

ENVIRONMENTAL PROTECTION AGENCY

[OPP-00679; FRL-6743-9]

Pesticides; Drinking Water Science Policies**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of availability.

SUMMARY: EPA is soliciting comments on two draft pesticide science policy documents concerning pesticide risk assessment in drinking water. These documents are entitled, respectively, "Drinking Water Screening-Level Assessments" and "Standard Operating Procedure (SOP) for Incorporating Screening-Level Estimates of Drinking Water Exposures into Aggregate Risk Assessments." Together, these documents describe EPA's approach to conducting a screening-level risk assessment of pesticide residues in water. This notice is one in a series of science policy documents related to the implementation of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act.

DATES: Comments, identified by docket control number OPP-00679, must be received on or before December 11, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00679 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: For "Drinking Water Screening-Level Assessment," contact James Hetrick, Environmental Protection Agency (7507C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 305-5237; fax number: (703) 308-6181; e-mail address: hetrick.james@epa.gov. For "Standard Operating Procedure (SOP) for Incorporating Screening-Level Estimates of Drinking Water Exposure into Aggregate Risk Assessments," contact Catherine Eiden, Environmental Protection Agency (7509C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 305-7887; fax number: (703) 308-5147; e-mail address: eiden.catherine@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 may, however, 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgrstr/>.

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 6083 for the document entitled "Drinking Water Screening-Level Assessments" and select item 6084 for the document entitled "Standard Operating Procedure (SOP) for Incorporating Screening-Level Estimates of Drinking Water Exposures into Aggregate Risk Assessments." 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-00679. 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 Hwy., 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00679 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described in this unit. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-00679. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI that I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of

the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the documents.
7. Make sure to submit your comments by the deadline in this document.
8. At the beginning of your comments (e.g., as part of the "Subject" heading), be sure to properly identify the document you are commenting on. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00679 in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

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 (SAP), 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) (FRL-6041-5), 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 two draft science policy documents concerning the methodology and standard operating procedures for conducting screening-level drinking water assessments.

III. Summary of Drinking Water Documents

A. Part A: "Guidance for Use of the Index Reservoir in Drinking Water Exposure Assessments"

The purpose of this draft science policy document is to provide guidance on using the index reservoir scenario for use in estimating the exposure in drinking water derived from vulnerable surfacewater supplies. Since 1996, the Agency has been using a standard small "farm pond" as an interim scenario for estimating a potential upper bound on drinking water exposure until more appropriate tools could be developed. The index reservoir is being implemented in conjunction with the percent cropped area factor to replace the farm pond scenario. These two steps are intended to improve the quality and accuracy of OPP's modeling of high-end drinking water exposure for pesticides.

The index reservoir is intended as a replacement for the farm pond for use in drinking water exposure modeling. It is used in a similar manner to the farm pond except that flow rates have been calibrated for local weather conditions. Instructions for using the index reservoir are provided in this guidance document. The Exposure Analysis Modeling System (EXAMS) parameters for the standard index reservoir are provided in Appendix C of this guidance document.

B. Part B: "Applying a Percent Crop Area Adjustment to Tier 2 Surface Water Model Estimates for Pesticide Drinking Water Exposure Assessments"

The current process for screening food-use pesticides for drinking water exposure concerns from runoff to surface water is to run the Generic Estimated Environmental Concentrations (GENEEC, the Tier 1 screening model) and compare the resulting concentration to the Drinking Water Level of Comparison (DWLOC). If the Tier 1 estimates exceed the DWLOC, then the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS, the Tier 2 screening model) is run. When running PRZM/EXAMS for drinking water assessments, the current policy is to select the crop use which is expected to result in the

highest runoff potential (based on application rate and method and on crop location). With issuance of this guidance document, OPP is changing its Tier 2 assessment process to incorporate the Percent Crop Area (PCA) concept.

The PCA is a generic watershed-based adjustment factor which will be applied to pesticide concentrations estimated for the surface water component of the drinking water exposure assessment using PRZM/EXAMS with the index reservoir scenario. The output generated by the PRZM/EXAMS model is multiplied by the maximum PCA (expressed as a decimal) generated for the crop or crops of interest. For purposes of conducting the Tier 2 drinking water assessment, the crop of interest would most typically be the labeled crop use that is anticipated to result in the greatest mass of pesticide entering the surface water body via runoff. Currently, OPP will apply PCA adjustments for four major crops—corn, soybeans, wheat, and cotton. For pesticides applied to corn, soybeans, wheat, and cotton, Tier 2 drinking water exposure assessments should utilize the appropriate index reservoir scenario and corresponding PCA(s).

This guidance results from a May 1999 presentation to the FIFRA SAP, "Proposed Methods For Determining Watershed-derived Percent Crop Areas And Considerations For Applying Crop Area Adjustments to Surface Water Screening Models," and the response and recommendations from the panel. A more thorough discussion of this method and comparisons of monitoring and modeling results for selected pesticide/crop/site combinations is located at http://www.epa.gov/scipoly/SAP/1999/may/pca_sap.pdf. The SAP did not provide guidance in a few critical areas, such as defining "major" versus "minor" uses or what to do in most cases where a pesticide is used on multiple crops.

This draft science policy document provides guidance on when and how to apply the PCA to model estimates, describes the methods used to derive the PCA, and discusses some of the assumptions and limitations with the process.

IV. Summary of "Standard Operating Procedure (SOP) for Incorporating Screening-level Estimates of Drinking Water Exposure into Aggregate Risk Assessments"

This draft science policy document is the SOP for a document entitled, "Estimating the Drinking Water Component of a Dietary Exposure Assessment" (notice of availability published in the **Federal Register** of

November 10, 1999, 64 FR 61346; FRL-6389-7). It outlines the general approach to incorporating screening-level estimates of drinking water exposure into OPP's human health aggregate risk assessments. Specifically, it provides:

(1) A step-by-step process for OPP staff to follow while coordinating their work on registration and reregistration actions.

(2) Terms, definitions, descriptions, and calculations for use in incorporating estimates of pesticide concentrations in surface water and groundwater from screening-level models into aggregate risk assessments.

(3) Examples of specific language that may be used in health effects risk assessment documents to characterize screening-level exposure estimates for drinking water.

(4) An appendix containing example scenarios and calculations.

Under the procedures outlined in this draft science policy document, the resulting estimates of risk associated with a pesticide in drinking water are considered to be unrefined, high-end, upper-bound values. However, since many compounds can be "cleared" of drinking water concerns using these screening-level procedures, the process saves limited resources by providing an efficient means to determine whether a more refined assessment of drinking water exposure for a specific compound is warranted. This document is an updated version of the existing SOP for incorporating drinking water exposure into aggregate risk assessment and replaces the previous SOP dated August 1, 1999 (HED SOP 99.5, 1999).

V. Questions/Issues for the Drinking Water Screening-Level Assessment and SOP Documents

A. Index Reservoir (Part A)

1. Is the index reservoir a suitable replacement for the standard farm pond for screening-level drinking water assessments?

2. Do the process and criteria used to select the index reservoir represent a reasonable approach? Are there any other criteria the Agency should consider when we reassess the reservoir scenario in the future?

3. There are many refinements to the reservoir approach and its screening approach in general. Which of these refinements should have the highest priority?

4. It is assumed that there is no spray drift buffer zone around the perimeter of the reservoir. Are there any suggestions on how to develop a standard spray drift buffer zone for the index reservoir?

B. Percent Cropped Area (Part B)

1. The PRZM runoff model in the index reservoir may be limited to watersheds of no more than 20 square miles. Are there any suggestions in addressing the scale limitation of the PRZM model?

2. Is it reasonable to use a PCA adjustment to PRZM/EXAMS modeling for more accurate and appropriately conservative estimates of pesticide concentrations in surface water for screening evaluations of drinking water exposure?

3. Is the GIS procedure for calculating PCA appropriate for accounting for the portion of the watershed planted to the crops or crops of interest?

4. A default PCA has been calculated for cases where a defensible PCA cannot be calculated. Is it appropriate to use a default PCA?

C. The Standard Operating Procedure

Given the limited information available on pesticides in drinking water, is the approach outlined in the SOP guidance document a reasonable way to incorporate the available information on pesticide concentration in surface and ground water from screening-level models into aggregate human health risk assessment?

VI. 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.

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