Administrative Law Judge, or court, the facility's monitoring reports, and EPA, state, or local inspection reports. EPA should encourage the defendant to agree to share information with the community, within parameters discussed above. This should help EPA and the defendant establish a positive relationship with the community and enable the community to participate in the SEP process more effectively.

VII. Conclusion

EPA is committed to involving communities in the consideration of SEPs in appropriate cases. This guidance is intended to facilitate community involvement in SEP consideration and helps effectuate the best possible SEPs in settlement of enforcement cases in a manner that promotes mutual trust and confidence, and builds positive relationships between the community and the Agency.

This document is guidance intended for the use of EPA personnel and does not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person. This guidance is not intended to supercede any statutory or regulatory requirements, or EPA policy. Any inconsistencies between this guidance and any statute, regulation, or policy should be resolved in favor of the statutory or regulatory requirement, or policy document, at issue.

Appendix A—Resources for Identifying Communities

Below are some suggested resources within and outside of EPA that may be useful in targeting community outreach efforts.

Suggested Internal Sources

1. Community involvement coordinators at OERR's Community Involvement and Outreach Center;
2. Headquarters offices, including: Office of Environmental Justice, American Indian Environmental Office, Federal Facilities Enforcement Office;
3. Colleagues in other media programs or regions;
4. Regional offices or coordinators who handle community involvement, environmental justice, tribal issues, or Community-Based Environmental Protection (CBEP);
5. ''Model Plan for Public Participation'' (November, 1996), developed by the Public Participation and Accountability Subcommittee of the National Environmental Justice Advisory Council (available at NEJAC website: www.epa.gov/oeca/oej/nejac).

Suggested External Sources

1. State, local, or tribal governments;
2. Educational or spiritual organizations;
3. Other federal agencies;
4. Neighborhood organizations or groups, and individuals in neighborhoods closest to the defendant's facility;
5. Community activists;
6. Environmental and environmental justice organizations and groups;
7. Local unions, business groups, and civic groups;
8. The defendant or other members of the regulated community (*i.e.,* trade associations);
9. Local newspapers, radio, television, local Internet sites.

Appendix B—Community Outreach Techniques

*This list is intended to provide a library of options available for use in conducting community outreach, and is not intended to suggest that all of these techniques be used in any given case.

1. Interview: Face-to-face or telephone discussions with community members provide information about local concerns and issues. A significant time commitment may be required to gather feedback representative of the community.
2. Small Group Meeting: Convening community members in a local meeting place stimulates dialogue, generates information, and may build rapport among participants.
3. Focus Group Meeting: Focus group participants are convened by a trained facilitator to provide answers to specific questions. This direct approach is an efficient information-gathering tool if participants represent a cross-section of the community.
4. Public Meeting: Public meetings are useful for hearing what people have to say about current issues and engaging community members in the process. At public meetings, EPA should focus on active listening and learning from the public.
5. Public Availability Session/Open House: A public availability session is a less structured alternative to a public meeting that provides everyone an opportunity to ask questions, express concerns, react to what is being proposed, and make suggestions. Typically, a public official announces she or he will be available at a convenient time and place where community members can talk informally.
6. Public Notice: Public notices in the print media or on radio and television are a relatively inexpensive way to publicize community participation opportunities. In addition to the mainstream media, minority publications, church bulletins and other such vehicles offered by local organizations can reach a more diverse audience.
7. Workshop: Workshops are participatory seminars to educate small groups of citizens on particular site issues. Workshops involve and empower participants; but they, too, can be time-intensive.
8. Site Tour: Site tours can familiarize citizens, the media and local officials with the nature of environmental concerns affecting a community near a specific site. Tours may result in better communication among the community, facility, and Agency, however, they are frequently resource-intensive to arrange and conduct.
9. Information Repository: An information repository is a project file containing timely information on site-specific activities and accurate detailed and current data about a site or enforcement action. Project files are typically kept at convenient public locations, *e.g.,* libraries, and publicized through various media.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–00658; FRL–6556–4]

Pesticides; Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: To assure that EPA's policies related to implementing the Food Quality Protection Act are transparent and open to public participation, EPA is soliciting comments on the pesticide draft science policy paper entitled ''Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.'' This document is the eighteenth in a series concerning science policy papers related to the Food Quality Protection Act and the Tolerance Reassessment Advisory Committee.

DATES: Comments for the draft science policy paper, identified by docket control number OPP–00658, must be received on or before August 28, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–00658 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Kathleen Martin, Environmental Protection Agency (7509C), 1200 Pennsylvania, Ave., NW., Washington, DC 20460; telephone number: (703) 308–2857; fax: (703) 305–5147; e-mail: martin.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Pesticide Producers	32532	Pesticide manufacturers Pesticide formulators

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action affects certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, the draft science policy paper, and certain other related documents that might be available from the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides. On the Office of Pesticide Programs' Home Page select ''FQPA'' and then look up the entry for this document under ''Science Policies.'' You can also go directly to the listings at the EPA Home Page at http://www.epa.gov. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under ''**Federal Register**—Environmental Documents.'' You can go directly to the **Federal Register** listings http://www.epa.gov/fedrgstr.

2. *Fax-on-demand*. You may request a faxed copy of the draft science policy paper, as well as supporting information, by using a faxphone to call (202) 401–0527. Select item 6049 for the paper entitled ''Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.'' You may also follow the automated menu.

3. *In person*. The Agency has established an official record for this action under docket control number OPP–00658. In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) (FRL–6041–5) have also been inserted in the docket under docket control number OPP–00658. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–00658 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania, Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–00658. Electronic comments may also be filed online at many Federal Depository Libraries.

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

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under ''FOR FURTHER INFORMATION CONTACT.''

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

EPA invites you to provide your views on the various draft science policy papers, new approaches we have not considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider. You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide solid technical information and/or data to support your views.

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

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

6. Provide specific examples to illustrate your concerns.

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

8. To ensure proper receipt by EPA, be sure to identify docket control number OPP–00658 in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background Information About the Tolerance Reassessment Advisory Committee

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. Effective upon signature, the FQPA significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other changes, FQPA established a stringent health-based standard (''a reasonable certainty of no harm'') for pesticide residues in foods to assure protection from unacceptable pesticide exposure; provided heightened health protections for infants and children from pesticide risks; required expedited review of new, safer pesticides; created incentives for the development and maintenance of effective crop protection tools for farmers; required reassessment of existing tolerances over a 10-year period; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that scientific data supporting pesticide registrations will remain up-to-date in the future.

Subsequently, the Agency established the Food Safety Advisory Committee (FSAC) as a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT) to assist in soliciting input from stakeholders and to provide input to EPA on some of the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs. The Agency has used the interim approaches developed through discussions with FSAC to make regulatory decisions that met FQPA's standard, but that could be revisited if additional information became available or as the science evolved. As EPA's approach to implementing the scientific provisions of FQPA has evolved, the Agency has sought independent review and public participation, often through presentation of the science policy issues to the FIFRA Scientific Advisory Panel (SAP), a group of independent, outside experts who provide peer review and scientific advice to OPP.

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

The Agency worked 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 believed 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 document published in the **Federal Register** of October 29, 1998 (63 FR 58038), EPA has been issuing a series of draft papers concerning nine science policy issues identified by the TRAC related to the implementation of FQPA. This document announces the availability of the draft science policy paper(s) as identified in the ''SUMMARY.''

III. Summary of ''Proposed Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity''

The Food Quality Protection Act of 1996 requires EPA to consider the cumulative effects to human health that can result from exposure to pesticides and other substances that have a common mechanism of toxicity. This document describes the process that OPP is developing for performing cumulative risk assessments. Such assessments will play a significant role in the evaluation of risks posed by pesticides, and will enable OPP to make regulatory decisions that fully protect public health and sensitive subpopulations, including infants and children.

The cumulative assessment of risk posed by exposure to multiple chemicals by multiple pathways (including food, drinking water, as well as from residential/non-occupational exposure to air, soil, grass, and indoor surfaces) presents a formidable challenge for OPP. Given that cumulative risk assessment is at an early phase of development, and will continue to evolve with experience and improved toxicological and exposure databases, the goal of this draft science policy paper is to describe the first generation of methods and approaches to the cumulative risk assessment process. Thus, this guidance for cumulative assessment should be viewed as a work in progress.

Before undertaking a cumulative risk assessment for a set of chemicals that have a common mechanism of toxicity, OPP will follow its procedures for identifying the chemicals that belong in that group (see ''Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity,'' 64 FR 5796, February 5, 1999 (FRL–6060–7); also see OPP's Home Page at http://www.epa.gov/pesticides). This process involves the use of a weight-of-the-evidence approach to identify a list of candidate chemicals, a ''Common Mechanism Group'' (CMG), for which scientifically reliable data demonstrate a common toxic effect by a common mechanism of action.

Also before conducting a cumulative assessment, OPP will perform an aggregate risk assessment for each chemical in a CMG. OPP will follow the guidance described in the draft science policy paper entitled, ''Guidance for Performing Aggregate Exposure and Risk Assessments,'' which was issued for public comment on November 10, 1999 (64 FR 61343) (FRL–6388–8); also see OPP's Home Page at http://www.epa.gov/pesticides). Using this guidance, OPP will simultaneously consider the exposures from dietary (food), drinking water, and residential/non-occupational uses of each pesticide. If the combined exposure from these sources exceeds the level of concern, then OPP would take appropriate regulatory action.

When the aggregate risk assessments for individual chemicals in a CMG are completed, OPP will perform the cumulative risk assessment in the four steps summarized below: (1) Hazard assessment and characterization; (2) Dose response assessment and characterization; (3) Exposure assessment and characterization; and (4) Risk characterization. OPP will carry out steps 1 and 2 by using a weight-of-the-evidence approach to determine the toxic endpoint that occurs through a common mechanism for the chemicals in the CMG, and by establishing a common measure of toxic potency (''common point-of-departure'') on which the cumulative risk assessment is based. For steps 3 and 4, OPP will estimate exposure and risks for the dietary (food), residential/non-occupational and drinking water pathways. However, due to limitations

in currently available data and assessment methodologies, OPP will usually not be able to simply add exposures across these pathways. While OPP has extensive data for dietary (food) exposures, the data for residential/non-occupational and drinking water exposure are comparatively less. OPP is working to improve its ability to develop better estimates of exposure both through drinking water and from residential use. For example, OPP is exploring the use of surrogate/bridging data for pesticides with similar use patterns that can be used to estimate residential exposures that are similarly descriptive as the dietary exposure assessment. This approach is comparable to the approach currently used for worker exposure assessments using the Pesticide Handlers' Exposure Database (PHED) where data from different pesticides with similar use patterns are used to estimate likely exposures to other pesticides. In fact, OPP is currently developing a pilot cumulative assessment on a set of organophosphates (OPs). OPP plans to present this assessment to the SAP for review/comment when completed. The assessment will provide tangible examples of how surrogate/bridging data may be used in such an assessment. Lessons learned from this use of surrogate data will be used to update this guidance in the future.

When data on and methods for estimating exposure by different pathways—food, drinking water, residential use—are of appropriate quality, OPP will combine exposure estimates for a quantitative, cumulative risk assessment. In other circumstances, however, OPP can perform sophisticated, refined probabilistic exposure and risk assessments for food exposure, but may only be able to conduct single-point (''deterministic'') exposure and risk assessments for non-occupational exposures, and screening level modeling estimates for potential drinking water exposures. Hence, OPP does not believe that it is scientifically appropriate in most cases to add exposures across these pathways to obtain a cumulative total. Nevertheless, OPP will consider the exposures and risks from all pathways ''in parallel'' and at a minimum will develop comparative qualitative assessments in order to complete the cumulative assessment and to help inform what regulatory action may be necessary to assure the full protection of human health.

It is OPP's goal to be able to combine exposures across all pathways as soon as scientifically reliable data and methodologies are available to do so. Toward this end, the Agency is making a concerted effort to develop or obtain new data and more sophisticated exposure and risk assessment methodologies. EPA's Office of Research and Development is planning and conducting new studies concerning exposure to infants and children related to non-occupational routes of exposure. OPP has also called in data from registrants for several non-dietary routes of exposure including dermal contact and hand/object-to-mouth contact with contaminated surfaces and toys. OPP is also working collaboratively with the U.S. Geological Survey to develop new regression-based, predictive modeling tools which OPP expects will allow for improved estimates of pesticide concentrations in finished drinking water. And many registrants are conducting studies on their own initiative that are generating additional exposure data for food, drinking water, and residential/non-occupational sources. Moreover, OPP is continuously developing and proposing through its science policies better methods for assessing exposure and risk. Finally, through publication of this draft science policy paper and others, OPP is seeking ideas, feedback, and recommendations from the SAP and the general public.

The guidance in this draft science policy paper lays down the following approaches and steps:

1. *Hazard assessment and characterization*. Hazard assessment and characterization emphasizes the analysis and integration of all relevant biological information in selecting the toxicological endpoint upon which to base the accumulation of the common hazard across multiple chemicals sharing a common mechanism of toxicity.

(a) *Weight-of-the-evidence*. A weight-of-the-evidence narrative should be included in the hazard characterization that clearly lays out a summary of the key evidence, describes the robustness of the data for characterizing the common mechanism of toxicity for each chemical member, characterizes the conditions under which the cumulative hazard may be expressed by route, pattern, duration and magnitude of exposure, and recommend the appropriate common toxicological endpoint(s) for dose-response assessment. Significant strengths, weaknesses, and uncertainties of the evidence are highlighted.

(b) *Common mechanism group*. A common mechanism group (CMG) is a group of pesticides determined to cause adverse effects by a common mechanism of toxicity. The CMG is defined using the previously released ''Guidance for Identifying Pesticide Chemicals and Other Substances that Have a Common Mechanism of Toxicity'' (64 FR 5796, February 5, 1999). Not all members of a CMG will necessarily be incorporated in the cumulative risk assessment.

2. *Dose-response assessment and characterization*. Dose-response assessment and characterization should provide a common and uniform basis for reliably determining each chemical member's relative toxic strength and contribution to the cumulative risk. For the common toxic endpoint, all dose-response assessments should include consideration of their relevance to assessing children's health risks by addressing whether key studies reflected dosing of adult age animals only.

(a) *Common point of departure*. A common point of departure (POD) on each chemical's dose-response curve is identified to determine its toxic potency relative to the other chemical members. This point of departure should be based on a common endpoint which is derived from studies using the same species/strain/sex and duration of exposure for each chemical member in the group. Thus, previous chemical-specific assessments and resulting reference doses may be inappropriate because they may be based on a different endpoint, strain, or duration of exposure.

(b) *Benchmark response or effective dose*. A common benchmark response or effective dose (ED) is the preferred point of departure to represent cumulative risk of the chemical group. Despite its limitations, the no-observed-adverse-effect-levels (NOAEL) will generally be used in the near term in many situations until the toxicological databases improve and permit reliable benchmark analysis.

(c) *Benchmark response or NOAEL*. After a benchmark response or NOAEL is designated for an individual chemical member, there may be chemical specific adjustments needed to normalize the response data across the chemical group to ensure a more nearly uniform point of departure.

(d) *Dose addition approaches*. Dose addition approaches are most appropriate to use for summing the cumulative hazard given that cumulative risk assessment will be based on chemicals sharing a common toxic effect that arises by a common mechanism of toxicity. Dose addition assumes that the chemicals of interest act on similar biological systems, behave similarly in terms of the primary physiologic processes (absorption,

metabolism, distribution, elimination), and elicit a common response. Thus, the cumulative margin of exposure approach or the relative potency factor approach are appropriate risk metric methods for normalizing exposure by accounting for the different relative toxic potencies of the group.

3. *Exposure assessment and characterization*. Exposure assessment and characterization for the cumulative risk assessment will, to the extent data permit, maintain the temporal and spatial linkages for the many factors defining a possible individual exposure. The assessment will be designed in cooperation with the risk manager to assure that all necessary questions regarding potential risk are answered, but that the assessment performed is consistent with the data available.

(a) *Aggregate assessment.* An aggregate assessment will be performed on each chemical that may be included in the cumulative risk assessment before the final assessment is designed. This step will ensure that the available data have been carefully evaluated with regard to their ability to describe the potential exposure of the population of interest to each chemical.

(b) *Focus on the major contributors to risk*. The cumulative assessment will focus on the major contributors to risk, permitting resources and risk mitigation activities to be developed that will most efficiently address likely risk reductions.

(c) *Data and exposure assessment methods' availability and quality*. Data and exposure assessment methods' availability and quality will also influence how comprehensive and refined an assessment can be performed. Data that lend themselves to distributional analyses should be used accordingly. Data that are less descriptive of the full range of potential exposures may be used in less comprehensive analyses. Where the quality of available data about exposure by different pathways varies greatly, cumulative assessments for individual pathways should be performed, but the exposure estimates for different pathways should not be combined quantitatively unless bridging data (surrogate data) are available. At a minimum, a qualitative assessment should be developed which covers topics such as comparative pathway analysis, high end exposure, variability, and uncertainty.

4. *Risk characterization*. The risk characterization contains the primary conclusions regarding the character and potential magnitude of the cumulative risk. Included in the characterization is a discussion of how well the data support the conclusions as well as identification of key uncertainties and uses of assumptions. The major chemical contributors to the cumulative risk, the scenarios of concern, and subpopulations of special concern including children, are also identified.

(a) A cumulative assessment group (CAG) is a subset of the CMG. The CAG is that group of pesticides selected for inclusion in the cumulative risk assessment. The chemicals in the CAG are judged to have a hazard and exposure potential that could result in the expression of a cumulative risk. Consideration of concurrent exposure is much greater for acute or short-term toxic effects because of the greater potential for more rapid onset of and recovery from the toxic effect. For chronic and cancer effects mediated through reversible precursor events, overlapping exposure should also be considered. For other chronic and cancer endpoints for which long-term exposure is necessary to cause the effect, concurrent exposures are not required for the chemicals to act by a common mechanism. Because of EPA's commitment to addressing those risks eliciting the greatest concern first, pesticides with essentially no exposure (as indicated by the single pesticide aggregate assessment) will be deferred from the CAG.

(b) The outcome of a cumulative risk assessment is viewed as important information that will help inform risk management decisions regarding possible mitigation options across all members of the CAG.

(c) There will not be one outcome but varying risk values for differing proportions of populations exposed to chances of adverse health effects resulting from different time scales of exposures.

(d) A composite group uncertainty factor is applied after estimating cumulative risk to account for inter-species and intra-species differences as well as uncertainties that are common and inherent to the chemical group.

In September 1999, EPA presented a preliminary draft of the hazard and dose response components of the draft science policy paper for review by the FIFRA SAP. The purpose of that review was to seek early comment from the SAP on the hazard and dose response analyses needed when accumulating risk from exposure to two or more chemicals that share a common mechanism of toxicity (i.e., guidance contained in chapters 3 and 5 of the draft science policy paper). The issues covered at the September SAP meeting included selection of chemicals, common end pont, and a point of departure; methods for estimating the cumulative effect of a common mechanism; and how to deal with uncertainty. Additionally, a preliminary case study was presented on organophosphorus pesticides illustrating the hazard and dose-response guidance. In November 1999, the SAP provided EPA comments on the September draft. A draft of chapters 4 and 6 of the draft science policy paper was also taken to the SAP in December 1999, for discussion of exposure and risk characterization components of this guidance document. The SAP's comments on the December draft were completed in February 2000. After the SAP comments and the public comments on the draft science policy paper are received and reviewed by the Agency, it will be reissued in a revised form for use within and outside of OPP.

The draft science policy paper discussed in this document 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.

IV. Questions/Issues

OPP invites public comment on the following issues and questions:

A. Issue 1. Selection of Chemicals for a Cumulative Risk Assessment

Chapter 3 of the draft science policy paper emphasizes that all chemicals which have been initially grouped by a common mechanism of toxicity are not necessarily appropriate for inclusion in a final cumulative risk assessment. There are both hazard and exposure considerations.

Question 1: Does chapter 3 clearly present additional hazard considerations that are needed to determine those chemical members which should be included in the final cumulative risk assessment?

B. Issue 2. Selection, Normalization, and Adjustment of the Point of Departure (PoD) for Cumulating the Common Toxicity

As discussed in chapter 5.1-5.2, a point of departure (i.e., a dose or

exposure metric corresponding to some fixed marker of toxicity) should be selected to sum the combined exposure for the chemical group. To the extent possible, the PoDs should reflect a uniform measure of the common toxic effect, which is produced by a common mechanism of toxicity, across the chemical members. A benchmark dose approach is preferred to derive the PoDs for each chemical member.

Question 2: In single chemical assessments, the Agency uses the upper bound estimates (i.e., the lower confidence limit on dose) for both cancer (called LED) and noncancer benchmark dose assessment. The concern has been raised, however, that summing upper bounds of multiple compounds may result in a exaggerated risk. Do you agree that it is more appropriate to sum the central estimates (i.e., ED) rather than combining upper bounds in the cumulative risk assessment of multiple chemicals? If not, why not?

C. Issue 3. Incorporation of Group Uncertainty Factors

As discussed in chapter 5.3, traditionally one or more of the uncertainty factors (UF) are used to derive a Reference Dose (RfD) for a single chemical. There are five uncertainty factors that are considered to account for the following extrapolations: LOAEL to NOAEL (UFL), subchronic NOAEL to chronic NOAEL (UFS), experimental animal to humans (UFA), interhuman variation (UFH), and incomplete database to complete database (UFD). It is proposed that the extrapolations of LOAELs to NOAELs or subchronic NOAELs to chronic NOAELs be applied as adjustments of a chemical's PoD before estimating the cumulative risk. These adjustments are meant to be based on some scientific data that permits a reasonable extrapolation or interpolation rather than applied solely as a science policy default decision. EPA further proposes that other traditional uncertainty factors be treated as a composite ''group uncertainty factor'' that pertains to the chemical members as a whole. Thus, the intra-species and inter-species UFs and the database completeness UF are applied as a composite group factor after cumulative risk is estimated (i.e., not before on each chemical's PoD). The rationale of the group UF is based on the premise that these factors should be viewed for the group as a whole given that all the chemicals are anchored by a common toxic effect produced by a common mechanism. Additionally, one is not simply evaluating risk in the context of a single chemical data base but the database for all the chemicals in the assessment. The advantage of a group uncertainty factor is that it allows one to separate the resulting risk that is based on scientific adjustments from judgmental policy decisions to account for uncertainty. Finally, EPA proposes that an FQPA safety factor decision be applied for the group rather than on individual pesticides.

Question 3: Do you agree with this approach, and does the draft science policy paper clearly describe the rationale and guidance for the implementation of chemical specific adjustment factors and of a group UF for the cumulative risk assessment? Has the draft guidance clearly presented the limitations and strengths of the group UF approach?

D. Issue 4. Methods for Estimating the Cumulative Toxicity

As discussed in chapter 5.6, one of the steps in the cumulative risk assessment process will be to select a method to cumulate dose or exposures. This method will serve to normalize differences in the toxic potencies among the chemicals in the cumulative assessment. Precedence in the Agency's 1986 and revised 1999 ''Guidance for Conducting Health Risk Assessment of Chemical Mixtures'' (http://www.epa.gov/ncea/pdfs/mixtures.pdf) describes several techniques for estimating risk to multiple chemicals. The cumulative guidance focuses on the component-based dose addition methods used in the EPA's chemical mixture assessment guidance document. Two methods, a margin-of-exposure approach and an approach using relative potency factors, are presented.

Question 4a: Do you agree that both methods are valid to consider for estimating cumulative risk associated with exposures to chemical that cause a common toxic effect by a common mechanism? Has the draft document clearly described these two approaches and their strengths and limitations? Are there other methods that OPP should consider?

Question 4b: EPA anticipates that most mechanisms of toxicity encountered currently will be nonlinear dose-response relationships. Nevertheless, for mechanisms of toxicity consistent with linear dose-response relationships, do you agree that using the relative potency factor approach by summing the slopes of the dose-response curves is an appropriate method? If not, what methods would you recommend for low-dose linear extrapolations of risk?

E. Issue 5. Case Study

In Appendix A of the draft science policy paper is a case study on organophosphorus pesticides.

Question 5: Does this case study provide a clear example of the application of the hazard and dose-response elements of the draft guidance?

F. Issue 6. Input Parameters

There are several types of data available for pesticide exposure assessment (e.g., field trial data, monitoring data, percent crop treated, label usage). For the food pathway, monitoring data are available from the USDA Pesticide Data Program (PDP). OPP conducts the majority of its drinking water assessments by calculating a screening level value. Similarly, residential assessments are conducted using the draft residential Standard Operating Procedures (SOPs) which also provide a screening level assessment. Thus, given PDP, the assessment of the food pathway will, in many cases, be based on higher quality data than for the residential and drinking water pathways where usually only screening values are available. Because of the different quality of data that will be encountered when conducting a cumulative exposure assessment, the concern is raised that the value and benefit of high quality monitoring data will be lost if combined with extrapolated exposure values from screening models.

Question 6.1: Please comment on how this concern could be addressed. For instance, should OPP at this time conduct separate pathway assessments for food, drinking water, and residential exposures so as to avoid combining higher quality monitoring data with more limited screening level data?

Question 6.2: Please comment on whether there are other means of dealing with existing data to reduce the uncertainties about exposure values derived from screening approaches.

Question 6.3: Please comment on whether and how OPP could incorporate quantitative uncertainty analyses in the overal cumulative risk assessment when OPP uses data of varying quality.

Question 6.4: Is it appropriate to extrapolate food exposure from residue field trials and use/usage information if food monitoring data such as USDA's PDP data are not available?

G. Issue 7. Deferral Criteria

OPP is proposing that deferral criteria be applied to ''negligible'' sources of risk in a full cumulative risk assessment. OPP believes that this

approach will permit a better focus on the more important sources of risk. It will also assist the risk manager in understanding and evaluating sources of risk that may provide the greatest benefit with risk mitigation activities.

Question 7.1: Please comment on whether the deferral criteria discussed in chapters 4 and 6 appear to be reasonable. Are there other exclusionary criteria that should be considered?

Question 7.2: Should OPP establish more specific criteria, for example, not only the magnitude of the exposure resulting from a particular chemical, use pattern or pathway, but also the size of the exposed population group?

H. Issue 8: National and Regional Exposures

The potential for people to encounter overlapping exposures to different pesticides will be influenced by many factors. One important consideration is the geographic effects and seasonal uses of pesticides. Thus, a framework is proposed for assessing different pathways of exposure that are essentially driven by these considerations. OPP believes that the food pathway should be approached on both a national and regional scale to account for both national and regional distribution of treated commodities. However, the OPP believes that residential and drinking water pathways are more appropriately dealt with on a regional or multi-state basis, since there is no single, national source of drinking water; and residential exposures may be driven by regional use patterns.

Question 8.1: Please comment on whether the concept of developing a series of cumulative assessments on a geographic scale for different pathways is reasonable.

I. Issue 9: Case Study

Cumulative risk assessment is at an early stage of development. Furthermore, there is very limited experience in conducting such assessments. Thus, the development of case studies using actual data are critical to refining useful and practical guidance, and to identifying future research and testing needs. OPP is taking a step wise approach to the development of such case studies by starting with simple examples and moving toward more complex situations.

Attached is a case study that uses actual food residue data on three pesticides and evaluates only a single pathway/route/duration of exposure. Certain assumptions were made in the case study. In single chemical exposure assessment, for example, nondetects are assumed to be one half the level of detection and composite samples are decomposited. In this case study, for illustrative purposes, nondetects were assumed to be zero, the samples were not decomposited, and surrogate data were not used.

Question 9.1: Given that an important goal of the cumulative assessment is to reliably determine sources of concern from a multi-chemical exposure, please comment on to what extent is it appropriate to apply standard practices and assumptions used in single chemical assessments.

V. Policies Not Rules

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

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

List of Subjects

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

Dated: June 22, 2000.

Susan H. Wayland,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–6727–5]

Draft NPDES General Permits for Water Treatment Facility Discharges in the States of Maine, Massachusetts, and New Hampshire

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notices of Draft NPDES General Permits—MEG640000, MAG640000, and NHG640000.

SUMMARY: The Director of the Office of Ecosystem Protection, EPA—New England, is issuing Notice of Draft National Pollutant Discharge Elimination System (NPDES) general permits for water treatment facility discharges to certain waters of the States of Maine, Massachusetts, and New Hampshire for the purpose of reissuing the current permit which expired on January 9, 2000. These general NPDES permits establish notice of intent (NOI) requirements, effluent limitations, standards, prohibitions and management practices for the water treatment facility discharges. Owners and/or operators of facilities discharging effluent from water treatment facilities including those currently authorized to discharge under the expired general permit will be required to submit to EPA—New England, a notice of intent to be covered by the appropriate general permit and will receive a written notification from EPA of permit coverage and authorization to discharge under one of the general permits. *The eligibility requirements are discussed in detail under section D.2.b and the reader is strongly urged to go to that section before reading further.* This general permit does not cover new sources as defined under 40 CFR 122.2.

DATES: For comment period: interested persons may submit comments on the draft general permits as part of the administrative record to the Environmental Protection Agency, New England Region, at the address given below no later than July 31, 2000. The general permit shall be effective on the date specified in the final general permit published in the **Federal Register** and will expire five years from the final publication date of the **Federal Register**.