

regulated entities the opportunity to develop alternative strategies that will replace or modify specific regulatory requirements on the condition that they produce greater environmental benefits. Under the Fort Worth XL project, the City of Fort Worth proposes to demonstrate that use of an alternative demolition method on abandoned buildings containing asbestos will protect the public from asbestos emissions as well as the demolition method specified in an asbestos emission standard issued by EPA under section 112 of the Clean Air Act. Moreover, the City expects that their lower cost demolition method will allow them to accelerate demolitions, thereby eliminating sites potentially harboring illegal activities and reducing safety/health hazards associated with the abandoned structures. To demonstrate the effectiveness of their method, the City will monitor asbestos emissions during the demolition of a single structure in Phase 1 of the project and, if Phase 1 monitoring results indicate the Fort Worth method is equivalent to the regulatory method, two additional structures during Phase 2. The project entails a set number of Fort Worth method demolitions under a third and final phase of the project, provided the results of Phase 2 continue to show equivalency.

The draft Monitoring Plan Agreement is a voluntary agreement developed with input from the City of Fort Worth, the Texas Department of Health, and EPA which lays out the protocol for capturing and analyzing asbestos emissions for Phase 1 of the project. The agreement also spells out the criteria by which the Fort Worth method can be shown equivalent to the Federal method, for the purposes of proceeding to Phase 2 of the project. The City does not require regulatory relief to perform the Phase 1 demolition, since the structure to be demolished is of a type that can be demolished under the asbestos standard using the Fort Worth method. To conduct phases 2 and 3 of the project, Fort Worth will need regulatory relief (specifically from 40 CFR part 61 subpart M—National Emission Standard for Asbestos). The details of these phases will be negotiated with stakeholders and set forth in a Final Project Agreement (FPA). A draft of the FPA will be available for public comment through a future **Federal Register** notice.

**Elizabeth A. Shaw,**

*Director, Office of Environmental Policy Innovation.*

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-00560A; FRL-6593-6]

### Pesticides; Science Policy on Use of Data on Cholinesterase Inhibition in Risk Assessment

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

**ACTION:** Notice of availability.

**SUMMARY:** EPA is announcing the availability of the revised version of the pesticide science policy document entitled "The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides." This notice is one in a series concerning science policy documents related to implementation of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act.

**FOR FURTHER INFORMATION CONTACT:** Dr. Penelope A. Fenner-Crisp, Environmental Protection Agency (7501C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 605-0654; fax number: (703) 308-4776; e-mail address: fenner-crisp.penelope@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 for 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 6065 for the document entitled "Office of Pesticide Programs' Science Policy on the Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides." Select item 6066 for the document entitled "Responses to Public Comments on the Office of Pesticide Programs' 1997 Science Policy: The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides." 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-00560A which includes a document summarizing an objection received during internal EPA review and EPA response to the objection. 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 About the Tolerance Reassessment Advisory Committee

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 some of 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 met FQPA's standard, but that could be revisited if additional information became available or as the science evolved. In addition, the Agency has sought 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 worked with the U.S. Department of Agriculture (USDA) and a second subcommittee of NACEPT, the Tolerance Reassessment Advisory Committee (TRAC) to address FQPA 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 towards 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 TRAC process, the Agency decided that the FQPA implementation process and related policies would benefit from notice and comment on the major science policy issues.

The TRAC identified nine science policy issue areas they 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 and revised documents concerning the nine science policies. This notice announces the availability of the revised version of the science policy document entitled "The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides."

## III. Summary of Revised Science Policy Guidance Document

In 1997, EPA's Office of Pesticide Programs presented a science policy document entitled "The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides" to the FIFRA Scientific Advisory Panel for review and comment. The 1997 science policy document described the approaches OPP would employ in assessing the potential for human health hazard from the cholinergic effects on nervous system function following exposure to cholinesterase-inhibiting pesticides.

In 1998, as part of its TRAC review of science policy issues, OPP published a draft version of the 1997 TRAC science policy document entitled "Office of Pesticide Programs' Science Policy on the Use of Data on Cholinesterase Inhibition for Risk Assessments of

Organophosphorus and Carbamate Pesticides" on November 5, 1998 (63 FR 59780) (FRL-6042-3) and comments were filed under docket control number OPP-00560. Many persons also submitted comments on the 1997 policy document under docket control number OPP-00480 relative to the 1997 SAP meeting (62 FR 19572, April 22, 1997) (FRL-5714-2) and under docket control number OPP-00557 relative to the TRAC process. All of the comments and recommendations have been reviewed by OPP and incorporated into the revised science policy document, as appropriate.

As did the 1997 policy, this revised science policy document emphasizes the weighing of all relevant evidence when selecting endpoints for the hazard assessment of anticholinesterase pesticides. This "weight-of-the-evidence" review, conducted on a case-by-case, chemical-by-chemical basis, is accomplished by performing an integrative analysis after assessing all the individual lines of evidence (including all available data on cholinesterase inhibition in all compartments—central nervous system, peripheral nervous system, red blood cells, and plasma—as well as data on clinical signs, symptoms and other physiological or behavioral effects). Weighing of the evidence must include considerations of many factors, including the adequacy of study protocols; quality of data; number of studies on each endpoint; dose-dependency of responses; time course and duration of effects; and similarities or differences of responses observed in all the species, strains, and sexes tested for each duration and route of exposure evaluated.

In a weight-of-the-evidence assessment of cholinesterase-inhibiting substances, acetylcholinesterase inhibition in the nervous system is viewed as a key event in the mechanism of toxicity of these compounds and an important critical effect to consider in the hazard assessment. Evaluations of the cholinergic effects (i.e., physiological and behavioral changes and measures of cholinesterase inhibition in the central and peripheral nervous systems) caused by exposure to the cholinesterase-inhibiting organophosphorus and carbamate pesticides provide direct evidence for characterizing potential human health hazard. Because of likely differences in both the chemicals' and the cholinesterases' pharmacodynamic properties, measures of cholinesterase inhibition in both the central and peripheral nervous systems are important for a thorough evaluation of

potential hazard. However, direct measurement of cholinesterase activity in peripheral nervous system tissues is rarely available at the present time. When these data are not available, as a matter of prudent science policy protective of human health, EPA will treat cholinesterase inhibition in the blood as a surrogate measure for the peripheral nervous system in animals and for both the peripheral and central nervous systems in humans. Information from blood cholinesterase inhibition data is considered to provide important insights into potential hazard.

Red blood cell (RBC) measures of acetylcholinesterase (AChE) are generally preferred over plasma measures of cholinesterase activity because data on red blood cells may provide a better representation of the inhibition of the neural target enzyme, acetylcholinesterase. OPP, however, may use plasma cholinesterase inhibition data under certain circumstances, such as if red blood cell data are insufficient, of poor quality, or unavailable; if there is a lack of dose-dependency for the red blood cell acetylcholinesterase inhibition; or, if the dose responses for inhibition of plasma cholinesterase more closely approximate those for AChE inhibition in the nervous system than do the dose responses for RBC acetylcholinesterase inhibition.

It should be noted that the present policy provides guidance only on how to deal with data as they relate to the cholinergic endpoints associated with nervous system function following exposure to organophosphorous and carbamate pesticides. This scope is consistent with all earlier descriptions of Agency assessment approaches as well as that of other organizations with regard to the evaluation of cholinesterase-inhibiting substances (e.g., WHO JMPR (1998), DPR-CalEPA (1997) and other national authorities). When applying the weight-of-the-evidence approach for selecting critical effect(s) for derivation of a reference dose (RfD) or concentration (RfC), however, the entire toxicological data base on a pesticide must be evaluated (i.e., there also must be consideration of endpoints not related to the cholinergic consequences of anticholinesterase activity, for instance, liver or developmental toxicity or carcinogenicity). It is possible that, for one or more of the exposure scenarios being evaluated, the non-cholinergic effects will be identified as critical or co-critical, and they may become a more appropriate basis for deriving RfDs or RfCs.

Finally, OPP policy documents are meant to be "living documents," that is, they are open to periodic updating and revision to reflect advances in the science. Thus, this policy, too, will be updated to incorporate important new scientific knowledge as it becomes available. For example, the routine availability of data on acetylcholinesterase activity in the peripheral nervous system may allow for refinements in the hazard assessment approach for anticholinesterase chemicals. Also, as knowledge increases about the potential roles of the different cholinesterases in the developing organism, particularly as they impact the development of the nervous system, it may allow for refinements in evaluating the potential differential sensitivity and susceptibility of the young versus adults. In fact, a substantial research effort has been, and continues to be, made to determine what roles acetylcholine-, butyrylcholine-, and other esterase may play in the development of the nervous system and in cell growth, proliferation, and death in other tissues. OPP encourages further discussion of the possible implications of the research findings, both for future research planning and for the Agency's regulation of cholinesterase-inhibiting pesticides.

#### IV. Summary of Comments and Responses

In the public comments referred to under Unit III., some commenters addressed the general policy and its rationale as well as all of the specific questions posed, while other reviewers provided detailed comments only on certain aspects of the policy. A listing of the names and affiliations of those who submitted comments is provided at the end of the document entitled "Responses to Public Comments on the Office of Pesticide Programs' 1997 Science Policy: The Use of Data on Cholinesterase Inhibition for Risk Assessments of Organophosphorus and Carbamate Pesticides." This document contains a summary of the most significant revisions to the 1997 science policy document, followed by responses to comments.

In the draft science policy document, the Agency requested comment on ten questions to help focus public comment. In order to organize the responses to these questions in the response to comments document, the ten specific questions have been combined into six somewhat broader topic areas:

1. General weight-of-the-evidence issues related to the use of blood and

brain measures as critical effects, differences between plasma and RBC measures and their use, and the weight-of-the-evidence approach (Questions 1, 2, and 9);

2. Peripheral nervous system measures (Questions 3 and 4);

3. Comparative measures in the young and adults (Questions 5 and 6);

4. Additional neurochemical measures (Questions 7 and 8);

5. Other comments.

6. Editorial comments on the science policy document (Question 10).

#### V. 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: August 29, 2000.

**Susan H. Wayland,**

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

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#### ENVIRONMENTAL PROTECTION AGENCY

[FRL-6866-8]

#### Proposed Administrative Cashout "Ability to Pay" Settlement Under Section 122(h)(1) of the Comprehensive Environmental Response Compensation and Liability Act; In the Matter of Powell Road Landfill, Dayton, Montgomery County, OH

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

**ACTION:** Notice; request for public comment.

**SUMMARY:** In accordance with section 122(i) of the Comprehensive