(d) disclaimers, warranties & limitations of liability.

(e) use of chlorine gas as agricultural pesticide.

(f) modification of Worker Protection Standard posting requirements.

14. Reports from committee members.
15. Other topics as appropriate.

List of Subjects

Environmental protection.

Dated: November 2, 1998.

Charles Franklin,

Acting Acting Director, Field and External Affairs Division.

[FR Doc. 98–29790 Filed 11–3–97; 3:37 pm]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00558; FRL–6042–3]

Pesticides; Science Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: To assure that EPA's science policies related to implementing the Food Quality Protection Act (FQPA) are transparent and open to public participation, EPA is soliciting comments on two draft science policy papers—''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs'' and ''Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides.'' These policies have been peer reviewed by the Agency's FIFRA Scientific Advisory Panel and are now ready for broader public comment.

DATES: Written comments for each science policy paper, identified by separate docket numbers provided in the ADDRESSES section, should be submitted by January 4, 1999.

ADDRESSES: The docket number for ''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs'' is OPP–00559 and for ''Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides'' is OPP–00560. By mail, submit written comments identified by the docket control number listed for each 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. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epa.gov. Follow the instructions under Unit V. of this document. No Confidential Business Information (CBI) 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 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. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: For ''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs'' contact by mail: Kathleen Martin, Environmental Protection Agency (7509C), 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail: 1921 Jefferson Davis Highway, Arlington, VA, 703–308–2857, fax: 703–305–5147, e-mail: martin.kathleen@epa.gov.

For ''Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides'' contact William Wooge, Environmental Protection Agency (7509C), 401 M St., SW., Washington, DC 20460. Office location, telephone number, e-mail: 1921 Jefferson Davis Highway, Arlington, VA, 703–308–8794, fax: 703–305–5147, e-mail: wooge.william@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Electronic Availability

A. Internet

Electronic copies of this document and the two science policy papers are available from the EPA Home Page at the **Federal Register** - Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

B. Fax-on-Demand

For Fax-on-Demand, use a faxphone to call 202–401–0527 and select item 6021 for the draft document entitled ''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs'' and item 6022 for the draft document entitled ''Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides.''

II. Background

On August 3, 1996, the 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 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. 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 five times as a full committee from May 27, 1998 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 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 addition to comments received in response to these **Federal Register** notices, EPA will consider comments received during the TRAC meetings. Each of these issues is evolving and in a different stage of refinement. Accordingly, as the issues are further refined by EPA in consultation with USDA and others, they may also be presented to the SAP.

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 is issuing a series of draft documents concerning nine science policy issues identified by the TRAC that are related to the implementation of FQPA. This notice announces the availability of two draft documents. The first paper relates to science policy area #2 (Dietary exposure and Monte Carlo techniques) as described in the framework notice published in the **Federal Register** of October 29, 1998 (63 FR 58038); this paper is one of three papers that will be issued for comment. The second paper addresses science policy area #9 (Cholinesterase (ChE) Inhibition) as described in the framework notice published in the **Federal Register** of October 29, 1998 (63 FR 58038); it is the only paper for this area.

III. Summary of Draft Papers

A. Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs

EPA assesses pesticide dietary exposure from raw and processed foods using two distinct pieces of information: The amount of pesticide residue that is present in and on food (i.e., the residue level) and the types and amounts of food that we eat (i.e., food consumption). The residue information comes from the numerous crop field trials and other sources where the amount of pesticide residues on a given commodity is measured. Consumption information comes primarily from USDA surveys of what people eat. In the past, EPA has used the Dietary Risk Evaluation System (DRES) to combine the residue and food consumption information with data on a pesticide's toxicity to calculate acute and chronic dietary risk from food. This deterministic model calculates an average value (sometimes referred to as a ''point'' estimate) for these exposure and risk assessments.

The science of risk assessment is constantly evolving. As better methods and techniques are developed, the Agency strives to incorporate these into its risk assessment methodologies. Over the last few years, a new technique has been applied to estimating acute pesticide dietary exposure during a single day, which is a probabilistic evaluation called Monte Carlo analysis. A probabilistic analysis uses the entire range of data from the numerous crop field trial studies or other sources to better estimate the distribution of exposure to the residues for the population of concern. This technique allows for a more realistic estimate of exposure, and depicts the variability in exposure that results from differences in individual eating patterns as well as differences in the levels of pesticide residues on food.

The Agency has been developing guidance on how to conduct probabilistic exposure assessments for pesticides as well as guidance to Agency reviewers on how to evaluate such assessments. In March 1998, draft guidance was presented to the SAP. The SAP was very supportive of the proposed guidance document and in general agreed with the proposed approach. EPA has since revised the draft guidance, incorporating the SAP's advice. Today, this revised draft guidance is being made available for public comment. EPA is inviting public comment on several issues listed in Unit IV.A.

The draft guidance is related to two of the other nine TRAC science policy issues as follows:

1. *Dietary exposure estimates (science policy issue area #4).* Dietary exposure estimates derived from probabilistic assessments are one input in the overall assessment of dietary exposures.

2. *Aggregate exposure (science policy issue area #7).* Again, exposure estimates derived from probabilistic assessments are part of the aggregate exposures. Also, the use of probabilistic techniques is being discussed among the scientific community as a method for aggregating exposure from multiple sources and pathways.

The draft guidance is not intended to address the following two other related issues:

1. The procedures (statistical and otherwise) used to address situations where no residue is detected.

2. The rationale for the Agency's interim decision to regulate at the 99.9th percentile of exposure when using probabilistic exposure evaluation techniques.

Separate issue papers will be prepared according to the schedule in the framework **Federal Register** notice to deal with these two topics.

A number of comments were provided by various industry and public interest groups in response to the TRAC meetings, which began in May 1998. Commenters included the Natural Resources Defense Council (NRDC), the National Food Processors Association (NFPA), Latham and Watkins, and the Implementation Working Group (IWG). However, only IWG's comments related to the draft guidance announced (in revised form) in this **Federal Register** notice. The IWG, a coalition of farm, food, pesticide manufacturing, and pest management organizations, provided a ''road map'' report entitled ''A Science-Based Workable Framework for Implementing the Food Quality Protection Act.'' The IWG report stated that the Agency should more fully utilize probabilistic techniques for dietary, non-dietary and aggregate exposure assessments and that EPA regulatory staff should become more familiar with the concepts of using probabilistic analysis in decision making.

B. Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides

Most organophosphate (OP) and certain carbamate insecticides exert their toxic effects on insects and mammals by the mechanism of ChE inhibition. Communication between a large number of nerve cells in the peripheral and central nervous system is by means of acetylcholine, a neurotransmitter. Acetylcholinesterase is the enzyme that breaks down acetylcholine after it has communicated the nerve signal between two nerve cells or nerve and muscle cells. Inhibition of this enzyme prolongs the action of acetylcholine and results in the acute toxic effects known for these chemicals such as nausea, dizziness, confusion and, at high concentrations, more serious effects such as respiratory paralysis and death. This can also result in chronic effects that have been observed with many of these insecticides. Measures of cholinesterase levels in the blood or nervous system after exposure to OPs and certain carbamates have become the most common endpoint used in risk assessments of these chemical classes. For at least the last 10 years, EPA has used plasma, red blood cells, and/or brain ChE inhibition as the basis for determining critical effect levels and setting reference doses.

Over the last several years, the Agency has engaged with outside scientists and the regulatory community about which measures of ChE inhibition may be used for setting reference doses in risk assessments. Much of the discussion focused on two issues:

1. The role of blood measures, since blood cholinesterases are not part of the nervous system and therefore are only an indirect measure of neurotoxicity.
2. Whether plasma cholinesterases should be treated differently from red blood cell cholinesterases.

In June 1997, the Agency made a presentation to the SAP including a literature review, a series of case studies, a summary of activities related to methodology of ChE measurement, and a briefing. This briefing paper presented to the SAP, ''Office of Pesticide Programs Science Policy on the Use of Cholinesterase Inhibition for Risk Assessment of Organophosphate and Carbamate Pesticides'' (draft, April 30, 1997), provided EPA's analysis of the issues and options and its proposed policy to use a weight of evidence approach that would consider all of the data that might result in the use of ChE measures in plasma, red blood cells, and/or the brain for defining critical effects. In addition, EPA also asked the SAP about the feasibility of using measures of peripheral nervous system tissue to replace blood measures, which largely serve as indirect estimators of ChE inhibition in the peripheral nervous system in animals. The report of the SAP addresses these issues and is also included in the docket. The Agency's briefing paper cited above has been updated and is being made available for comment with this notice.

The IWG prepared a paper evaluating several science policy issues relating to EPA's implementation of FQPA. Issue paper II of the IWG report discussed the choice and use of endpoints in risk assessments of ChE inhibitors and provided a number of comments about their use. The IWG asserted several opinions: that ChE inhibition in blood itself is not an adverse effect; that use of ChE inhibition in blood has the effect of adding a safety factor; and that the additional safety factor should be considered when applying other safety factors related to infants and children.

During the public comment period for the SAP review, the Acute Cholinesterase Risk Assessment Work Group, a group of pesticide manufacturing organizations, proposed a complex alternative policy for using measures of ChE inhibition in risk assessments. They proposed not using plasma measures, reducing the uncertainty factor for red blood cell measures, establishing a generic threshold of 20 percent difference for blood or brain measures, and provided other comments.

The Natural Resources Defense Council, an environmental group, in a brief oral presentation to the SAP, provided general support for the Agency's proposed policy, but emphasized the need for broader pre-natal and post-natal testing of pesticides to provide more data specific to fetuses, infants, and children. This would, in their view, include both cholinesterase data and data on a variety of neurological functions, including in particular learning and memory.

Other regulatory bodies (i.e., agencies from California and Canada) and public commenters from outside the United States (including scientists from Great Britain and individual physicians who have worked with the World Health Organization) described their own policies and how those policies generally placed less reliance on plasma measures of ChE inhibition as a risk assessment endpoint.

IV. Questions/Issues for Comment

A. Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs

1. Should outlier data points in residue or consumption data sets be excluded from consideration? If so, then what should be the criteria for excluding a data point from either food consumption or residue data sets on the grounds that it is an outlier?
2. What criteria should be used to determine if a data set is sufficiently ''representative'' of the population of interest to be used in a probablistic assessment? Are there minimum size or Quality Assurance/Quality Control (QA/QC) requirements that should be met?
3. Should the Agency allow exposure assessments to include data reflecting the range of typical application parameters? Are the conditions for accepting residue data based on typical parameters appropriate, or should they be modified?
4. Do the currently available consumption data permit probabilistic assessment of chronic dietary risk? If not, is there an appropriate process for using the available consumption data to permit probabilistic assessment of chronic dietary risk?
5. Is there a process or procedure which would allow the Agency to utilize post-farm monitoring data on composite samples (e.g., from the Food and Drug Administration (FDA), USDA, and State pesticide monitoring data) to assess acute dietary exposure for unblended commodities?
6. Is it appropriate to assess acute dietary risk on a population basis, and to assess short- and intermediate-term occupational and residential exposure on an exposed-individual basis? If it is more appropriate to assess short- and intermediate-term occupational and residential risk on a population basis, is there a process to do so?
7. What changes or additions to the document would improve its readability and make it easier for general audiences to understand? For example, would it be helpful to include a glossary of terms? Are there key scientific concepts that need to be better explained for a lay audience? Would the addition of a case study make any of the concepts easier to understand?

B. Office of Pesticide Program's Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides

1. How should EPA use measures of ChE inhibition in plasma, red blood cells, and brain in determination of

critical effect levels and setting reference doses?

2. Should plasma and red blood cell measures of ChE inhibition be treated differently from brain measures of ChE inhibition and/or from one another?

3. How should measures of peripheral tissues be used in these processes of risk assessment, both in a practical sense and a science policy sense?

4. Can measures of ChE inhibition in peripheral tissues, such as the heart and salivary glands, be used as a supplement or even an alternative to blood measures?

5. Should comparative data on ChE inhibition in the young exposed pre-natally, during infancy (nursing), and during childhood be considered essential for defining the relative sensitivity of the young and adults?

6. Are other measures, such as functional measures of clinical signs, or learning and memory, similarly important?

Based on special additional recommendations of the SAP, EPA wishes to highlight two other issues for public comment.

The first is the SAP's recommendation that plasma cholinesterase be differentiated by use of selective inhibitors into acetylcholinesterase and butyrylcholinesterase. At present, most animal studies received by EPA do not differentiate between these enzymes. An important part of the argument made for consideration of plasma activity was the fact that for rat studies, nearly half of the plasma cholinesterase is acetylcholinesterase, identical to the neuronal form. Such differential analyses would provide additional data on this topic.

7. Should EPA require the differentiation of acetylcholinesterase and butyrylcholinesterase in plasma, and how might this data be used?

The second is the SAP's recommendation that EPA ask for receptor binding assays for long term studies. A common consequence of prolonged ChE inhibition in the nervous system is the down regulation of cholinergic receptors. This represents a longer term response to exposure than the inhibition of enzyme activity. This effect might be differentially affected by some chemicals, and its time course might differ from enzyme activity. Such data would help to broaden the data base on which to characterize the hazards of these chemicals.

8. Should EPA require receptor binding assays for long term (subchronic and chronic) studies, and how should such data be interpreted?

9. A number of parameters related to the neurotoxicological potential of cholinesterase-inhibiting pesticides are measured and considered when developing a hazard characterization for these chemicals. Some of these parameters (e.g., clinical signs) represent direct observations of this potential; others serve as surrogates (e.g., inhibition of red cell cholinesterase) for potential effects not currently measured or observed directly. OPP has proposed to use a weight-of-the-evidence approach when characterizing the hazard of these chemicals and developing health-based benchmarks such as reference doses. A weight-of-the-evidence approach obligates the risk assessor to consider all of the study results as a whole, rather than focusing on any single result in isolation of the others. Is this approach a reasonable means for evaluating the overall significance of the potential neurotoxic effects associated with this type of pesticide?

10. What changes or additions to the document would improve its readability and make it easier for general audiences to understand? For example, would it be helpful to expand the glossary of terms? Are there key scientific concepts that need to be better explained for a lay audience? Would the addition of more examples make the concepts easier to understand?

V. Public Record and Electronic Submissions

A record has been established for these policy guidances under docket control numbers OPP–00559 and OPP–00560 (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 include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on 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 numbers OPP–00559 and OPP–00560. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

VI. Contents of Docket

Documents that are referenced in this notice document will be inserted in the docket under the document control numbers OPP–00559 and OPP–00560. In addition, documents referenced in in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) will also be 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: October 30, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 98–29665 Filed 11–4–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–51917; FRL–6040–7]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical to notify EPA and comply with the statutory provisions pertaining to the manufacture or import of substances not on the TSCA Inventory. Section 5 of TSCA also requires EPA to publish receipt and status information in the **Federal Register** each month reporting premanufacture notices (PMN) and test marketing exemption (TME) application requests received, both pending and expired. The information in this document contains notices received from September 1, to September 30, 1998.

ADDRESSES: Written comments, identified by the document control number ''[OPPTS–51917]'' and the specific PMN number, if appropriate, should be sent to: Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. ETG–099 Washington, DC 20460.

Comments and data may also be submitted electronically by sending