The most sensitive sub-population, children 1-6 years old, had acute dietary MOEs of 202 and 103 at the 99th and 99.9th percentile of exposure, respectively. Nursing infants had MOEs of 198 and 146 at the 99th and 99.9th percentile of exposure, respectively. Non-nursing infants had MOEs of 300 and 156 at the 99th and 99.9th percentile of exposure, respectively. The registrant has no cause for concern if total acute exposure calculated for the 99.9th percentile yields a MOE of 100 or larger.

The potential short- or intermediate-term aggregate exposure of esfenvalerate from chronic dietary food and water plus indoor and outdoor residential exposure to children (1-6 years old) is 0.0113 mg/kg/day with an MOE of 177. For infants (less than 1–year old) the exposure is 0.0098 mg/kg/day with an MOE of 204. Thus, the registrant concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to esfenvalerate residues (62 FR 63019).

F. International Tolerances

There are no Codex MRL values established for fenvalerate on cardoon, bok choy, sweet potatoes, canola, brussels sprout, and rapeseed; therefore, no harmonization is required.

[FR Doc. 99–29184 Filed 11–9–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00625; FRL–6388–8]

Pesticides; Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice of availability.

SUMMARY: To assure that EPA's policies related to implementing the Food Quality Protection Act are transparent and open to public participation, EPA is soliciting comments on the pesticide draft science policy paper entitled ''Guidance for Performing Aggregate Exposure and Risk Assessments.'' This notice is the thirteenth in a series concerning science policy papers related to Food Quality Protection Act and the Tolerance Reassessment Advisory Committee.
DATES: Comments for the draft science policy paper, identified by docket control number OPP–00625, must be received on or before January 10, 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.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–00625 in the subject line on the first page of your response.
FOR FURTHER INFORMATION CONTACT: Carol Christensen, Environmental Protection Agency (7505C), 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–6230; fax: (703) 305–7147; e-mail: christensen.carol@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 action 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 draft science policy paper, 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'' and then look up the entry for this document under ''**Federal Register**--Environmental Documents.'' You can go directly to the **Federal Register** listings http://www.epa.gov/fedrgstr/.

2. *Fax on demand*. You may request a faxed copy of the draft science policy paper, as well as supporting information, by using a faxphone to call (202) 401–0527. Select item 6043 for the paper 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–00625. 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 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–00625 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, 401 M St., SW., 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 Highway, Arlington, VA. The PIRIB is open from 8 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 above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–00625. 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 identified under ''FOR FURTHER INFORMATION CONTACT.''

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

EPA invites you to provide your views on the various draft science policy papers, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider. 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 solid technical information and/or data to support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate.

5. Indicate what you support, as well as what you disagree with.

6. Provide specific examples to illustrate your concerns.

7. Make sure to submit your comments by the deadline in this notice.

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–00625 in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background for the Tolerance Reassessment Advisory Committee

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. Effective upon signature, 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; provided heightened health protections for infants and children from pesticide risks; required expedited review of new, safer pesticides; created incentives for the development and maintenance of effective crop protection tools for farmers; required reassessment of existing tolerances over a 10-year period; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that scientific data supporting pesticide registrations will remain up-to-date in the future.

Subsequently, 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. 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. As EPA's approach to implementing the scientific provisions of FQPA has evolved, the Agency has sought independent review and public participation, often through presentation of many 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.

In addition, as directed by Vice President Albert Gore, EPA has been working with the U.S. Department of Agriculture (USDA) and another subcommittee of NACEPT, the Tolerance Reassessment Advisory Committee (TRAC), chaired by the EPA Deputy Administrator and the USDA Deputy Secretary, to address FQPA issues and implementation. TRAC comprises more than 50 representatives of affected user, producer, consumer, public health, environmental, states and other interested groups. The TRAC has met six times as a full committee from May 27, 1998 through April 29, 1999.

The Agency has been working with the TRAC to ensure that its science policies, risk assessments of individual pesticides, and process for decision making are transparent and open to public participation. An important product of these consultations with TRAC is the development of a framework for addressing key science policy issues. The Agency decided that the FQPA implementation process and related policies would benefit from initiating notice and comment on the major science policy issues.

The TRAC identified nine science policy issue areas they believe were key to implementation of FQPA and tolerance reassessment. The framework calls for EPA to provide one or more documents for comment on each of the nine issues by announcing their availability in the **Federal Register**. In accordance with the framework described in a separate notice published in the **Federal Register** of October 29, 1998 (63 FR 58038), EPA has been issuing a series of draft papers concerning nine science policy issues identified by the TRAC related to the implementation of FQPA. This notice announces the availability of the draft science policy paper as identified in the ''SUMMARY.''

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

Pesticides are regulated under both FIFRA and FFDCA. In 1996, Congress passed FQPA which amended both FIFRA and FFDCA. Through these laws,

EPA evaluates risks posed by the use of each pesticide to make a determination of safety. FQPA amended FFDCA to require the Agency to consider aggregate exposure. Section 408(b)(2)(ii) requires EPA to find for each tolerance ''a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' Section 408(b)(2)(C)(ii)(I) requires the Agency to find ''a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residues . . . .'' Finally, Section 408(b)(2)(D)(vi) directs EPA, when deciding on tolerances, to consider ''aggregate exposure levels...to the pesticide chemical residue . . . including dietary exposure and exposure from other non-occupational sources.''

Implementation of FQPA has led to refinement of many decision tools, including methods for assessment of aggregate exposure and risk. The methods described in this paper increase the completeness and realism of EPA's estimates of potential exposures to pesticides in the environment. The Agency believes that these new assessment methods will substantially improve protection of public health.

This draft science policy paper builds on the Interim Approach Paper for the March 1997 Scientific Advisory Panel (USEPA, 1997c.) It is one in a series of science policy papers developed to address new requirements imposed by FQPA. It also relies heavily on the following documents:

1. Exposure Factors Handbook.
2. Residential SOPs.
3. Interim Guidance for Conducting Aggregate Exposure and Risk Assessments.
4. Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs.

An earlier draft of this science policy paper was reviewed by the FIFRA SAP in February 1999. The Panel's comments and recommendations were considered in this revision.

This draft science policy paper describes the general principles and specific procedure for assessing aggregate non-occupational human exposure and risk from a single chemical by all relevant pathways. The routes and pathways considered at this time are oral (from food, drinking water, and residential scenarios), inhalation (residential pathway), and dermal (residential pathway). EPA recognizes the gaps in understanding the interdependencies and linkages between and among exposure pathways when assessing exposure to an individual, and that further data collection is warranted in this area.

Currently, EPA combines single point estimates from the relevant pathways to assess aggregate exposure. Under EPA's current interim guidelines, for example, point estimates for drinking water and residential exposure pathways are typically added to a point (such as the 99.9th percentile) selected from the distribution of dietary exposures. This draft science policy paper proposes a different approach. Under these new guidelines an analyst first assesses exposure by all pathways for one individual at a time; then the analyst combines individual assessments into an overall assessment of exposures of a sample population of interest. This method keeps each individual's characteristics consistent; all exposures agree in time and place; and all individual demographic characteristics are consistent and reasonable. Using this approach an assessor can create a distribution of total exposures to many individuals in a population of interest, while retaining inter- and intra-individual variability. And, analysis of distributional data can improve understanding, and even allow quantification of the uncertainty and variability in the data sets. EPA believes that these proposed changes to the performance of aggregate exposure and risk assessment will lead to better and more realisitic assessments of actual exposure and risk.

IV. Questions/Issues for Comment

While comments are invited on any aspect of the draft science policy paper, OPP is particularly interested in comments on the following questions and issues:

1. The draft science policy paper describes methodologies for assessing pesticide risks from single exposure pathways (food, residential and drinking water). Are these methodologies complete and satisfactorily described, or are changes/additions recommended?

2. The draft science policy paper describes a process for combining pesticide exposures and risk from multiple routes for a given pathway of exposure. Is the process, as described, logical, scientifically defensible, and complete?

3. A basic concept underlying the draft aggregate exposure and risk assessment methodology is that of the individual being exposed through calendar time with all model parameters referring back to that specific individual. Is use of this fundamental principle as the basis for the aggregate exposure and risk methodology appropriate and, if not, how should it be modified?

4. The draft science policy paper acknowledges the need to understand how exposures co-occur. OPP is developing standards to identify co-dependencies and inter-relationships between events, and recognizes that product marketing data may be available to aid in this task. Are there any suggestions on how OPP can best evaluate and incorporate into its assessments co-occurrences of exposure events?

5. During an aggregate exposure and risk assessment, some specific exposure scenarios may be identified as having a minimal contribution to the total aggregate risk. Is it appropriate to exclude specific exposure scenarios that contribute minimally to the total aggregate risk, and if so, at what risk level should an exposure scenario be dropped from further consideration?

6. In certain cases and with certain pathways, it may not be necessary, advisable, or even possible to develop probabilistic exposure estimates and OPP may simply rely on deterministic (or point) estimates of a pathway-specific exposure instead. When aggregating, it will be necessary to combine the pathway-specific exposure estimates to develop an estimate of aggregate exposure. Is OPP's general approach to combining deterministic and probabilistic exposure estimates appropriate? If not, how should it be modified?

7. The draft science policy paper describes three methods for combining risks from the three routes (oral, dermal, and inhalation). The Total MOE (MOET) and the Aggregate Risk Index (ARI) are currently being used by OPP. Should OPP continue to use these approaches or should OPP consider using the other described approach?

V. Policies Not Rules

The draft science policy paper 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 be abandoned.

EPA has stated in this notice that it will make available revised guidance after consideration of public comment. Public comment is not being solicited for the purpose of converting any policy document into a binding rule. EPA will not be codifying this policy in the Code of Federal Regulations. EPA is soliciting public comment so that it can make fully informed decisions regarding the content of each guidance document.

The ''revised'' guidance will not be unalterable. Once a ''revised'' guidance document is issued, EPA will continue to treat it as guidance, not a rule. Accordingly, on a case-by-case basis EPA will decide whether it is appropriate to depart from the guidance or to modify the overall approach in the guidance. In the course of inviting comment on each guidance document, EPA would welcome comments that specifically address how a guidance document can be structured so that it provides meaningful guidance without imposing binding requirements.

List of Subjects

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

Dated: October 29, 1999.

Susan H. Wayland,

Deputy Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 99–29296 Filed 11–9–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00577A; FRL–6389–7]

Pesticides; Policy Issues Related to the Food Quality Protection Act

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 ''Estimating the Drinking Water Component of a Dietary Exposure Assessment.'' This notice is the fourteenth in a series concerning science policy documents related to the Food Quality Protection Act and developed through the Tolerance Reassessment Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Nelson Thurman or Sid Abel, Environmental Protection Agency (7506C), 401 M St., SW., Washington, DC 20460; telephone numbers: (703) 308–0465 or (703) 305–7346; fax: (703) 305–6309; e-mail: thurman.nelson@epa.gov and abel.sidney@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:

Category	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 action 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 electronically, 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'' and then look up the entry to this document under ''**Federal Register** -- Environmental Documents.'' You can go directly to the **Federal Register** listings http://www.epa.gov/fedrgstr/.

2. *Fax on demand*. You may request to receive a faxed copy of the revised science policy paper, as well as supporting information, by using a faxphone to call (202) 401–0527. Select item 6044 for the paper entitled ''Estimating the Drinking Water Component of a Dietary Exposure Assessment.'' 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–00577A. 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, any public comments received during an applicable comment period, 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 for the Tolerance Reassessment Advisory Committee (TRAC)

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. Effective upon signature, 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; provided heightened health protections for infants and children from pesticide risks; required expedited review of new, safer pesticides; created incentives for the development and maintenance of effective crop protection tools for farmers; required reassessment of existing tolerances over a 10-year period; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that scientific data