

**ENVIRONMENTAL PROTECTION
AGENCY**

[OPP-00732; FRL-6792-8]

**Pesticide Science Policy: Guidance for
Performing Aggregate Exposure and
Risk Assessments; Notice of
Availability**

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 "Guidance for Performing Aggregate Exposure and Risk Assessments." This notice is one in a series concerning science policy documents related to the implementation of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

FOR FURTHER INFORMATION CONTACT: Beth Doyle, Environmental Protection Agency (7503C), 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-2722; fax number: (703) 305-0871; e-mail address: doyle.elizabeth@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 codes	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 6087 for the document entitled "Guidance for Performing Aggregate Exposure and 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-00732. In addition, the documents referenced in the framework notice, which published in the **Federal Register** of October 29, 1998 (63 FR 58038) (FRL-6041-5), under docket control number OPP-00557, are considered as part of the official record for this action under docket control number OPP-00732 even though not placed in the official record. 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.

II. Background Information

On August 3, 1996, FQPA was signed into law. The FQPA significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and 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, 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.

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 aggregate exposure and risk assessment.

III. Summary of "Guidance for Performing Aggregate Exposure and Risk Assessments"

EPA is responsible for regulating pesticide residues in food under the FFDCFA. In 1996, Congress passed the FQPA which amended FFDCFA. The FQPA amendments to the FFDCFA directed EPA to consider "aggregate exposure" in its decisionmaking. Aggregate exposure and risk assessment involve the analysis of exposure to a single chemical by multiple pathways and routes of exposure. The pathways of exposure considered in this guidance document include the potential for pesticide residues in food and drinking water, as well as residues from pesticide use in residential, non-occupational environments. The pathway of exposure refers to how human behavioral patterns potentially interact with pesticides in the environment. All potential, relevant routes of exposure are analyzed within an aggregate exposure assessment. These include the oral, dermal (absorption), and inhalation routes of exposure. Thus, OPP was required by the FQPA amendments to modify its exposure and risk assessment methods to consider that pesticide chemicals may enter the body through various pathways (through food, drinking water, and residential uses) and routes (ingestion, dermal, and inhalation).

In response to the FQPA mandates to consider aggregate exposure, OPP implemented HED SOP 97.2 Interim Guidance for Conducting Aggregate Exposure and Risk Assessments (November 26, 1997) (Stasikowski, 1997a) (Interim Guidance) in 1996 for

assessing aggregate exposure and risk. This guidance uses a mix of data as point estimates and data in a distributional form. According to the interim guidance, most frequently the "high-end" or "upper bound" point estimates from the drinking water and residential exposure pathways are added to an estimate of food ingestion exposure from food (for acute exposures, the 99.9th percentile on the distribution of daily exposures). The aggregate guidance presented in this document supports a different approach. This guidance expands upon the interim guidance to include the way in which aggregate exposure and risk assessment may be performed when "ideal" data, methods and tools are available.

The current guidance document discusses the interim guidance methods, but emphasizes an expanded approach which looks beyond the interim guidance to encompass the use of distributional data for all pathways of exposure when data are available. A distributional data analysis (as opposed to a point estimate approach) is preferred because this tool allows an aggregate exposure assessor to more fully evaluate exposure and resulting risk across the entire population, not just the exposure of a single, high-end individual. The expanded guidance encourages assessment techniques which, using a combination of data, models, and reasonable judgements, represent each potentially exposed "individual" in the population over calendar time. A baseline requirement of this approach is that the exposure parameters associated with each hypothetical individual must be coherent, consistent, and logical. This means the hypothetical individual's temporal exposure characteristics, spatial exposure characteristics, and demographic and behavioral exposure characteristics should be consistent and reasonable for each type of individual, for each day in the assessment, over all days in the assessment. The use of distributional data sets which comprise the aggregate exposures to many individuals in the population of interest and the principle that the individual's aggregate exposure be consistent in temporal, spatial and demographic characteristics are two central components to this expanded aggregate exposure and risk guidance document. Using this approach OPP and others in the risk assessment community can move toward using a distribution of total aggregate exposures to many types of individuals potentially exposed in a population of interest.

A version of the aggregate guidance was presented to the FIFRA Scientific Advisory Panel (SAP) in February of 1999. SAP member comments were incorporated into the guidance document where appropriate. On November 10, 1999, the availability of the draft "Guidance for Performing Aggregate Exposure and Risk Assessment" (Aggregate Guidance) was published in the **Federal Register** (64 FR 61343) (FRL-6388-8), and public comments were requested on the overall content of the document as well as seven specific questions. Based in part on the comments received, this science policy paper was revised and is now being issued in its revised format. In addition, OPP has prepared a separate Response-to-Comment document which specifically addresses comments received.

This revised document is organized to present an overview of aggregate exposure and risk assessment highlighting revised and expanded concepts. Section I describes the regulatory background of aggregate assessment, gives a brief introduction to the scope and organization of the document, and provides a review of some of the key terms and definitions in this document. Section II of the document provides a description of current practices and data sources utilized in conducting aggregate exposure analysis, including an explanation of the combination of probabilistic (food pathway only at this time) and deterministic types of exposure assessments. Section III provides a general framework and set of key concepts for the refinements put forth in the Aggregate Guidance. Pathway-specific considerations based upon the revised guidance are for performing aggregate exposure and risk assessment, expanding upon the Interim Guidance for Conducting Aggregate Exposure and Risk Assessment. Following this section, there are recommendations for future data and research needs (Section V) as well as an acknowledgment of the limitations in conducting aggregate exposure assessments (Section VI). The last section of the document, Section VII, describes approaches to model validation and verification, an important part of evaluating aggregate exposure and risk assessments, as assumptions embedded in any model and/or method and uncertainties and variability in the input data can be significant to the outcome of the assessment.

The current guidance document is one of a series of documents that OPP is issuing with specific emphasis on

addressing new facets of the risk assessment process as required by FQPA. In particular, the current document relies heavily on the Exposure Factors Handbook (USEPA, 1997b), the Residential SOPs (USEPA, 1997a), the Interim Guidance (Stasikowski, 1997a) and Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs (USEPA, 1998c). These earlier documents provide substantial background to the information provided.

IV. Policies Not Rules

The policy document discussed in this notice is intended to provide guidance to EPA personnel and decisionmakers, 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: November 16, 2001.

Susan B. Hazen,

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

[FR Doc. 01-29386 Filed 11-27-01; 8:45 am]

BILLING CODE 6560-50-S

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2514]

Petition for Reconsideration of Action in Rulemaking Proceeding

November 20, 2001.

Petition for Reconsideration has been filed in the Commission's rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR section 1.429(e). The full text of this document is available for viewing and copying in Room CY-A257, 445 12th Street, SW., Washington, DC or may be purchased from the Commission's copy contractor, Qualex International (202) 863-2893. Oppositions to this petition

must be filed by December 13, 2001. See section 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of the Table of Allotments for FM Broadcast Stations (MM Docket No. 00-169, RM -9953).

Number of Petitions Filed: 1.

Magalie Roman Salas,

Secretary.

[FR Doc. 01-29575 Filed 11-27-01; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011782.

Title: COSCON/HJS/SEN Slot Allocation & Sailing Agreement.

Parties: COSCO Container Lines Company, Ltd., Hanjin Shipping Co., Ltd., Senator Lines GMBH.

Synopsis: The proposed agreement authorizes the parties to charter container space to and from each other and rationalize port calls and sailings in the trade between ports in Asia, including China, Hong Kong, Taiwan, Korea, and Japan, and the U.S. Pacific coast.

Dated: November 23, 2001.

By Order of the Federal Maritime Commission.

Theodore A. Zook,

Assistant Secretary.

[FR Doc. 01-29589 Filed 11-27-01; 8:45 am]

BILLING CODE 6730-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meeting of the Advisory Committee on Blood Safety and Availability

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of meeting.

The Advisory Committee on Blood Safety and Availability will meet on

Thursday, January 31, 2002 and Friday, February 1, 2002 from 8 a.m. to 5 p.m. The meeting will take place at the Hyatt Regency Hotel on Capitol Hill, 400 New Jersey Ave., NW., Washington, DC 20001. The meeting will be entirely open to the public.

The purpose of this meeting will be to discuss what lessons can be learned from the events surrounding September 11, 2001 regarding the safety and the availability of the nation's blood supply.

Public comment will be limited to five minutes per speaker. Those who wish to have printed material distributed to Advisory Committee members should submit thirty (30) copies to the Executive Secretary prior to close of business January 17, 2002. In addition, anyone planning to comment on either item is encouraged to contact the Executive Secretary at her/his earliest convenience.

FOR FURTHER INFORMATION CONTACT:

Stephen D. Nightingale, MD, Executive Secretary, Advisory Committee on Blood Safety and Availability, Department of Health and Human Services, Office of Public Health and Science, 200 Independence Ave., SW., Room 736-E, Washington, DC 20201. Phone (202) 690-5558, FAX (202) 260-9372, e-mail StephenDNightingale@osophs.dhhs.gov.

Dated: November 21, 2001.

Stephen D. Nightingale,

Executive Secretary, Advisory Committee on Blood Safety and Availability.

[FR Doc. 01-29604 Filed 11-27-01; 8:45 am]

BILLING CODE 4150-28-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-02-12]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information