Register** notice updates the public on the status of one of those papers. EPA is withdrawing this policy because EPA has been using a less resource-intensive and generally comparable method of analyzing data on pesticide residues.

FOR FURTHER INFORMATION CONTACT:

David J. Miller, Health Effects Division, Office of Pesticide Programs (7509P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5352; fax number: (703) 305-5147; e-mail address: miller.davidj@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action, however, may be of interest to persons who produce or formulate pesticides or who register pesticide products. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2008-0935. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

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II. Discussion

A. Background on the Food Quality Protection Act of 1996

The Food Quality Protection Act of 1996 (FQPA) significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other changes, FQPA established a stringent health-based standard (“a reasonable certainty of no harm”) for pesticide residues in foods to assure protection from unacceptable pesticide exposure and strengthened

health protections for infants and children from pesticide risks.

During 1998 and 1999, EPA and the U.S. Department of Agriculture (USDA) established a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT), the Tolerance Reassessment Advisory Committee (TRAC), to address FFDCA issues and implementation. TRAC comprised more than 50 representatives of affected user, producer, consumer, public health, environmental, states, and other interested groups. The TRAC met from May 27, 1998, through April 29, 1999.

As a result of the 1998 and 1999 TRAC process, EPA decided that the FQPA implementation process and related policies would benefit from providing notice and comment on the major science policy issues. The TRAC identified nine science policy areas it believed were key to implementation of tolerance reassessment. EPA agreed to provide an opportunity for public comment on each of the nine issues by announcing their availability in the **Federal Register**. In a notice published in the **Federal Register** of October 29, 1998 (63 FR 58038) (FRL-6041-5), EPA described its intended approach. Since then, EPA has issued a series of draft and revised documents concerning the nine science policy issues. Publication of today's notice is intended to update the public on the status of the science paper "Use of the Pesticide Data Program (PDP) in Acute Risk Assessment."

B. EPA's Use of a Decomposition Methodology for Acute Dietary Risk Assessment

In May 1999, EPA published the policy paper "Use of the Pesticide Data Program (PDP) in Acute Risk Assessment" (<http://www.epa.gov/fedrgstr/EPA-PEST/1999/May/Day-26/p13034.htm>) for public comment. This science policy document was developed to explain a particular statistical methodology, known as decomposition, for using information from the U.S. Department of Agriculture's (USDA) PDP in risk assessments of acute exposure to pesticide residues in food. The PDP tests commodities in the U.S. food supply for pesticide residues. The decomposing methodology consists of extrapolating from data on pesticide residues in composite samples of fruits and vegetables to residue levels in single units of fruits and vegetables.

Prior to publishing this policy, EPA policy did not use PDP residue data in acute dietary exposure assessments because of a concern that using these composite results could produce

exposure estimates that would be biased low, underestimating high-end pesticide residues, and therefore would be inappropriate for human health risk assessments. Using a decomposing methodology could address these concerns.

OPP consulted the FIFRA Scientific Advisory Panel (SAP) in 1999 and 2000 on a variety of decomposition methodologies and technical issues surrounding the use of those methodologies. The SAP reports from those meetings are available at: <http://www.epa.gov/scipoly/SAP/meetings/1999/may/final.pdf> and <http://www.epa.gov/scipoly/sap/meetings/2000/february/partialfinalreport06292000.pdf>. The SAP recommended that the Agency use decompositing and stated that "for acute dietary exposure estimation, it is the residues in single items of produce that are of interest rather than 'average' residues measured in composited samples." The Panel concluded that overall, a methodology called MaxLIP was the preferred method, but recommended additional studies and validation using actual individual samples of residues to develop a more complete understanding of methods of analysis.

For a time, OPP incorporated decomposition into risk assessment of acute exposure to pesticide residues in food. However, due to the time-consuming nature of the analysis, combined with the perception that utilizing decomposition was not making much of a difference in terms of risk estimates, the practice was discontinued. OPP has continued to evaluate the impact of conducting acute dietary risk assessments using residue levels measured in composite samples versus residue levels estimated to be present in decomposited samples. The key question has been the degree to which use of composite samples may underestimate risk at the high end of the exposure distribution. This assessment, though still exploratory, confirms OPP's initial impression that decomposition does not have a critical influence on the risk assessment. While, as expected, the results vary for each pesticide-commodity combination, findings suggest that use of composite residues may result in estimated exposures that are reasonably similar to those resulting from single-units (i.e., decomposited results).

III. International Interest in Working Together on Dietary Risk Assessment Analysis

EPA's evaluation of the impact of decompositing is ongoing. Currently,

EPA is in the process of comparing results from the decomposition methodology to a method known as the "variability factor" used in other countries, including the member States in the European Union. EPA anticipates working collaboratively with the European Union, through the European Food Safety Authority (EFSA), to share data, to better characterize the differences between the two methodologies, and to better understand the risk assessment and risk management implications. EPA believes that seeking to develop a globally harmonized approach in this aspect of dietary risk assessment will benefit all involved by increasing understanding and facilitating the sharing of data as well as the assessments derived from those data. In addition, the process will facilitate better understanding and resolutions of trade questions and issues that may result from differences in approach.

IV. Withdrawing this Science Policy is Responsive to EPA's Office of Inspector General's Recommendations

This action is responsive to the recommendations made by EPA's Office of Inspector General during its review of EPA's implementation of FQPA. In its report "Opportunities to Improve Data Quality and Children's Health through the FQPA" issued January 10, 2006, <http://www.epa.gov/oig/reports/2006/20060110-2006-P-00009.pdf>, the Office of Inspector General recommended that EPA should update the status of its Science Policy issue papers. This **Federal Register** notice updates the public on the status of one of the Science Policy papers.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: September 22, 2010.

Steve A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2010-24307 Filed 9-28-10; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2010-0248; FRL-8845-9]

Notice of Receipt of Requests for Amendments to Delete Uses in Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).