Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: state or local governments or nongovernmental organizations.

Estimated Number of Respondents: 28.

Frequency of Response: annual workplans; biennial reviews.

Estimated Total Annual Hour Burden: 5,967 hours.

Estimated Total Annualized Cost Burden: $0.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 1500.04 and OMB Control No. 2040–0138 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OP Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the EPA, 725 17th Street, NW, Washington, DC 20503.

Dated: March 31, 1999.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 99–8633 Filed 4–6–99; 8:45 am]

BILLING 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00593; FRL–6074–7]

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 (FQPA) are transparent and open to public participation, EPA is soliciting comments on a draft policy paper entitled ''Choosing a Percentile of Acute Dietary Exposure as a Threshold of Regulatory Concern.'' This notice is the seventh in a series concerning science policy documents related to FQPA and developed through the Tolerance Reassessment Advisory Committee (TRAC).

DATES: Written comments for this policy paper, identified by docket control number OPP–00593, should be submitted by June 7, 1999.

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'' section of this document.

FOR FURTHER INFORMATION CONTACT: Kathleen Martin, Environmental Protection Agency (7509C), 401 M St., SW., Washington, DC 20460. Telephone number: (703) 308-2857, fax: 703-305-5147, and e-mail address: martin.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Notice Apply to Me?

You may be potentially affected by this notice 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. If available, 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 announcement to you, consult the person listed in the ''FOR FURTHER INFORMATION CONTACT'' section of this document.

B. How Can I Get Additional Information or Copies of This Document or Other Documents?

1. *Electronically*. You may obtain electronic copies of this document and the science policy paper at http://www.epa.gov/pesticides/. On the Office of Pesticide Program Home Page select ''TRAC'' and then look up the entry for this document. You can also go directly to the listings at the EPA Home Page at the **Federal Register** — Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/) to obtain this notice and the science policy paper.

2. *Fax on Demand*. You may request to receive a faxed copy of this document, as well as supporting information, by using a faxphone to call (202) 401–0527 and selecting item 6034. You may also follow the automated menu.

3. *In person or by phone*. If you have any questions or need additional information about this action, you may contact the person identified in the ''FOR FURTHER INFORMATION CONTACT'' section of this document. In addition, the official record for the science policy paper listed in the ''SUMMARY'' section of this document, including the public version, has been established under docket control number OPP–00593 (including comments and data submitted electronically as described below). A public version of each record, including printed, paper versions of any electronic comments, which does not include any information claimed as Confidential Business Information (CBI), is available for inspection in 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 Public Information and Records Integrity Branch 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. Be sure to include docket control number OPP–00593 in your correspondence.

1. *By mail*. Submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

2. *In person or by courier*. Deliver written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of

Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

3. *Electronically*. Submit your comments and/or data electronically by e-mail to: opp-docket@epa.gov. Do not submit any information electronically that you consider to be CBI. Submit electronic comments as an ASCII file, avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard computer disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

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

You may claim information that you submit 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. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please call the Public Information and Records Integrity Branch telephone number is (703) 305–5805.

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. You can do this by providing the docket control number assigned to the notice, along with the name, date, and **Federal Register** citation.

II. Background

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 Office of Pesticide Programs (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 five times as a full committee from May 27 through September 16, 1998.

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) (FRL–6041–5), EPA has been issuing a series of draft documents concerning nine science policy issues identified by the TRAC related to the implementation of FQPA. This notice announces the availability of one of those draft documents as identified in Unit I.C. of this document.

III. Summary of Draft Paper

EPA is responsible for regulating the nature and amount of pesticide residues in food under FFDCA. FFDCA section 408 authorizes EPA to set a tolerance or an exemption from the requirement of a tolerance if the Agency determines that the residues would be ''safe.'' The Agency performs various types of risk assessments to evaluate the safety of pesticides in food, including analyses to determine the nature and the amounts of pesticides that people might be exposed to over a single day. This paper discusses how EPA applies the statutory safety standard to acute dietary risk assessments.

The Environmental Protection Agency's Office of Pesticide Programs has previously announced that, on an interim basis, it intends to regulate

pesticides at the 99.9th percentile of the distribution of estimated acute dietary exposures when probabilistic assessment techniques are used to model the distribution. EPA will compare this percentile of estimated exposure to the Population Adjusted Dose (PAD), a value that reflects an amount of a pesticide to which a person may safely be exposed in one day. This draft science policy paper describes OPP's interim policy, concerns that have been raised about it, associated public health issues, and OPP's plans for further evaluation and implementation. This policy has broad applicability to many pesticides and potentially significant impact on the assessment of these pesticides. Moreover, a number of concerns and issues have been raised about the policy. Therefore, the Agency is seeking public comment so that OPP policy is transparent and that the views of all interested parties are considered.

OPP's interim position with respect to assessing and regulating the food uses of pesticides, when using a probabilistic method of estimating acute dietary exposure, is as follows:

If the 99.9th percentile of acute dietary exposure (together with exposure from other non-dietary, non-occupational sources), as estimated by probabilistic (e.g., Monte Carlo) analysis, is *equal to or less than* the Population Adjusted Dose (PAD) for the pesticide, OPP will determine that the safety standard of FFDCA sec. 408(B)(2)(A) is met with respect to acute dietary risk. However, if the analysis indicates that exposure at the 99.9th percentile *exceeds* the PAD, OPP will conduct a sensitivity analysis to determine to what extent the estimated exposures at the high-end percentiles may be affected by unusually high food consumption or residue values. To the extent that one or a few values from the input data sets seem to ''drive'' the exposure estimates at the high end of exposure, OPP will consider whether these values are representative and should be used as the primary basis for regulatory decision making. The Office will also examine the consequence of removing such high-end food consumption or residue values when estimating the 99.9th percentile of exposure.

The first section of this paper provides an overview of OPP's present practice and interim policy for acute dietary risk assessment. It describes the statutory, regulatory and policy framework for this interim policy, as well as prior reviews and comments. In addition, this section provides background information on dietary risk assessment in general and explains how the previous system (DRES--Dietary Risk Evaluation System) and the current system (DEEM--Dietary Exposure Estimating Model) work, as well as what input data sources are used and how.

The second section addresses some of the specific issues and concerns raised about regulating at the 99.9th percentile. One issue is whether the nature of the databases available (i.e., robustness, adequacy, etc.) should preclude the use of the 99.9th percentile for regulatory purposes since some consider the uncertainties associated with this threshold of concern to be too great. Examples of data used are USDA's food consumption survey data, registrant crop field trials, USDA Pesticide Data Program (PDP) data, FDA monitoring data, market basket surveys, etc. Other issues include the treatment of data ''outliers,'' representativeness and adequacy of the databases, and the impact of Agency default values on exposure estimates. Concerns, therefore, exist about whether the estimates of the 99.9th percentile of exposure are sufficiently representative of actual exposure to be meaningful. This paper summarizes these concerns and invites comment on them.

The third section addresses the issue of protectiveness of the 99.9th percentile with respect to the general public health. One view is that regulating at the 99.9th percentile is insufficiently conservative because very large numbers of people could be exposed every day to pesticide intakes which are estimated to exceed the Agency's ''level of concern.'' This section also explores the contrary view that the interim policy is over-protective because of the conservative assumptions used in the estimation methods and the retention of potentially unrepresentative values in the data base. The section discusses as well as the view that, whether it over- or under-estimates actual exposure, the 99.9th percentile is simply too uncertain to be used in risk management decisions. This section also explains that OPP considers a number of factors in considering which percentile to use: The size of the exposed population and the proportion that might receive daily doses above the benchmark of safety, the aRfD; the level of confidence OPP has in its exposure estimates; and the extent to which such estimates may overstate potential exposure because they incorporate conservative assumptions or rely on atypical and unrealistic data. Further, to the extent understood, OPP considers by how much individual exposures would be estimated to exceed the aRfD. Finally, the OPP takes into account the degree of public health protection incorporated into the determination of the aRfD.

The fourth section addresses the areas in which OPP and USDA propose to collaborate in performing further exploratory analysis with the DEEM software and the 99.9th percentile issue.

The fifth and sixth sections list questions and issues on which the Agency would most like commenters to focus and respond, and provide a list of the documents referenced in this paper, respectively.

The Appendix, entitled ''Primer on Interpretation of Exposure Distribution Curves,'' is a ''plain English'' guide to Monte Carlo analysis and how to interpret results from it.

IV. Questions/Issues for Comment

While comments are invited on any aspect of the draft paper, EPA is particularly interested in comments on the following questions and issues.

1. What are the appropriate statistical techniques for characterizing the uncertainty at the high end of the distribution of probabilistic exposure assessments? At what point does an exposure estimate become so uncertain that it would be inappropriate to use the estimate in regulatory decision making? How does uncertainty about one or more high-end values in a data set affect the reliability of the output of probabilistic models using that data set as an input?

2. Regarding the Agency's current methodology for performing Monte Carlo analyses, at what percentile of estimated exposure is it appropriate for the Agency to establish its threshold of concern? 99.99th, 99.9th, 99th, 95th, or some other percentile? What are the reasons for recommending that percentile? How should the characteristics of the data sets used as input to the assessment (e.g., the type of residue data, field trials vs. PDP monitoring data) affect the choice of a percentile exposure for OPP's threshold of concern?

3. If OPP chooses to set its threshold of concern lower than the 99.9th percentile, should any other steps, such as the application of an additional safety factor, be employed to assure that the statutory safety standard is satisfied?

4. Some advocate a ''sliding regulatory scale'' with more serious toxic effects regulated at higher thresholds; they contend that such an approach would explicitly acknowledge all aspects of the risk management decision and incorporate the nature of the toxic effects and the built-in conservatism on the hazard identification and dose response side of the equation. Instead of regulating at only a single percentile for all toxicological effects (regardless of severity), should the Agency regulate pesticides at a variety of percentiles, depending upon the toxic effect

observed? For example, would a lower threshold of regulation (perhaps the 98th percentile) be warranted for fully-reversible effects (such as mild anemia) or would a more stringent threshold (perhaps the 99.9th percentile or higher) be justified for severe, non-reversible effects (e.g., birth defects)? Finally, should the Agency regulate pesticides at different percentiles according to the nature and size of the subpopulation groups (i.e., use the 99.9th percentile for larger groups and another percentile for smaller groups)?

5. How should ''outliers'' be identified for food consumption data sets? For residue data sets? When an ''outlier'' is identified, how should the data point be handled in generating probabilistic exposure estimates?

6. If OPP conducts a Critical Exposure Contribution (CEC) analysis, and excludes one or more data points because they appear to drive the high-end estimates of exposure, should OPP perform an additional CEC analysis on any revised estimate of the exposure distribution?

7. Should OPP's probabilistic assessments attempt to reflect variability in human sensitivity to toxic effects, as suggested by the FIFRA Scientific Advisory Panel? If so, how should this be done?

V. Policies Not Rules

The draft 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 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.

VI. Contents of Docket

Document that are referenced in this notice will be inserted in the docket under the docket control number ''OPP–00593.'' In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) have also been inserted in the docket under docket control number OPP–00557.

List of Subjects

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

Dated: April 1, 1999.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 99–8636 Filed 4–6–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–867; FRL–6069–8]

AgrEvo USA Company; Cry9C Plant-Pesticides; Notice of Filing of Pesticide Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the amendment of a regulation to exempt from the requirement of a tolerance residues of plant-pesticides *Bacillus thuringiensis* subsp. *tolworthi* Cry9C and the genetic material necessary for the production of this protein in or on all raw agricultural commodities.

DATES: Comments, identified by the docket control number PF–867, must be received on or before May 7, 1999.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Mike Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division, (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 9th floor, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. 22202, telephone (703) 308–8715; e-mail:mendelsohn.mike@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on all raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–867 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not