

extremely low probability of significant contact by the general public following animal treatment.

#### D. Cumulative Effects

The cumulative exposure assessment provides an estimate of the extent to which a defined population is exposed to two or more chemicals that share a common mechanism of toxicity by all relevant routes and from all relevant sources. Essentially all exposure from this proposed use of BIT will occur via the diet in the form of meat consumed from animals treated topically with products intended to control external parasites. As discussed above, the levels consumed should not exceed 0.0001 mg/kg/day for adults and 0.00007 mg/kg/day for children. No additional exposure of the general public is expected from either drinking water or non-dietary sources. Even using extremely conservative assumptions, the calculated exposure levels are so low as to be insignificant. The risk of cumulative effects and/or toxicity from BIT is negligible.

#### E. Safety Determination

1. *U.S. population.* No adverse effects of any kind would be expected from the extremely low dietary levels of BIT that may result from the proposed use of BIT in animal pesticide formulations.

2. *Infants and children.* Nothing in the available literature would suggest that infants and children are more sensitive to the effects of BIT than adults. Since the calculated dietary exposure of children to BIT is even less than adults, this proposed use of BIT should not pose a risk to this population subgroup. Exposure of infants to BIT resulting from its proposed use is expected to be negligible based on the fact that beef is not a normal dietary component for this population. In summary the proposed use of BIT as an inert ingredient in certain animal pesticides formulations will not put infants and children at risk.

#### F. International Tolerances

No Codex maximum residue levels have been established for BIT.  
[FR Doc. 00-25751 Filed 10-10-00; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-00609A; FRL-6741-2]

### The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability.

**SUMMARY:** EPA announces the availability of the revised version of the pesticide science policy document entitled "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management." This notice is one in a series concerning science policy documents related to the implementation of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act.

**FOR FURTHER INFORMATION CONTACT:** Deborah Sisco, Environmental Protection Agency (7503C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 308-8121; fax number (703) 308-8090; e-mail address: sisco.deborah@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Pesticide producers	32532	Pesticide manufacturers Pesticide formulators

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this notice affects certain entities. 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 Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, the science policy documents, and certain other related documents that might be available from the Office of Pesticide Programs' Home Page at <http://www.epa.gov/pesticides>. On the Office of Pesticide Programs' Home Page select "FQPA" and then look up the entry for this document under "Science Policies." You can also go directly to the listings at the EPA Home page at <http://www.epa.gov>. On the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry to this document under "**Federal Register**—Environmental Documents." You can go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr>.

2. *Fax-on-demand.* You may request a faxed copy of the science policy documents, as well as supporting information, by using a faxphone to call (202) 401-0527. Select item 6069 for the document entitled "The Role of Use-Related Information in Pesticide Risk Assessment and Risk Management." Select item 6070 for the document entitled "EPA's Responses to Public Comments on the Draft Policy Document." You may also follow the automated menu.

3. *In person.* The Agency has established an official record for this action under docket control number OPP-00609A. In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) (FRL-6041-5) have also been inserted in the docket under docket control number OPP-00557. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The PIRIB telephone number is (703) 305-5805.

## II. Background Information

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. The 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.

Thereafter, the Agency established the Food Safety Advisory Committee (FSAC) as a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT) to assist in soliciting input from stakeholders and to provide input to EPA on the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs (OPP). The Agency has used the interim approaches developed through discussions with FSAC to make regulatory decisions that meet the new FFDCA standard, but that could be revisited if additional information became available or as the science evolved. In addition, the Agency seeks independent review and public participation, generally through presentation of the science policy issues to the FIFRA Scientific Advisory Panel, a group of independent, outside experts who provide peer review and scientific advice to OPP.

During 1998 and 1999, as directed by Vice President Albert Gore, EPA and the U.S. Department of Agriculture (USDA) established a second subcommittee of 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.

In order to continue the constructive discussions about FFDCA, EPA and USDA have established, under the auspices of NACEPT, the Committee to Advise on Reassessment and Transition (CARAT). The CARAT provides a forum for a broad spectrum of stakeholders to consult with and advise the Agency and the Secretary of Agriculture on pest and pesticide management transition issues related to the tolerance reassessment process. The CARAT is intended to

further the valuable work initiated by the FSAC and TRAC toward the use of sound science and greater transparency in regulatory decisionmaking, increased stakeholder participation, and reasonable transition strategies that reduce risks without jeopardizing American agriculture and farm communities. The CARAT held its first meeting on June 23, 2000.

As a result of the 1998 and 1999 TRAC process, EPA decided that the implementation process and related policies would benefit from providing notice and comment on major science policy issues. The TRAC identified nine science policy areas it believed were key to implementation of tolerance reassessment. EPA agreed to provide one or more documents for 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), EPA described its intended approach. Since then, EPA has been issuing a series of draft documents concerning the nine science policy issues. This notice announces the availability of the revised science policy document concerning the role of use-related information in pesticide risk assessment and risk management.

## III. Summary of Revised Science Policy Guidance Document

EPA is charged with regulating the sale and use of pesticides in the United States. In order to evaluate the risks of pesticide use and the benefits derived from pesticide use, and to evaluate the potential ramifications of regulatory decisions about the sale and use of pesticides, regulators must have information about how, where, when, why, and how much each pesticide is used in the United States.

This document provides an overview of the role of use-related information in the regulatory process in terms that can be understood by the educated lay public. The document summarizes the types of use-related data used by EPA in pesticide risk assessment and risk management. It further describes where the data come from, how the Agency employs these data, and how EPA organizes and evaluates pesticide use data. However, this document is not intended to delve into the technical details of quantitative pesticide usage analysis, such as calculation of likely maxima, weighting methods, and prediction intervals.

The document goes on to describe the role of use-related data in human health risk assessments, including drinking water, and in ecological risk assessments, and, finally, the role of

use-related information in risk management decisions. The final discussion of future steps for improving the quality and quantity of pesticide use data and strengthening the Agency's analytical approaches highlights the limitations of the available use-related data.

EPA published a draft version of this document in the **Federal Register** of July 14, 1999 (64 FR 37977) (FRL-6088-6) and comments were filed in docket control number OPP-00609. All comments were considered by the Agency in revising the document. Many of the comments were similar in content, and pertained to general issues concerning the proposed policy or specific sections within the draft document. The Agency grouped the comments according to the nature of the comment and the issue or section of the document which they addressed. The Agency's response to the comments is available as described in Units I.B.1. and I.B.2.

## IV. Policies Not Rules

The policy document discussed in this notice is intended to provide guidance to EPA personnel and decision-makers, and to the public. As a guidance document and not a rule, the policy in this guidance is not binding on either EPA or any outside parties. Although this guidance provides a starting point for EPA risk assessments, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that a policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a policy should not be applied.

## List of Subjects

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

Dated: September 27, 2000.

**Susan H. Wayland,**

*Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

[FR Doc. 00-25933 Filed 10-10-00; 8:45 am]

BILLING CODE 6560-50-S