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ENVIRONMENTAL PROTECTION AGENCY

[OPP–00557; FRL–6041–5]

Framework for Addressing Key Science Issues Presented by the Food Quality Protection Act (FQPA) as Developed Through the Tolerance Reassessment Advisory Committee (TRAC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The notice announces a schedule and framework for EPA issuance of a series of science policies to implement provisions in the Food Quality Protection Act of 1996 (FQPA). The notice and comment approach described in this notice was created following discussion with the Tolerance Reassessment Advisory Committee (TRAC), a subcommittee of the National Advisory Council on Environmental Policy and Technology (NACEPT), a committee established pursuant to the Federal Advisory Committee Act. Comments on individual interim science policy documents will be invited through separate notices in the **Federal Register** as outlined in the framework. While refining its approach to FQPA science policies, EPA will use the policies described in the interim documents when making decisions on pesticide actions.

ADDRESSES: 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. 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@epamail.epa.gov. Follow the instructions under Unit VII. 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: Jeff Kempter, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 713D, CM #2, 1921 Jefferson Davis Highway, Arlington, VA; (703) 305–5448; kempter.carlton@epa.gov.

SUPPLEMENTARY INFORMATION: The following documents 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/):

1. This document.
2. A table entitled ''Framework for Refining FQPA Science Policy.''
3. A timeline entitled ''Schedule for Release of Guidance on Science Policy Issues.''

Copies of the above-mentioned table and timeline may also be obtained from the OPP docket at the location listed under ADDRESSES or by contacting Jeff Kempter at the telephone number listed above.

I. Background

A. Food Quality Protection Act (FQPA)

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. Effective upon signature, 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 data supporting pesticide registrations will remain up-to-date in the future.

B. Food Safety Advisory Committee (FSAC)

When FQPA took effect, EPA was immediately faced with having to implement new standards and requirements. The Agency established the FSAC as a subcommittee of the NACEPT to assist in soliciting input from stakeholders and to provide input to EPA on some of the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs (OPP). With the guidance and input of the FSAC, the Agency issued several key documents concerning how it would implement FQPA: (1) On January 31, 1997, Pesticide Registration Notice 97-1 entitled ''Agency Actions Under the Requirements of the Food Quality Protection Act'' provided an interim decision logic for making regulatory decisions; (2) the ''1996 Implementation Plan,'' made available in March 1997, described EPA's overall plan for implementing the requirements of FQPA; and (3) on August 4, 1997, a **Federal Register** notice entitled ''Raw and Processed Food Schedule for Pesticide Tolerance Reassessment'' announced a specific plan for conducting reassessments of tolerances in effect as of the passage of FQPA.

The Agency has used the interim approaches developed through discussions with FSAC to make regulatory decisions that met FQPA's standard and 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.

C. Tolerance Reassessment Advisory Committee (TRAC)

Although the Agency has sought independent review and public participation on a wide variety of issues, the Agency has decided that the implementation process would benefit from a more thorough process of notice and comment on major science policy issues. As directed by Vice President Albert Gore, EPA has been working with the U.S. Department of Agriculture (USDA) and a new subcommittee of

NACEPT, the 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 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 document for addressing key science policy issues. This **Federal Register** notice is based on, but not identical to, the EPA staff paper #26 which is the draft framework document presented to the TRAC that identified the issues relating to these science policy issues.

The TRAC identified nine science policy issues it believed were key to the implementation of FQPA and tolerance reassessment. The framework calls for EPA to provide one or more documents for public comment on each of the nine issues over the course of the next several months. EPA will issue **Federal Register** notices announcing the availability of each of these science policy documents for comment. Other opportunities for public involvement in the refinement of these policies may also be available, depending on the current status of the individual science policy. 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. This notice describing the framework briefly summarizes each of the nine science policy issues, the efforts underway to refine them, plans for notice and comment, and the timelines for completing refinements.

II. The Nine Science Policies

A. Science Policy 1: Applying the FQPA 10-Fold Factor

FQPA requires EPA to use an additional 10-fold factor when assessing a pesticide's dietary risk to take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children. The additional FQPA factor may be reduced or removed only if, on the basis of reliable data, the factor used will be safe for children. (It should be noted that, under certain circumstances, the Agency may use a higher factor than the traditional 100-fold uncertainty factor, for example, because of a limited toxicity data base.) In assessing risk, the Office of Pesticide Programs (OPP) applies the 10-fold factor unless it determines, based on a weight-of-the-evidence evaluation of all reliable, available information on toxicity and exposure, that it should be modified.

The major science policy issue related to the 10-fold FQPA factor is the establishment of appropriate, clear, and transparent criteria for retaining or modifying the 10-fold factor. Another closely related issue is determining what constitutes a complete and reliable data base for toxicology and exposure data to assess risks to children.

In part, to address these issues, an intra-agency workgroup is looking at general considerations regarding the FQPA factor decisions such as: establishing procedures for consistency and documentation; ensuring the adequacy of the data set for decision-making; and establishing criteria for retaining or modifying the FQPA factor. This workgroup includes representatives of the Office of Research and Development, the Office of Children's Health Protection, the Office of Water, the Office of Solid Waste and Emergency Response, as well as the Office of Prevention, Pesticides and Toxic Substances. In addition, OPP has completed a draft Standard Operating Procedure (SOP) that provides procedural guidance at the working level for making recommendations for retaining or modifying the 10-fold factor.

In addition, EPA has solicited advice from the SAP. In October 1996, EPA first brought to the SAP a paper that described a ''weight-of-evidence'' approach for the 10x FQPA factor, that was developed prior to the passage of FQPA. In March 1998, the Agency brought OPP Health and Effects Division (HED) draft guidance on the application of the FQPA factor to the Panel. In July 1998, EPA updated the SAP on its progress in responding to their comments.

The Intra-Agency workgroup draft guidance document will be completed and available for comment in January 1999. At that time, EPA will publish a notice of availability and a 60–day opportunity to comment on the guidance document. A revised document will be ready no later than June 1999. The draft working level document (the SOP) is complete; it will be issued with the Intra-Agency document in February 1999, for comment and will be revised in light of public comment by July 1999.

B. Science Policy 2: Dietary Exposure Assessment - Whether and How to Use ''Monte Carlo'' Analyses

EPA assesses dietary exposure to pesticides in 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 (such as monitoring data) where the amount of pesticide residue on a given commodity is measured. Routinely, consumption information comes from USDA surveys of what people eat. In the past, EPA has used the Dietary Risk Evaluation System (DRES) which is a deterministic model to combine the residue and food consumption information with data on a pesticide's toxicity to calculate acute and chronic dietary risk. This deterministic model calculates a single value (sometimes referred to as a point estimate) for all the residues for a given commodity.

Over the last few years, a different technique has been applied to estimating acute dietary exposure—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 estimate the distribution of exposure to the residues for the population of concern. This technique allows for a more realistic estimate of exposure.

There are three issues associated with the use of probabilistic techniques:

1. Probabilistic analyses often exhibit a level of uncertainty at the extremes of the distribution. This uncertainty makes it difficult to judge if the results reflect an accurate estimate of risk, or an overestimate or underestimate risk.

2. EPA needs to make decisions that are appropriately protective of larger numbers of people, especially children, necessitating estimates of ''high end'' exposures (e.g., 99.9th percentile).

3. There is a concern over statistical treatment of data that are inputted into the Monte Carlo model. For example, how USDA's high end consumption estimates combine with the use of a 99.9th percentile output needs to be resolved.

The following steps have been taken or are being taken to address these issues:

1. In March 1998, the Agency presented to the SAP for comment draft

guidance for submission of probabilistic exposure assessments.

2. USDA and EPA are jointly assessing how best to treat data representing the extremes of exposure.

3. The issue of the appropriateness of using the 99.9th percentile was presented to the SAP. SAP comments are being considered.

4. EPA is drafting a policy paper on use of the 99.9th percentile in decision-making.

5. The Agency is working on statistical methods for effectively using composite data to estimate exposure from single-serving-sized food items.

These products will result:

1. SAP comments will be considered when preparing the next iteration of the draft document entitled ''Guidance for Submission of Probabilistic Exposure Assessments to the Office of Pesticide Programs' Health Effects Division.'' The document will be issued in October 1998 for a 60–day comment period. Revised guidance will be issued no later than March 1999.

2. In addition, USDA is reviewing its existing (1989–1991) food consumption data to ensure accuracy. This process will be completed in October 1998.

3. The policy paper exploring probabilistic techniques and the 99.9th percentile (draft working title ''Monte Carlo Techniques and the 99.9th Percentile'') will be issued for a 60–day comment period in December 1998. A revised document will be available no later than May 1999.

4. Finally, the draft paper on statistical methods on using composite data to estimate exposure from single serving food items (draft working title ''Use of the Pesticide Data Program in Acute Dietary Assessment'') will be issued for a 60–day public comment period in April 1999. The Agency will issue a revised document no later than September 1999.

C. Science Policy 3: Exposure Assessment - Interpreting ''No Residues Detected''

Pesticide manufacturers (i.e., registrants) seeking to have a tolerance established are required to submit data on the level of pesticide residues that remain in or on food. Often, instrumentation in the laboratory is not able to detect any residue below a specified level, which is called the ''limit of detection'' or LOD. However, even though the laboratory instrumentation cannot detect a residue, a residue may be present, at some level below the LOD, which may still present a potential concern to human health. Current EPA policy is to assume that non-detectable residues remain on treated commodities at ½ LOD.

How the Agency should interpret non-detects and how they should be incorporated into risk assessments presents these issues:

1. The Agency's method for incorporating non-detectable residues into its risk assessment (½ LOD) may either overestimate or underestimate risk depending on the actual distribution of data below the LOD.

2. There are potential trade and public health impacts if the Agency cancels a use, and subsequently revokes the corresponding tolerance in the U.S., based upon apparent unacceptable risks attributable in significant part to non-detectable residues, while other countries allow that use. If risks were accurately assessed or were underestimated, crops posing unacceptable risks may be imported into the U.S. because residues cannot be detected. If risks were overestimated, U.S. pesticide users may unnecessarily lose tools available to foreign growers.

EPA, FDA, and USDA are working together to develop and validate improved analytic chemistry methods for detecting residues of organophosphate pesticides. These improved methods are expected to be adapted to routine surveillance monitoring programs and to provide greater sensitivity than currently used methods. The use of more sensitive analytical methods should lessen the chance that imported food commodities may be treated with pesticides whose use is not allowed in the United States. In short, new, more sensitive methods should help to establish a ''level playing field'' for domestic growers and better protect U.S. consumers.

FQPA requirements to combine exposures from all sources (e.g., food, drinking water, and residential exposure) and from all chemicals with a common mechanism of toxicity magnify this problem. The resulting risk estimates may be significant even when a substantial portion of residues are below the level of detection.

The Agency has two initiatives underway to address the above issues:

1. An EPA workgroup is examining approaches that could allow EPA to determine that there is ''no reasonable expectation of finite residues.'' With sufficient data and clearer guidelines, uses for which food residues are truly insignificant could be demonstrated to have practically no dietary risk associated with them. This change would allow the Agency to focus its resources on evaluating exposures to pesticides at levels below the LOD, for which there is potential risk of concern. This change would also improve international harmonization. A paper entitled ''Threshold of Regulation'' will be issued in November 1998 for a 60–day comment period and will be revised in light of public comment no later than April 1999.

2. An OPP group is examining the availability of better statistical methods for assessing data sets that contain both detectable and nondetectable residues. Two papers will be issued as a result of this effort and will describe EPA's approaches to lessen the likelihood that the Agency's assessments either overestimate or underestimate food-borne exposure. The first paper (draft working title ''Use of Censored Data in Risk Assessments'') describes how to use statistical methods for situations where some of the residues are undetectable. The second paper (draft working title ''ChemSAC decision regarding use of LOD vs. LOQ (Limit of Quantitation) in dietary exposure assessments'') describes the use of limit of detection versus limit of quantitation in dietary exposure assessment. Both of these papers will be released for a 60–day public comment period in November 1998, with revised guidance to be issued no later than April 1999.

D. Science Policy 4: Dietary (Food) Exposure Estimates

In assessing dietary exposure from pesticide residues in food, EPA starts out with the ''worst-case'' residue level, which is the tolerance. Tolerances are regulatory levels and are set to accommodate the highest residue level that may be found in crops at the farm gate. Crop field trials are used to determine the highest residue level that can result from maximum legal use of a pesticide. As discussed below, actual residues on food are much lower, and may be virtually non-existent. Assuming that residues are present at tolerance level and that 100% of the crop is treated allows rapid cost-effective decision-making in many cases where risks are low. In these cases, there may be no need for registrants to collect additional data or for the Agency to use resources to review additional data.

Food exposure assessments can be improved with information on actual pesticide use, agricultural practices, processing practices, and actual or anticipated residues. This type of information includes data on pre-harvest intervals, actual application rates, application frequency, percent of the crop that is treated, pesticide degradation between harvest and the time the crop reaches the consumer (degradation over time), cooking and commercial processing studies, and

other related information, such as more comprehensive monitoring data for food and water. To estimate anticipated residue levels, the Agency may also need certain supporting residue data, such as residue decline studies, or procedures to translate or model residue data for typical use practices.

USDA provides the Agency with extensive information on pesticide use, food consumption data, and pesticide residues. The USDA information and information from other sources are key to the preparation of more realistic exposure assessments which then lead to more realistic acute and chronic dietary risk assessments. USDA and EPA work to ensure that the needed information is identified, collected, and used appropriately in the risk assessment. USDA and EPA have and will continue to obtain use information from growers which is then reviewed by the Agency and the registrants. EPA then identifies data gaps or the need for supplemental information.

The Agency has been working to complete the National Pesticide Residue Database (NPRD), a comprehensive database that will contain information about actual pesticide residues in raw and processed foods. A complete version of the NPRD is expected in November 1998, and will be available on EPA's web page. EPA will provide a description on the history, development, and use of NPRD; this will be available in December 1998.

There are several issues associated with the need for data to estimate food exposure more realistically:

1. Dietary risk estimates may be unrealistically high when typical use practices have not been factored in.

2. Information on actual pesticide use may be available, but residue levels resulting from such use cannot be calculated without certain residue testing, modeling efforts, or bridging data to meld the guideline studies with actual usage information.

3. Monitoring data are not available for all commodities, resulting in use of significantly different data in risk assessments for different chemicals and/or foods, and high risk estimates for those pesticides and crops that lack monitoring data.

To address the issues discussed above, the following products are forthcoming:

1. EPA will issue for comment in December 1998 a draft overview document (draft working title ''Framework for Dietary (Food) Exposure Assessment'') that describes how OPP does acute and chronic food exposure assessments and, more importantly, where in the existing guidance one can find methods for doing such exposure assessments; it will also provide guidance for growers, states, and others when collecting use information to explain the need for certain residue information (a revised document will be issued no later than April 1999).

2. EPA will complete matrices describing organophosphate use and usage on individual crops by December 1998. These matrices present real-world information on pesticide usage and the pests which drive the usage, and are developed with support from USDA and the grower community.

High quality consumption data are also critical to developing more accurate risk assessments. EPA recently acquired the capability to perform acute dietary risk assessments using state-of-the-art software and the most recently available USDA food consumption data (1989–91). In addition, USDA, in cooperation with EPA, is translating the most recently conducted food consumption survey information (1994–96) into a data format that can be used in EPA's risk assessments (i.e., from foods as eaten to the raw agricultural commodities which make up those foods). A peer review of the assumptions or ''recipes'' used in the translation of this consumption data will be held in April 1999. The final translation should be completed and available to EPA no later than June 1999. In addition, USDA is currently completing collection of supplementary food consumption data for children under the age of nine years to improve the precision of the dietary risk estimates. These data are being collected in such a manner that they will be combinable with the 1994–96 data. The translated form of the supplemental children's survey should be available to EPA no later than December 1999.

E. Science Policy 5: Dietary (Drinking Water) Exposure Estimates

For tolerance decisions under FQPA, EPA must now aggregate exposures to a pesticide from both dietary sources (food and drinking water) and all non-occupational sources for which there is reliable information. There are two complementary methods for estimating concentrations of pesticides in drinking water. The first is to measure pesticide residues in drinking water by taking samples of drinking water in use areas at appropriate times, especially during the use season for surface water supplies. The second is to develop and use mathematical models to predict pesticide levels in drinking water.

The Pesticide Program's currently available model-based approaches for predicting potential drinking water exposure are based on screening models that predict pesticide levels in vulnerable groundwater and surface water. These predictions are generally believed to overestimate the concentration of pesticides in most drinking water sources, and hence, in some cases drinking water exposure may appear to present an unacceptable dietary risk even though actual risks to most people may in fact be lower.

Several efforts are underway to address the problem that current screening models, particularly surface water screening models, do not well represent drinking water systems and may significantly overestimate residue levels in most drinking water sources. First, OPP developed and presented to the FIFRA SAP in July 1998 a proposed ''reservoir scenario'' model as a replacement for the ''small field pond'' model that is currently used to produce screening level estimates of pesticide concentrations in drinking water derived from surface water. By replacing the ''small field pond'' model with an actual reservoir, EPA expects that its screening level drinking water estimates for surface water will be more accurate. Subsequent to the SAP presentation, OPP developed a list of about 20 possible reservoirs that it may further evaluate for use as an index reservoir in its screening level assessments. This list is currently available in the public docket for this notice.

Second, OPP is working to develop the necessary data bases and Geographical Information System-based tools to enable it to consider the percentage of the area around a reservoir that is cropped and, thus, potentially treated with a pesticide when it uses its model to predict pesticide levels in a drinking water reservoir. Currently, OPP assumes that the entire area surrounding a body of water is planted with the crop and treated; this generally results in an overestimate of the amount of pesticide leaving the field and running off into surface water, and, therefore, an overestimate of pesticide concentrations in surface water used as drinking water.

Third, OPP completed and presented to the FIFRA SAP in July 1998, its preliminary evaluation of watershed-scale surface water models. Further efforts are ongoing to conduct preliminary model validation of the basin-scale models for the White River watershed in Indiana. This model validation effort is expected to provide some preliminary understanding of the relative accuracy of each of these models. OPP expects that these basin-scale models will ultimately be used to produce more refined estimates of

pesticide concentrations in drinking water for those cases where an unreasonable risk is estimated by the use of a screening level estimate.

In addition to the efforts described above, EPA has entered into a cooperative agreement with the International Life Sciences Institute (ILSI) to advance probabilistic drinking water exposure assessment methodology. ILSI is working to independently develop long-term recommendations for model development and data collection so that estimates of pesticide concentrations in drinking water can be used in probabilistic aggregate exposure analyses in the future. In September 1998, ILSI convened a panel of over a dozen scientists to consider such issues as: (1) What drinking water related data are necessary to use in probabilistic aggregate risk analyses and how can these data be collected; and (2) what role modeling can play in generating information/estimates on pesticide concentration distributions in drinking water sources. Recommendations from the September 1998 meeting will then be used in a follow-up meeting in December 1998, to develop detailed recommendations on how to collect information that can be used in probabilistic aggregate exposure analysis. ILSI expects to finalize its recommendations in early 1999.

Finally, OPP continues efforts to gather and interpret available drinking water monitoring data and to obtain additional monitoring of pesticides in drinking water as individual registration and reregistration decisions are made. Further, OPP is working with Federal government-sponsored water monitoring programs such as the United States Geological Survey's National Ambient Water Quality Assessment Program to ensure that key pesticides and drinking water source waters are covered; OPP is coordinating pesticide monitoring needs with EPA's Office of Water and the states as well.

EPA is currently using interim policy and interim operating procedures to factor drinking water exposure into tolerance decision-making. EPA will continue to update its interim policy and interim operating procedures as important new information becomes available.

Over the next 12 months, OPP expects to see three products completed. First, the Agency will address the July 1998 SAP comments on replacing the ''small field pond'' scenario with the reservoir scenario and revise its operating policy to include the reservoir scenario in screening level assessments. In its revision to its operating policy, OPP expects also to propose a change in the Drinking Water Level of Concern (DWLOC) terminology. This revised policy will be made available for a 60–day comment period in December 1998, and will be revised in light of public comment no later than May 1999. EPA expects to solicit comment on the concept of replacing the ''small field pond'' scenario with a specific type and size of reservoir, as well as on the timing for implementation.

Second, the Agency will complete development of an approach to factoring the percentage of land surrounding a reservoir that is ''cropped'' into its screening level assessments and revise its operating policy to include this approach. The Agency plans to present to the SAP in February 1999, a specific methodology for developing cropped area factors, proposed cropped area factors for 5-10 major crops and 5-10 minor crops, and examples of how cropped area factors would be applied in screening level drinking water assessments. EPA expects to resolve any issues raised by the SAP and expects to make this revised policy available for a 60–day public comment period by May 1999. After consideration of public comments, a revised policy issue paper will be issued no later than October 1999.

Third, the current HED SOP for factoring drinking water exposure into dietary risk assessments will be updated in June 1999, to include the reservoir scenario and will be published for a 60–day comment period. EPA expects that the new SOP which incorporates the reservoir scenario will be completed no later than November 1999. A revised SOP that includes the percent cropped area treated will be made available in December 1999, for comment and will be revised in light of public comment no later than May 2000. The SOP will be periodically updated thereafter as needed.

F. Science Policy 6: Assessing Residential Exposure

EPA must now include residential and other non-occupational exposures in the aggregate exposure assessments for pesticides. Generally speaking, residential exposure monitoring data have not been routinely required. Thus, EPA has been relying on existing monitoring, survey, and modeling data, including information on activity patterns, particularly for children, to estimate residential exposure to pesticides.

Because highly specific residential exposure data are generally lacking and there is not wide understanding and acceptance of existing models and assumptions, several workgroups and task forces are working to generate data and improve methods for conducting residential exposure assessments. Proposed Agency SOPs, which provide standard methods for developing residential exposure assessments when data are limited, were drafted and taken to the SAP for comment in November 1997. They are being revised based on the SAP comments and new information from the published literature and other sources.

Additionally, the Indoor Residential Exposure Joint Venture, an industry/Agency task force, is developing information on indoor pesticide treatments and pet uses. In Phase I, the Joint Venture will provide information to better characterize pesticide use patterns and practices. In Phase II, it will apply these data to exposure assessments, including, for example, looking at transferable residue data from treated surfaces. The Task Force is generating these data to support a consortium of registrant products; that is, these chemical-specific data will be used in conjunction with or in lieu of the SOPs (where deemed appropriate). Also, the Outdoor Residential Exposure Task Force, another industry/Agency taskforce, is in the midst of generating lawn and turf data to assess pesticide exposure from mixing, loading, and applying pesticides, as well as exposure to people who enter a recently treated turf area.

The Agency plans to incorporate the 1997 SAP comments on the SOPs by December 1998. The revised SOPs will then be published with a 60–day comment period. Revised documents will be completed no later than May 1999. On the same schedule, EPA plans to draft an overview document (draft working title ''Framework for Residential/Public Area Exposure Assessment'') on how it proposes to develop and use exposure estimates for pesticides applied around residences and public areas. In addition, the Indoor Residential Joint Venture Task Force is expected to have a Phase 1 draft document available in March 1999; Phase 2 will be completed by October 2000. Preliminary results from the Outdoor Residential Exposure Task Force are expected in August 1999. The Agency will review these chemical-specific data and information developed by the Task Forces and use this information in conjunction with or in place of the current SOPs, as appropriate.

G. Science Policy 7: Aggregating Exposures from all Non-Occupational Sources

As noted in sections E. and F. of this unit, under the requirements of FQPA, in setting tolerances EPA must now aggregate exposures from all sources where there is available information. Methods for aggregating exposures are being developed.

The current method for aggregating exposures using simple addition provides only point estimates. Methods that more clearly demonstrate the range of risks across the general population and population subgroups would better characterize risk for risk management decisions regarding pesticide use. These methods generally use probabilistic analyses.

In addition to Agency efforts to address these issues, the scientific community is examining comprehensive aggregate exposure assessment approaches. In February 1998, ILSI conducted a public workshop where three groups of experts presented their proposed approaches. Workshop participants evaluated and commented on the approaches.

ILSI will issue an independent scientific assessment of the technical issues surrounding aggregation of distributions. This report is scheduled to be completed in November 1998. After evaluation of this report, along with other comments by the scientific community, the Agency will develop a draft guidance document in April 1999 for a 60–day comment period. A revised version in light of public comment should be available no later than September 1999. In addition, EPA is developing a Standard Operating Procedure paper which will follow the same time line.

H. Science Policy 8: How to Conduct a Cumulative Risk Assessment for Organophosphate Insecticides or Other Pesticides With a Common Mechanism of Toxicity

Under FQPA, EPA is required to consider available information on the effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity. EPA believes that the organophosphate insecticides, the first group examined for tolerance reassessment, should be considered to operate via at least one common mechanism of toxicity-cholinesterase inhibition, unless and until the Agency receives data demonstrating otherwise.

In the **Federal Register** of August 6, 1998 (63 FR 42031) (FRL–5797–9), EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document entitled ''Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity for Use in Assessing the Cumulative Toxic Effects of Pesticides.'' The guidance document describes the approach that EPA proposes to use for identifying and categorizing pesticide chemicals that have common mechanisms of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. There is a 60-day comment period for this document that ends in October 1998. Revised guidance will be issued no later than January 1999. In developing this document, the Agency solicited advice from the SAP in February 1997; a year later (March 1998), OPP reported its progress to the SAP.

Since there are currently no standard methods for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop approaches to cumulative risk assessment. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, ILSI is independently exploring appropriate methods and developing a framework for performing a cumulative risk assessment. ILSI held a workgroup on this subject in September 1998, and a report is expected in early 1999. The Agency will continue its ongoing efforts in this area along with examining the ILSI work and other sources of information in preparation for release of an Agency draft guidance document by June 1999 with a 60–day comment period. The guidance will be revised no later than November 1999.

I. Science Policy 9: Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates

Most organophosphate (OP) and certain carbamate insecticides exert their principal toxic effects on insects, mammals, and other animals by the mechanism of cholinesterase inhibition, which may lead to neurotoxicity. Measurement of cholinesterase levels in the blood or nervous system after exposure to OPs has become the most common endpoint used in risk assessments of this chemical class.

Over the last several years, the Agency has engaged outside scientists and the regulatory community about how measures of cholinesterase inhibition should be used in risk assessments. EPA has also discussed more generally how these data should be viewed along with other types of data in risk assessments. Two issues focused on were: (1) The role of blood measures in risk assessment since plasma and red cell cholinesterases are not part of the nervous system but they may be an indirect measure of what is occurring in the central and peripheral nervous systems; and (2) whether plasma cholinesterase should be treated differently from red blood cell cholinesterase.

In June 1997, OPP made a comprehensive presentation to the SAP on cholinesterase inhibition. The presentation included a literature review, a series of case studies, a summary of activities related to methods of cholinesterase measurement, and a proposed policy to use a weight-of-evidence approach considering all of the data that might result in the use of cholinesterase measures in plasma, red blood cells, or brain for defining critical effects and no-effects levels. 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 cholinesterase inhibition in the peripheral nervous system in animals. The positions contained in the paper presented to the SAP, entitled ''Office of Pesticide Programs Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides,'' draft April 30, 1997, will be issued for a 60–day comment period in October 1998. The SAP comments on that document will be provided in the docket with that **Federal Register** notice. Revised guidance will be issued no later than March 1999.

III. How EPA Will Address Comments

A. Comments Already Received

Before and during the TRAC meetings, the Agency received comments on how to approach and improve its interim policies. Specifically, EPA received several petitions, including those from the National Food Processors Association, the Natural Resources Defense Council (NRDC) and others, a report from the Implementation Working Group (IWG), letters from the Environmental Working Group, and various correspondence from Congress and others. These documents will be considered as the Agency refines its science policies, and will also be made available through the public docket. Additionally, the U.S. House Agriculture Committee has held a hearing on FQPA implementation and there have been legislative or public hearings in California, Idaho, and

Michigan as well at which comments were solicited and offered.

B. NRDC Petition

On April 23, 1998, the NRDC and various individuals and other public interest organizations filed a petition requesting that EPA issue an interpretive rule/policy statement regarding EPA's implementation of the FQPA provision concerning the additional 10-fold factor to protect infants and children. The petition seeks three specific actions:

1. Issuance of a policy statement/interpretive rule providing that EPA ''maintain the ten-fold safety factor unless the Administrator has determined that there are reliable data on [evolving] pre- and post-natal toxicity and exposure for fetuses, infants, and children.'' The petition sets forth a minimum set of data that petitioners believe constitutes ''reliable data'' and requests that the statement/rule direct EPA to apply the additional 10-fold factor if any of these data are absent.

2. Convene a ''blue ribbon panel'' to assist EPA ''in determining when there are 'reliable' data for pre- and post-natal toxicity to fetuses, infants, and children.'' NRDC recommends that this panel be convened under the auspices of the Children's Health Protection Advisory Committee.

3. Issuance of a policy statement/interpretive rule providing that, pending completion of the panel's report, EPA will apply the 10-fold FQPA factor.

C. Grower Group and Trade Association Petition

On May 26, 1998, EPA received a Petition on Rulemaking Under the Food Quality Protection Act submitted on behalf of several grower groups and trade associations. The petition requested EPA to use notice and comment rulemaking to establish policies and procedures for implementing FQPA. The petitioners claim that rules are needed to establish policies and procedures for assessing aggregate exposures, common mechanism of toxicity, and cumulative effects, and for determining when the FQPA 10-fold factor may be reduced or removed. The petitioners state that EPA is using its current science policies as though they were binding requirements. The petitioners maintain that neither the advisory panel process nor the notice and comment rulemaking on individual tolerances appropriately substitute for notice and comment rulemaking on major procedural or policy issues.

D. IWG Report

The IWG, a coalition of farm, food, manufacturing, and pest management organizations, issued a ''road map'' report on June 18, 1998, which ''presents the IWG's views on how EPA can ensure a more balanced and workable implementation of FQPA.'' The sections of the report include the IWG's general recommendations, their interpretation of Congress's intent, EPA actions to date, ''an approach to aggregate risk assessment and the assessment of cumulative effects of chemicals with a common mechanism of toxicity,'' other recommendations, and issue papers.

IV. EPA's Interim Approach While Assessing the Nine Science Policies

A. Interim Approach

While refining its approach to the nine issues, EPA will use the policies described in its interim science policy documents when making decisions on actions such as establishing tolerances for registrations under section 3 of FIFRA, emergency exemptions under section 18 of FIFRA, and tolerance reassessments.

B. EPA's Approach to Notice and Comment

The Agency intends to refine each of the nine science policy issues by seeking public input through the notice and comment process explained in this notice. In announcing the availability of the nine science policy documents for comment, the Agency will:

1. Identify any significant comments EPA has already received on the various policy documents.

2. Where appropriate, ask specific questions based on pivotal issues in those comments.

3. Provide a comment period through the **Federal Register** notice on each science policy issue, as described in this notice, after which the Agency will respond to significant comments received in response to the Agency's notices, and revise each policy as appropriate.

C. Documents Available in the Docket

The following documents prepared for the TRAC are available in the docket: A table entitled ''Framework for Refining FQPA Science Policy'' and a timeline entitled ''Schedule for Release of Guidance on Science Policy Issues.'' In addition, a compendium of the Agency's current operating guidelines is available in the docket; however, comment is not being requested at this time on these documents since they are being revised. Opportunity for comment will be offered as noted earlier in this notice.

V. Policies Not Rules

The numerous science policy documents discussed in this notice are intended to provide guidance to EPA personnel and decision-makers, and to the public. As guidance documents and not rules, these policies are not binding on either EPA or any outside parties. Although these guidance documents provide a starting point for EPA risk assessments, EPA will depart from these policies 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 given policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a given policy should be abandoned.

Throughout this notice, EPA has stated that it will make available revised guidances after consideration of public comment. Public comment is not being solicited for the purpose of converting these policy documents into binding rules. EPA will not be codifying these policies in the Code of Federal Regulations. EPA is soliciting public comment so that it can make fully informed decisions regarding the content of these guidances.

The ''revised'' guidances will not be unalterable documents. 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 commenting on the individual guidance documents, EPA would welcome comments that specifically address how the guidance documents can be structured so that they provide meaningful guidance without imposing binding requirements.

VI. Closing

This is EPA's approach to providing for notice and comment regarding the nine science policy issues discussed above and on the timing of the process set out in the framework. Under this approach, for each science policy issue described above, a document which describes the Agency's approach for each issue will be published separately, as available, for public comment through the **Federal Register**.

VII. Public Record and Electronic Submissions

The official record for this action, as well as the public version, has been established for this action under docket control number ''OPP–00557'' (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@epamail.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 number ''OPP–00557.'' Electronic comments on this action may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, FQPA, Pesticides.

Dated: October 23, 1998.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 98–29013 Filed 10–28–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6181–6]

National Environmental Justice Advisory Council Workgroup on Waste Transfer Stations; Notice of Public Hearings

The Environmental Protection Agency (EPA) is sponsoring a fact finding meeting held by the National Environmental Justice Advisory Council (NEJAC) working group on Waste Transfer Stations (WTS) for the purpose of gathering information related to potential environmental issues related to Waste Transfer Stations. Information gathered from these meetings will be gathered in a report for recommendations to EPA.

The WTS working group was formed after a NEJAC resolution calling for EPA to ''examine the risks from the siting and operation of Waste Transfer Stations for the purpose of determining its regulatory responsibilities and prescribe requirements to reduce health risks associated with such facilities.'' The WTS working group consists of representatives of community based organizations, business interests, and elected officials from impacted communities for the purposes of advising on the design and implementation of the WTS study.

The workgroup plans to conduct two-fact finding meetings: the first one will take place in New York City on November 10, 1998; the second meeting will take place in Washington, D.C., meeting day and location to be announced. The New York meeting will take place at the Marriot Hotel in Brooklyn on November 10, 1998, 333 Adams Street, Brooklyn, NY 11021, (718) 246–7000.

Please call Kent Benjamin, Office of Solid Waste and Emergency Response at (202) 260–2822 for more information or Nancy Wilson at, 202–260–1910, if Kent is unavailable.

Dated: October 26, 1998.

Linda Garczynski

Director, Outreach Special Projects, Office of Solid Waste and Emergency Response.

[FR Doc. 98–29018 Filed 10–28–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6181–5]

Notice of Policy and Procedures for Voluntary Preparation of National Environmental Policy Act (NEPA) Documents

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of new policy and repeal of existing policy.

SUMMARY: EPA is today withdrawing its May 7, 1974 Statement of Policy for Voluntary Environmental Impact Statements (EIS) (39 FR 16186) and publishing a Statement of Policy for Voluntary Preparation of National Environmental Policy Act (NEPA) Documents. The new Statement of Policy updates Agency policy to make it more consistent with current practice. This policy change widens the scope of Agency activities for which a NEPA document may be prepared voluntarily and enables EPA to address actions for which a voluntary EIS would have been prepared previously with a voluntary Environmental Assessment (EA) if appropriate. Additionally, EPA is withdrawing the Procedures for the Voluntary Preparation (39 FR 37419, October 21, 1974) and instead will use procedures as set out at 40 CFR Part 6, Subparts A through D, as specified below.

DATES: This policy shall take effect October 29, 1998.

FOR FURTHER INFORMATION CONTACT: Joseph Montgomery at (202) 564–7157; *Email: montgomery.joseph@epamail.epa.gov;* or Marguerite Duffy at (202) 564–7148; *E-mail:duffy.marguerite@epa.gov;* U.S. Environmental Protection Agency, Office of Federal Activities (2252–A), 401 M Street, SW, Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. Background

In the November 28, 1997 **Federal Register** (62 FR 63334), EPA proposed changes in its Statement of Policy for Voluntary EISs, which it had adopted and published on May 7, 1974 in the **Federal Register** (39 FR 16186). This revised policy updates EPA's 1974 policy to reflect how Congress and the Courts have defined EPA's NEPA obligations and to ensure that EPA's voluntary practices regarding NEPA compliance are consistent with practices provided in the NEPA regulations issued by the Council on Environmental Quality (CEQ) at 40 CFR Parts 1500 through 1508. The revised policy also encourages expansion of the increased discretionary use of NEPA procedures voluntarily in circumstances where they can be particularly helpful for decision-making involving other federal agencies, cross-media issues, or other concerns such as environmental justice. The revised policy affects certain EPA standard-setting and cancellation procedures.

II. Response to Comments

A total of four comments were received in response to the November 28, 1997 proposed changes. Three organizations were supportive of the proposed changes. One state government concurred with the proposed changes but requested that EPA consult with states regarding any actions which were previously reviewed through the EIS process but which EPA believes should be evaluated through environmental assessments in the future. The state also requested that EPA continue to prepare EISs in the case of site designations under the Marine Protection, Research and Sanctuaries