U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Food Safety Advisory Committee

September - December 1996
Meeting Summary Compilation

Table of Contents

Documents referred to in the Meeting Summaries and other meeting materials can be accessed by browsing our website at
http://www.epa.gov/docs/opp00001/index.htm
or refer to the Docket #00450
The OPP Public Docket is located at
Room 1132
Crystal Mall II
1921 Jefferson Davis Hwy.
Arlington, VA 22202
703-305-5805

Summary Report

SUMMARY REPORT OF FOOD SAFETY ADVISORY COMMITTEE

Background on the Food Safety Advisory Committee

On August 3, 1996, President Clinton signed into law the Food Quality Protection Act of 1996 (FQPA) (P.L. 104-170). After years of debate in Congress over food safety and the inconsistencies between the two major pieces of legislation addressing pesticide usage, FQPA was passed unanimously by the 104th Congress with support from the Administration and a broad coalition of environmental, public health, agricultural, and industry groups. FQPA amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA gives EPA authority to register pesticides for use in the United States and prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on human health and the environment. Under FFDCA, EPA establishes tolerances (maximum legally permissible levels) for pesticide residues in food. Tolerances are enforced by the Department of Health and Human Services/Food and Drug Administration (HHS/FDA) for most foods, and by the U.S. Department of Agriculture/Food Safety Inspection Service (USDA/FSIS) for meat, poultry, and some egg products.

The new law is a comprehensive overhaul of the nation's food safety system that regulates pesticides on foods. The FQPA replaces the current tolerance-setting system with a single, stringent health-based standard for all pesticides in all foods to assure protection from unacceptable pesticide exposure ("a reasonable certainty of no harm"), provides new health protections for infants and children from pesticide risks, expedites approval of safer pesticides, creates incentives for the development and maintenance of effective crop protection tools for farmers, and requires periodic re-evaluation of pesticide registrations and tolerances to ensure that scientific data supporting pesticide registrations will remain up-to-date in the future, and contains new measures to expand consumers' right-to-know about pesticide health risks. Specific provisions include:

FEDERAL FOOD, DRUG, AND COSMETIC ACT PROVISIONS (FFDCA)

* General Standards for Tolerances
* Resolution of the "Delaney Paradox"
* Special Provisions for Infants and Children
* Consideration of Pesticide Benefits
* Endocrine Disruptors (Estrogenic Substances)
* Other Factors to be Considered in Setting Tolerances
* Consumer "Right to Know" Provisions

* Re-evaluation of Existing Tolerances

* International Standards for Pesticide Residue Levels

* National Uniformity of Tolerances

* Residue Monitoring and Civil Penalties

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT PROVISIONS (FIFRA)

* Periodic Review of Pesticide Registrations

* Emergency Suspension Authority

* Extension of Reregistration Fee Authority

* Minor Use Pesticides (including Public Health Uses)

* Review of Antimicrobial Pesticides

* Expediting Review of Safer Pesticides

* Maintenance Applicator and Service Technician Training

Most of FQPA took effect immediately upon the President's signature. Thus, the U.S. Environmental Protection Agency was immediately faced with having to implement new standards and requirements. Most of the pending decisions were put on hold until the Agency could determine how to implement the new requirements. To assist them as the Agency began implementation efforts, the Agency established an advisory committee, the Food Safety Advisory Committee (FSAC), as a subcommittee of EPA's National Advisory Council for Environmental Policy and Technology to assist them in soliciting input from stakeholders, including industry, environmental and health groups, scientists, pesticide user groups, farmers, state and federal agencies, public health community, Congressional staff, and American consumers. (A list of members and their alternates is contained in Appendix A.) The purpose of the Advisory Committee was to provide input to EPA on some of the broad policy choices facing the Agency and on strategic direction for the Pesticides Program.

The Food Safety Advisory Committee was chaired by Deputy Administrator Fred Hansen with Assistant Administrator for Prevention, Pesticides and Toxic Substances Lynn Goldman serving as Vice-Chair. Keystone Center staff facilitated the meetings. As a subcommittee of a federally chartered advisory committee, FSAC operated under the provisions of the Federal Advisory Committee Act (FACA). Thus, the meetings were open to the public, notice of meetings were placed in the Federal Register, at each meeting there was opportunity for public comment, and a

docket was kept. All materials related to the FSAC are maintained as a public record in the docket, number 00450.

The objectives of the Food Safety Advisory Committee (FSAC) were to:

- provide an opportunity for participants to inform EPA of issues regarding the new statute;
- identify several priority issues to pursue through discussion and possible consensus building; and,
- discuss aspects of the Agency's implementation plan presented to the Advisory Committee for review.

Given the Agency's desire to have the Office of Pesticide Programs making decisions under the new law as soon as possible, it was decided that the FSAC should meet four times between September and December. The short duration of the Advisory Committee reflected the need and desire of the Agency to have the Committee address strategic, policy-level questions, not the details of implementation. It was explained that the Agency's goal was to publish a detailed implementation plan early in 1997. The first meeting of FSAC was held on September 26, 1996. Subsequent meetings were held October 14-15, November 21-22, and December 5, 1996.

An important point that was reiterated frequently throughout the four meetings is that the goal of the FSAC discussions was NOT consensus; it was to get input from the members. If consensus developed, it would be documented.

Questions posed to the FSAC initially to guide discussions included:

- What priorities should EPA establish for implementation of the FQPA (e.g., within all of the new provisions)?

- Given the new provisions and associated requirements, are there current regulatory activities in EPA's Pesticide Program that should be eliminated or given lower priority as EPA begins implementation of the FQPA?

- How can EPA most effectively balance its mandate to protect human health with its mandate for protecting the environment?

- What are the roles for growers, other federal agencies, states, registrants, the public, etc. in implementation of FQPA?

- What are the communication activities that should be undertaken as a part of implementation?

- How should environmental justice concerns be considered as a part of implementation?

- How can the concept of community-based environmental protection be incorporated into implementation of FQPA?

Topics Addressed by FSAC

During the FSAC meetings, input was given to EPA on which provisions should be given priority during the implementation process. As a part of these meetings, FSAC members also identified and discussed concerns related to the interpretation of specific provisions. Following are brief summaries of the topics and concerns raised at each of the FSAC meetings. More detailed meeting summaries, for each meeting, are attached as appendices to this report.

First Meeting - September 26, 1996

This was an organizational meeting. EPA outlined the objectives of the Committee which are to provide input on implementation of the FQPA; it was noted that consensus would not be sought. EPA provided a review of the major provisions of the FQPA and indicated the major changes from previous law. The Committee agreed to groundrules. The remainder of the meeting was spent identifying issues to be covered at the subsequent three meetings including:

- Section 18's
- Worker Concerns
- Infant and Children Provisions
- Minor Uses
- Communication and Right to Know
- Impacts on IPM
- Resources for Implementation
- Transition Issues - Both Short and Long Term
- Aggregate Exposure
- Common Mechanism of Toxicity
- 10-fold Uncertainty Factor
- Reduced Risk Pesticides

Second Meeting, October 22-23, 1996

Prior to the second meeting, conference calls were held for participants to discuss questions raised by EPA in a series of prepared background papers. Written summaries of the conference calls were distributed to FSAC members and a brief verbal summary was used to initiate discussion of each topic. The topics addressed were communication, risk, minor uses, reduced risk pesticides, and benefits. The main points made in the plenary discussion for each topic are outlined below.

Resources

The following reflects many of the concerns raised by members during the discussion:

- Recognition of the tremendous size of the task before EPA to implement the FQPA (e.g., currently making 300 tolerance decisions a year; under FQPA, EPA will need to make about 900 per year.) and the amount of resources that will be needed.
- Congress has appropriated an additional $30 million for implementation of FQPA and the Safe Drinking Water Act. Many members urged EPA to allocate much of it to FQPA activities.

Communication and Right-to-Know

The following reflects many of the concerns raised by members during the discussion:

- Brochure for distribution in grocery stores is required by FQPA. Many members felt that development of it should be the Agency's priority.
- A number of members stressed the need to test the message to be used in the brochure to determine the best message to use (i.e., communicates the message in an understandable manner.)
- Several members suggested that EPA needs to identify the audience for the brochure and write the materials towards that group.
- Many members suggested that the audience should include low income consumers; it was observed that this is a different audience than that being reached by the EPA hotline. (Resource problems associated with the hotline were raised and discussed.)
- Some members urged the use of partnerships to leverage resources as well as to provide additional credibility.

Risk: Aggregate Exposure and Common Mechanism of Toxicity

The following reflects many of the concerns raised by members during the discussion:

- Some members raised concerns about data gaps and how they would be addressed.
- Most members seemed to support the idea of using defaults when data are not available; they did not, however, agree on how defaults would be determined.
- Concern was expressed by a number of members about the quality of data to be used in decision-making.
- Many members identified the need for a transparent process so that growers and others would understand how decisions are made.
- Members considered the three approaches outlined by EPA in the background paper (requiring data that demonstrate common mode of action, using structure activity relationships to group chemicals, and grouping chemicals with common endpoints) to determine common mode of toxicity. Many of them felt that all three should be considered and the appropriate one used for each case.

- Some members suggested that EPA should consider the use of time limited tolerances when they use defaults.
- Issues around lack of data on aggregate exposure were raised.

Minor Uses

The following reflects many of the concerns raised by members during the discussion:

- Communication to growers about products at risk.
- Discussion of uses retained tends to include only registrants and EPA; a number of members urged greater and earlier involvement of growers.
- It was observed by several members that the need for additional data under FQPA places an increased burden on growers to gather and provide data. It was also noted several times that growers can provide data on actual usage.
- The idea of reserving a portion of the risk cup for minor uses was raised. It received mixed reviews.
- Concern was raised by a number of members about the impact of FQPA on the adoption of IPM.
- Some members suggested that the loss of minor use products may drive fruit and vegetable production offshore.
- A number of members urged that USDA and EPA look proactively for alternatives to chemicals that are likely to be canceled.

Reduced Risk Pesticides

The following reflects many of the concerns raised by members during the discussion:

- Many members pointed to the current lack of resources in this program. The background paper had noted that more than two applications will overwhelm the program's capabilities.
- Discussion by the members reflected confusion over whether the goal of this program was to address absolutely safe products or those that are relatively safer.
- Members acknowledged that if the scope is defined too broadly, too many applications will qualify and the program will be overwhelmed.
- Possible measures for success of a reduced risk pesticides program were identified.

Benefits

The following reflects many of the concerns raised by members during the discussion:

- Members discussed what kind of benefits are to be considered under FQPA and which under FIFRA.
- FQPA allows the consideration of benefits only if there is a "significant disruption of the food supply." Members questioned how that would be defined.

- It was observed that decisions have rarely been driven by economic considerations in the past, it is unclear how benefits will be used in the future.

Proposed Interim Decision Logic

EPA staff presented a proposed interim decision logic that outlined how an application for a chemical may be handled under FQPA. Many of the members stated that at first glance the logic seemed to make sense. Several noted that the devil is in the details, but it at least gave them something to consider. The proposed logic or process was refined further between the October and November meetings.

Third Meeting, November 14-15, 1996

The third plenary session addressed the topics originally identified at the first meeting as well as some that had arisen during the October meeting. Topics included workers' issues, human health risk assessment (in utero, 10-fold uncertainty factor, and aggregate exposure), tolerance reassessment, Section 18's, and the proposed interim decision process. At the meeting, USDA staff provided brief overviews of their programs that address pest management and information collection.

Tolerance Reassessment

The following reflects many of the concerns raised by members during the discussion:

- EPA presented its proposed strategy for reassessing tolerances. It was noted that FQPA will change the Agency's priorities for the reregistration process.
- Several members raised concerns about the lack of adequate data on aggregate exposure.
- This discussion resulted in members identifying concerns about the process to be used for categorizing chemicals under the common mode of toxicity requirement. That such grouping will draw in other chemicals was addressed and members explored with EPA staff how this would be handled.
- Problems with data on exposure and on common mode led to the restatement of concerns about defaults, data gaps and the magnitude of resources needed to accomplish this task.

Worker Risk

- EPA staff presented their current activities to address risk to workers: the worker protection standard, certification, decontamination procedures, etc.
- Some members detailed their experiences which suggest that workers have safety problems due to increased exposure and increased risk of injury and disease.
- Several members urged EPA to consider worker exposure when they are calculating aggregate exposure.
- Concerns about the quality of information on worker exposure was raised by some members.
- Some members noted that worker training and education are successful in protecting workers.

Human Health Risk Assessment

- In utero testing and the 10-fold uncertainty factor were presented to the Scientific Advisory Panel (SAP) at its' October meeting. Dr. McConnell, chair of the SAP, explained the SAP process and its preliminary findings. Based on the studies reviewed, the SAP agreed with the Agency that there is not convincing data that pre-natal exposure does increase the incidence of cancer. Thus, in utero testing would not be required in all circumstances.
- On the 10-fold uncertainty factor, the SAP agreed that there is a need for an additional uncertainty factor on a case-by-case basis and that the Agency should use a weight-of-evidence approach.

Section 18's

- EPA explained the Section 18 process and how decisions are made, especially that EPA now has to establish a time limited tolerance when it grants a Section 18.
- Some members expressed concern about the potential for Section 18's to utilize all available resources.
- A number of members pointed to the amount of information that will now be required and questioned whether Section 18's will be viable since emergencies cannot be planned.
- Concern was also raised about the potential that the Agency may not be able to respond in a timely manner.
- Some members suggested that one way to address some of the anticipated problems with Section 18's is to give more responsibility to the states.
- Some members urged that there be a special process for deciduous, perennial crops that allows them to submit Section 18's months in advance.

Proposed Interim Decision Process (Revised)

EPA presented a flow chart of the revised process to further reflect the comments received. Subsequent discussion addressed issues raised such as aggregate exposure and different ways to handle defaults as presented in the handout illustrating possible options.

- Many members asked clarifying questions. Many of the members preferred the option that provided the most detail. EPA staff noted that the tradeoff is between the amount of data needed for that option versus the need to make decisions in a timely manner.
- Some members suggested that EPA use a phased approach - start with the option that requires the least data and move through the others if the product would not qualify and if additional information is available.

Fourth Meeting, December 5, 1996

At the fourth and final plenary meeting, the FSAC was asked to comment on the Draft Implementation Plan Outline and to continue discussions on minor uses and the Section 18 program. The discussion of the Draft Implementation Plan included their consideration of the approach to science assessment, interim decision logic for screening risks, and the tolerance reassessment program. Following the group's discussion of these topics, EPA expressed appreciation for the time and commitment of Committee members throughout the process and invited them to take part in future fora which would provide additional opportunities for public comment.

Draft Implementation Plan Outline

EPA presented an overview of the Draft Implementation Plan Outline. They explained that, in addition to providing context and background on the FQPA, the plan includes guidance on the approach to risk assessment, requirements for minor uses, description of other regulatory requirements, plans for public outreach, and additional sources of information.

Approach to Science Assessment

Following is a summary of key discussion points made by members:

- EPA addressed three major issues addressed by the science assessment: protecting sensitive populations, including children; aggregate exposure; and common mode of action. They noted that a fourth major issue, endocrine disruptors, would be addressed in another forum.
- Several participants wanted EPA to explain their choice to use common mode of action versus mechanism of action and expressed concern that the choice be consistent with the meaning of the law. EPA is currently trying to determine how to pragmatically comply with the "common mechanism" provision; this issue was taken up at the March SAP meeting. In the meantime, EPA felt that describing the "common mechanism" provision using the term "common mode" was a compromise.
- Other participants requested that EPA clarify how they interpreted the additional uncertainty factor (up to 10-fold); starting with 10-fold uncertainty factor unless data showed otherwise, or basing it on the weight-of-evidence? EPA explained that additional information about the uncertainty factor will be available soon after the Agency considers the SAP review of the issue.
- Many members wanted reassurance that there would be additional opportunities to evaluate and comment on the issues presented. EPA assured members that there would be additional opportunities.

Interim Decision Logic for Screening Risks

Key aspects of EPA's presentation and subsequent discussion on the interim decision logic for screening risks are summarized below:

- EPA presented an updated proposal for the reregistration and registration decision process and summarized the interim decision logic, stressing that it was conditional and time-limited.
- EPA explained the three revised risk cup options to determine the percent of risk to reserve in the risk cup. EPA identified Option 2, which allows categorization of active ingredients based upon the level of risk (high and low), as their preferred option.
- Several members raised concerns about the use of defaults to determine the percent of the risk cup to reserve, particularly for lawn and residential exposure. EPA explained that they would use defaults only when data were not available. They welcomed other sources of data and requested that members provide guidance on how to allocate the risk cup fairly.
- Some members wanted clarification on how this process would apply to non-food uses. EPA explained that they would consider non-food uses when characterizing aggregate exposure and when sensitive populations could be affected.
- Many members were concerned about what and how subpopulations would be addressed. EPA noted that there were 22 subpopulations identified in the food consumption surveys and that subpopulations are generally the driving force when allocating risk.
- After some discussion, many members supported the use of Option 2.
- At the close of the discussion, EPA reiterated that members were invited to take part in the information-sharing meeting on interim decision logic on December 12, 1996 at EPA.

Tolerance Reassessment Program

After EPA presented a summary of the proposed tolerance reassessment program, the following key points were made:

- Several members were concerned about whether EPA had sufficient resources to devote to the proposed program. EPA noted that they were evaluating the demand for resources.
- Other members wanted EPA to explain what happens to pesticides for which reregistration is close to completion. EPA explained that they will be scheduled for consideration in 1997 and 1998.
- Some members questioned the efficacy of time-limited decisions. EPA acknowledged the concern and suggested that the group consider and propose more effective alternative strategies using coalitions in the user community.

Minor Uses and Section 18 Program

Some of the key elements of the discussion on minor uses and the Section 18 program are summarized below:

- EPA addressed the overall implementation plan of the minor use program, the results of the Section 18 Workshop, the status of Section 18 activities, and current Section 18 decisions facing EPA.
- Several members wanted to know how EPA planned to involve the grower community to address concerns which included crop size, expediting reduced risk pesticides, the safety of using weight-of-evidence to address worker safety, and criteria for risk allocation. In addition, suggesting that the grower community could become more involved by providing EPA with additional data, some members proposed that EPA arrange to hold structured meetings with the minor use community and work closely with other affected agencies.
- EPA supported this suggestion and requested that USDA lead the effort to bring the registrant community, grower groups, and the agencies together to recommend to EPA what criteria should be used to allocate risk.
- EPA also presented an example of a pending Section 18 decision on two unregistered fungicides on seed corn. EPA indicated that it was concerned about whether these could be granted based on its interpretation of the new requirements. [Note: Since the meeting, these two Section 18's were granted.]
- Many members felt that the example was not a good one because seed corn is not a food. They urged EPA to use common sense when assessing risk.

Next Steps for Implementation of the Food Quality Protection Act of 1996

At the conclusion of the last meeting on December 5, both Fred Hansen and Lynn Goldman thanked Committee members for the time they spent participating in the FSAC and their input. From their perspective, the Committee's discussions had met the objectives laid out for the Committee. As a result, EPA had a clear sense of stakeholders' concerns and had received valuable feedback on initial policy directions. (e.g., the decision process and the risk cup).

Even though the FSAC will no longer exist, Committee members and others were encouraged to continue to provide EPA staff with input as implementation of the FQPA proceeds. They were reminded that a number of other fora exist for providing input including the Pesticide Program Dialogue Committee, the Endocrine Disruptors Screening and Testing Advisory Committee, the Scientific Advisory Panel, etc.

Building on these discussions and efforts underway within the Agency, the Office of Pesticide Programs noted that they hoped to receive comments on the draft implementation plan outline from Advisory Committee members by December 20, 1996.

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September 26, 1996
Meeting Summary

FOOD SAFETY ADVISORY COMMITTEE
First Plenary - Meeting Summary
September 26, 1996
Washington, D.C.

Chairman: Fred Hansen, Deputy Administrator, US EPA

Vice Chair: Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, US EPA

Members: Jose Amador, Texas A & M University; Ira Arlook, Citizen Action; Mark Atwood, American Cyanamid; Elaine Auld, Society for Public Health Education, Inc.; Cynthia Bearer, Case Western Reserve University; Emilio Bontempo, Ciba-Geigy Corporation; Daniel Botts, Florida Fruit and Vegetable Association; Carolyn Brickey, National Campaign for Pesticide Policy Reform; Arnold Donald Monsanto Company; John Hagaman, DowElanco; Richard Jackson, Centers for Disease Control and Prevention; William Kirk, DuPont Agricultural Products; Dean Kleckner, American Farm Bureau Federation; Ramon Llenado, The Clorox Company; Genevieve Matanowski, John Hopkins University; Kathleen Merrigan, Henry A. Wallace Institute; David Moore, Western Growers Association; Jane Perkins, AFL-CIO; Jean Pettibone, American Agri-Women; Richard Rominger, USDA; James Wells, California EPA

Alternates: Steven Balling, Del Monte Foods (alternate to B. Haycox); Philip Barnett, FDA (alternate to B. Schultz); John Barnett, Ciba-Geigy Corporation (alternate to E. Bontempo); Stephen Berzon, Altshuler, Berzon, Nussbaum, Berzon & Rubin (alternate to J. Perkins); Mark Childress, Environmental Working Group (alternate to K. Cook); Judith Conover, League of Women Voters (alternate to B. Cain); Luke Cole (alternate for R. Abascal); Larry Elworth, USDA; Jeff Foran, ILSI Risk Science Institute (alternate to G. McConnell); Anthony Hepton ; Richard Kirchhoff, National Association of State Departments of Agriculture (alternate to A. Tracy); Lynn Jenkins, NIOSH (alternate to Linda Rosenstock) Elin Miller, DowElanco (alternate to John Hagaman); Al Meyerhoff, NRDC (alternate to John Adams); Eric Olson, NRDC (alternate to John Adams); Nancy Rachman, American Cyanamid Company (alternate to M. Atwood); Jan Relford, Gerber Products Company (alternate to A. Piergallini); William Spain, Del Monte Foods (alternate to B. Haycox); Richard Wiles, Environmental Working Group (alternate to K. Cook)

Ex Officio Members: Linda Fisher, Monsanto Company; Steve Jellinek, Jellinek, Schwartz & Connolly, Inc.; Jack Moore, Institute for Evaluating Health Risks

Congressional Participants: Eric Berger, US House of Representatives; Howard Cohen, US House of Representatives; Curt Mann, US House of Representatives; Greg Dotson, US House of Representatives Dale Moore, US House of Representatives; Terri Nintemann, US Senate; Philip Schiliro, US House of Representatives;

OPENING COMMENTS

Deputy Administrator Fred Hansen welcomed everyone and asked them to introduce themselves. Fred Hansen noted that the Agency is wrestling with the issues of finding resources to implement the Food Quality Protection Act of 1996 (FQPA). He jokingly commented that with the amount of interest expressed about participating in this Committee, if EPA had charged admission, they could offset a large amount of the costs. On a serious note, he commented that it is gratifying to see the level of interest and participation. He stated that he values the commitment people from all sectors have made to participate in this process.

He stated that EPA is committed to implementing the FQPA in the most effective way; as a part of that effort, he and the Agency feel the need to involve stakeholders in processes such as the Food Safety Advisory Committee (FSAC).

He noted the feedback Keystone has received regarding the adequacy of the Agency's resources to implement the law. He commented that the Agency and the Administration are working with Congress to ensure adequate resources for proper implementation of the FQPA as well as for the recently enacted Safe Drinking Water Act. He went on to explain that the on-going budget process is quite advanced for the next fiscal year but they are still trying to address the need for additional money to support these recently passed pieces of legislation.

He then explained that those in the Agency see FQPA as a sweeping change in the way pesticides are regulated in the country. From the Agency's perspective, this Advisory Committee is vital to help EPA shape the strategic direction for the Pesticides Program. This Committee provides an opportunity to look forward to implement a new law and to have input on some of the broad policy choices the Agency is facing. He cautioned however, that the purpose of this Committee is not to re-argue old issues or re-open the Act.

He explained that the purpose of the Advisory Committee is to identify critical issues associated with the law, assist EPA in making the choices, and set a direction that will shape not only pesticide policy but also policies across EPA. He further explained that the goal is not to address the details of implementation, but to convene a broad, high-level stakeholder group that will assist the Agency in some of the broad policy choices. He counseled the Committee members that they will need to focus on broad policy not details. It is an opportunity that is aimed at enhancing communication among all parties.

To provide a bit of background on the FQPA, Hansen noted that this major piece of new law did not have extensive hearings and debates at all stages of the legislative process to provide a legislative history to guide implementation. The law went through Congress quickly and received unanimous passage. As a result, he explained that the Agency lacks some of the direction which normally arises from such documentation. This lack of background presents both an opportunity and a challenge. It will be a hard task for the Agency, but, it gives them a chance to help define the direction of the implementation.

He then stated that the existence of this Committee is not intended to slow down progress being made by the Agency to implement the law. He noted that those in the Agency are aware that the decisions being made by the Agency are time-sensitive and need to be made without delay. He commented that it is critically important to remember that the standards of the new law immediately became effective upon the President's signature. He believes that all Agency decisions must reflect the new standard from its effective date. They will do the best job they can to insure that interim decisions made while the law is being implemented reflect the requirements of the new law. He commented that he is aware that there are a number of parties interested in every step of the law's implementation. He observed that if all had been invited to be involved in the Committee, it would have required a huge table. To accommodate those not at the table, time has been set aside time for public comment.

He expects that the Advisory Committee will only last three to four months. The short duration for the Committee underscores the need and desire to address strategic, policy-level questions, not the details of implementation. He also stated that the Committee will not be seeking consensus. The primary objective is to seek a wide spectrum of input from all stakeholders. He noted that, if in the course of discussions the members can reach consensus, that is all for the better and will help the Agency, but it is not the goal. The goal is to have dialogue and provide opportunities for input.

He also noted that other mechanisms exist for input; they are either being put in place currently or already exist. Some of the existing entities (e.g., FIFRA Scientific Advisory Panel, Science Advisory Board) will give expert advice on scientific issues to EPA. At its next meeting in October, the Scientific Advisory Panel (SAP) will address the 10-fold uncertainty factor for the protection of infants and children among other issues. Additionally, the Pesticide Program recently established the Pesticide Program Dialogue Committee that will play a long term role in providing guidance on policy and program implementation issues. He also noted that the Agency is in the process of establishing the Endocrine Disruptor Screening and Testing Advisory Committee. It will assist the Agency in developing a strategy to screen and test endocrine disrupting chemicals and pesticides in humans, fish, and wildlife as called for in FQPA. As well, the Agency has other standing groups or committees that seek input from states (co-regulators) and others. Thus, this is not the only forum from which the Agency will receive input.

He then observed that some issues may be better handled by one of these other groups. He further noted that the Agency also has plans for numerous workshops, meetings, etc. to provide forums for discussion.

Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances and Vice Chair of the Committee spoke next. She, too, stated that she appreciated everyone's participation in Advisory Committee. Next, she explained that her program is responsible for implementation of FQPA. She and her staff feel that input from people such as those on this Committee is essential. They feel the new law creates unprecedented opportunities to protect the health of people, specifically children. She observed that the new law builds on principles that have been used by the Program as they have made decisions which include the protection of

children, use of sound science, expansion of information available to the public, common sense, and pollution prevention.

Although FQPA was passed in a relatively short time, she noted that the new law builds on years of discussion including several National Academy of Science (NAS) studies, the Keystone National Policy Dialogue on Food Safety and Pesticides, Congressional hearings, etc. To provide further background, she explained that in 1993, EPA, USDA, and FDA worked together to develop a policy package that was acceptable to all agencies; they then announced a joint food safety initiative which was submitted to Congress as proposed legislation in 1994. This initiative provides part of the basis for the passage of FQPA.

With passage of the new law, she explained that EPA is working hard to make the substance and spirit of the law reality. She noted that the Agency recognizes the need to move expeditiously so that industry can make strategic decisions.

She then stated that decisions must be fair and take advantage of sound science. She observed that the workload associated with implementation is substantial. However, for her program, the work is meaningful and important for safeguarding the health of the American public.

Next, Michael Lesnick, from The Keystone Center and one of the facilitators for the FSAC, explained the role of The Keystone Center which is to facilitate the meetings, document the discussions in meeting summaries, and handle meeting logistics. He then reviewed the suggested ground rules. A copy of the ground rules as agreed to by the FSAC members is attached. Lesnick stressed the importance of adhering to a key ground rule that addresses members' interactions with the media. It states that members are free to speak for themselves; however, they are asked to not characterize the opinions of others. They should suggest that the media go directly to those people to receive their opinion.

He also explained that this Advisory Committee will operate under the provisions of the Federal Advisory Committee Act (FACA). This means that meetings will be open, notice of meetings will be placed in the Federal Register; and a docket will exist. The number of the docket for this Advisory Committee is (#00450). During each meeting, at least a half hour will be designated for public comment.

He also reiterated the objectives for the Advisory Committee. They are to: help shape the strategic direction taken to implement the legislation; provide an opportunity for participants to inform and provide assistance to EPA on issues of concern; and, react to EPA proposals. He reiterated that the goal of the Advisory Committee is to provide input; it is not necessarily to develop a consensus although if one emerges it will be documented. On procedural matters, the Committee will operate on a consensus basis. On substantive matters, any recommendations made will reflect an explicit consensus of the Committee, if one exists. Where differences exist, the differences will be clarified and presented.

He further explained that members are appointed to the Advisory Committee by Fred Hansen. The three former Assistant Administrators will serve in an ex-officio capacity; congressional staff

will participate as observers. The Committee will operate generally as a committee of the whole. Sub-groups may be created to develop materials to place before the Committee; their membership will be structured to insure diversity in membership. As a housekeeping matter, he asked members to please identify an individual who will serve as their alternate.

Next, Michael Lesnick reviewed the agenda. He explained that the first meeting is primarily organizational in focus. During the course of the meeting, members would be presented with an overview of the legislation and what is going on currently in the Agency to implement the law; participants would be asked to identify key issues of concern to them; and, based on those discussions, the Committee would develop a work plan for committee and subsequent meetings.

Being responsive to the scheduling needs of several of the congressional staff who were scheduled to speak later in the day, Fred Hansen modified the agenda to allow them to present their perspective on FQPA immediately.

Howard Cohen, Counsel, House Committee on Commerce, spoke first. He noted that FQPA went through the Commerce Committee in July. He observed that it is truly a product of bipartisan negotiation. As many on the Committee are aware, he stated that the issue has been around for years. As one example of the length of time the topic has been debated, at the signing of the law, Congressman Roberts said he had worked on this issue as a staff person and thought it would never be solved. He noted that the law passed with unanimous votes in the Committee and in both bodies. He stated that the original Keystone National Policy Dialogue on Food Safety and Pesticides enabled the passage of the law to happen. Many of key actors on this issue were involved in that effort and they had wrestled with many of the ideas in the bill during their discussions in the Dialogue. He further noted that the bill's passage required give and take. A coalition made up of growers, farmers, producers, and chemical companies supported the legislation. He observed that any one of them could have stopped the bill at any time. He stated that the Commerce Committee Chairman was pleased such a diverse group supported this bill.

He then noted that the regulatory process is now upon all concerned. Due to their busy schedules over the past few months, congressional staff have not had the time to focus on implementation issues. They look forward to having the opportunity to do so. He noted that the Commerce Committee will have a very active role in oversight because of their interest. In terms of implementation, he urged the Agency: be timely with implementation; utilize sound science; have a transparent decision-making process; and, to use a problem solving approach to developing recommendations in order not to create new Delaney paradoxes. He noted that the intent behind the law was to remove a roadblock. He hopes that oversight will be bipartisan. He also wanted to thank The Keystone Center for their role in this meeting and having convened the original Dialogue. He felt that the Dialogue contributed substantively to educating staff so that they were able to address a set of complicated issues.

Phil Schiliro, Chief of Staff, Office of Representative Waxman, spoke next and stated that he would not be here without the work that Howard Cohen and Eric Berger did to find creative solutions to these issues. He stated that the effort was a wonderful bipartisan process. He then

observed that the challenges faced by EPA are not much different than those faced during the legislative negotiation.

He explained that in the passage of the legislation, they tried to draft a law that addressed pesticides that are not safe and to eliminate unnecessary risk. The goal was not to eliminate all pesticides and all risk. He stated that significant foci of the law were protection of children, increasing consumer information, and ensuring the use of sound science in decision-making. In that spirit, a balanced law was sought; staff and members were not just looking out for their own respective interests but for the common good. He suggested that this Committee do likewise. He noted that the regulatory process outlined is aggressive, but, he stated that it is not in anyone's interest to go slow. He urged the Agency to implement the law as competently as possible. He explained further that industry needs to be certain of how the law will be implemented and consumers need to be assured that their food supply is safe. He concluded that he will try to participate in the Advisory Committee as much as possible.

Dale Moore, Legislative Director of the House Committee on Agriculture, thanked EPA for the invitation. He stated that during the debate over the legislation, jurisdictional issues had existed between the Agriculture Committee and the Commerce Committee. He explained that the Agriculture Committee was not trying to usurp jurisdiction from the Commerce Committee. He noted that the hard work done by the Commerce Committee needs to be acknowledged. He observed that resolving the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) side of the food safety issues was easy; the Federal Food and Drug Cosmetic Act (FFDCA) was far more difficult. He echoed what had been stated by the other Congressional staff. He stated that the House Agriculture Committee wants to see sound science be the guiding principle. They feel that the law gives the Agency maximum flexibility to be "creative" and reasonable and rational in addressing these issues and to take advantage of changes in technology. He urged the Agency to move expeditiously as it proceeds to implement the law. He noted that the Agriculture Committee was aware of the lack of transition time in the law; however, they feel that the needed flexibility and authority exists in the law for the Agency to use during the transition. Thus, more time is not needed.

Next, Jim Aidala, Associate Assistant Administrator for Prevention, Pesticides, and Toxic Substances, presented an overview of the FQPA and explained the current activities underway. As already mentioned, the FQPA amends FFDCA and FIFRA and took effect immediately. He explained that key points to the legislation are that the law: replaces the Delaney clause by providing for a single uniform health-based safety standard of "reasonable certainty of no harm;" incorporates children concerns with special provisions for infants and children; calls for consideration of aggregate exposure when setting tolerances; includes benefits considerations for tolerances with specific limits; requires review of all tolerances within ten years of August 3, 1996; identifies explicit factors to consider in setting tolerances; sets up a process for consideration of endocrine disruptors; includes a consumer Right-to-Know Provision which require the development of an annual pamphlet on risks and benefits of pesticides; sets a national standard for tolerances; and allows states to petition for exceptions based on specific local situations. The law also enhances enforcement of pesticide residue standards, provides for FDA

to assess civil penalties, and allows for additional money to be raised to support the reregistration program.

In considering the changes, Jim Aidala explained that most of the work on the FIFRA amendments was done in 1995. Specific to FIFRA, the new law changes the registration program; it requires that every fifteen years a registration must be renewed to make sure that it meets current standards. On the reduced risk pesticide program, the law provides incentives for "safer" pesticides so that they will reach the market quicker. The reregistration program fee authority was extended. He observed that the reregistration process is the place where much risk reduction is achieved.

He explained that the law establishes programs in EPA and USDA to support minor use pesticides. This includes a revolving grant program, the extension of time for data submission, and the exclusive use of data for one year. For antimicrobials, the law makes changes that result in shorter review and decision times.

Having identified the major provisions of the new law, Jim Aidala asked a number of EPA staff to present the current Agency activities to implement the law.

Anne Lindsay, Director, Policy and Special Projects Staff, OPP, OPPTS, reviewed the overall organization of EPA's efforts. She referred members to the organizational chart contained in the notebook. The three boxes -- antimicrobial, food quality implementation committee, and endocrine disruptors committee represent the three main activities underway. The bulk of the concern for most people is with the middle box. Senior managers in the Pesticide Program have identified six initial teams to address the most critical areas of implementation.

Also included in the notebook, is a chart of the other on-going efforts being used by the Agency. These include the FIFRA Scientific Advisory Panel, Science Advisory Board, Pesticide Program Dialogue Committee, etc. She reiterated that there are numerous ways to get advice and input to EPA. The Pesticide Program intends to take advantage of all sources of input.

Dr. Penny Fenner-Crisp, Deputy Director, OPP, OPPTS, provided more detail on the Agency's efforts to address risk. This task is being coordinated by the Risk Characterization Committee. Much of the risk aspects were addressed in amendments to FFDCA. This committee, composed of EPA staff, will attempt to address data and science gaps. She commented that it is not an easy process. They have started to address specific aspects of the law, many of which they had been considering for the last three years, since release of the National Academy of Sciences Study on infants and children. Some of the questions they are facing include the uncertainty factor as outlined in the law and in-utero exposure. Both of these issues will be discussed at the next meeting of SAP.

Other risk issues are not ready for consideration by the SAP; these include age-related differences (i.e., children may be more sensitive). Other issues of concern to FSAC include:

- Cumulative exposures -- How does EPA take this into account? Include non-food sources or not? Are there potentials for exposures from non-pesticide uses (e.g., Superfund sites)?

- Common mechanism of toxicity -- The Agency addressed this recently in the cancer guidelines but will need input about how to define this term and what groups of chemicals should be evaluated as a group.

- Endocrine screening program -- the very short time-frame required within the law.

Stephen Johnson , Director, Registration Division, OPP, OPPTS, spoke next about efforts underway to address Section 18 requests and the overall registration process. He stated that the first issue they faced associated with implementation was Section 18 decisions. They had 30 Section 18 requests pending for 19 pesticides and 28 different crops. Under the provisions of the new law, they need to establish a tolerance and meet new standards in setting that tolerance.

To address the requests that had already been received, he explained that they put together a team to develop interim criteria to consider when examining these requests. While developing these screening criteria which are really questions to consider, they have made their first Section 18 decision; it applies to a miticide.

He noted that the remaining requests have been screened. They have determined that two chemicals did not meet the new standard based on available information; therefore, there will be no tolerance at this time and a Section 18 will not be granted. In the next week or two, the Agency will provide guidance to state officials to clarify information that the Agency will need for Section 18 decisions. The new law requires the issuance of regulations by one year from the August 3 date of enactment. A public meeting will be held November 1996 to receive input to assist in the development of the new Section 18 regulations.

He went on to note that the Agency is phasing in newly required activities related to registration. Many products are pending. He explained that they are examining all actions in the queue; they are inventorying them by asking a series of questions. He then presented the questions being considered, the number of chemicals and crops involved in each category, and how EPA intends to handle them:

* Which will expire between now and January?
  There will be 17 chemicals affecting 27 crops.
  EPA has determined that their top priority is to act on these.

* What actions were ready to have tolerances issued?
  There are 25 chemicals and 50 crops.
  The Agency needs to go back and reassess tolerances to see if they comply with the new law's requirements.

* The remainder of actions are waiting for consideration.
  300 other food use actions have been filed and are in the queue.
  For those, the Agency is continuing to do science assessments.

Lois Rossi, Director, Special Review and Reregistration, OPP, OPPTS, spoke next about the reregistration process. She explained that close to 40 percent of the products being reviewed are being considered for reregistration. She commented that FQPA did not change the deadlines for reregistration. She noted that eighteen reregistration decisions had been completed in FY 96 prior to August 3. They were put through a screen similar to that done for Section 18 to determine if the assessments done were adequate without further work. If they met the criteria, then they were considered to be okay. EPA determined that eleven chemicals had assessments that were acceptable. Seven were conventional pesticides and four were biopesticides. All decisions had already included some modifications and conditions-to-terms of registration. They are working on the other chemicals to get additional information needed.

Lynn Goldman commented that the brief presentations should give Committee members a sense of the challenges faced by the Agency and the immediacy of actions needed to be undertaken. She emphasized the urgency driving the Agency to move forward with policy decisions and actual actions. Despite that, she stated that it is critical that EPA directly grapple with the science issues that have been posed by the new law. She noted that the Agency has processes in place to address the scientific issues and seek advice, specifically the FIFRA Scientific Advisory Panel and Science Advisory Board. Decisions on the science will help to bring these issues into the policy context; she sees that as a role for this Committee. She also warned the Committee that the Agency does not have the answers to all of these questions now and that they may never have all the answers. Thus, what to do with limited information is something that needs to be addressed.

CLARIFYING QUESTIONS

Following the summary of EPA activities, Michael Lesnick invited Advisory Committee members to ask clarifying questions.

Jack Moore, former AA and ex-officio member, asked Stephen Johnson, US EPA, if a tolerance set for Section 18 addresses life span? Mr. Johnson answered that a time limit of one year is established if the food is treated legally and not adulterated.

Linda Fisher, former AA and ex-officio member, asked Stephen Johnson if the pending interim criteria for Section 18 will be used for upcoming actions? Mr. Johnson responded affirmatively, but indicated that EPA is trying to remain open to alternative criteria. He added that EPA plans to share the interim criteria with registrants and states in the next few weeks.

Jane Perkins, AFL-CIO, inquired about how worker aggregate exposure will be addressed with the new law? EPA staff commented that for tolerance setting, worker exposure is not included. They plan to evaluate worker exposure separately in the registration process.

Steve Jellinek, former AA and ex-officio member, commented that several Section 18 submissions were rejected and wanted to know what criteria under the new law had not been met. He also inquired whether they would have been approved under the old law? EPA representatives responded that one of the Section 18 submissions was rejected because it was over the acceptable level for carcinogenic risk. They commented that under the old law that determination would have been close and the Section 18 may have been approved. One of the other Section 18 submissions was rejected because of an inadequate margin of exposure to children. They noted that under the old law it would have been turned down as well. The third Section 18 was determined to be a marginal exposure and would have been borderline under the old law.

Daniel Botts, Florida Fruit and Vegetable Association, appreciated the recognition by EPA of industry paying the fees which enable them to do their work, but clarified that it was the growers who actually pay the fees, not the manufacturers. He commented that this reality is and will be magnified amongst growers in the minor use sector.

Ramon Llenado, The Clorox Company, inquired about what impact the new law will have on the Toxic Substances Control Act (TSCA)? EPA staff noted that endocrine disruptors is the only area addressed within FQPA that is within TSCA jurisdiction.

Al Meyerhoff, Natural Resources Defense Council (NRDC), asked a procedural question about whether a tolerance has to precede a Section 18. Representatives of EPA responded that the tolerance needs to be in place before a commodity enters commerce. A risk assessment must be done because EPA does not want to put farmers in a position of using a product without a tolerance.

Jeff Foran, ILSI Risk Science Institute, inquired whether there was any distinction between how threshold versus non-threshold pesticides would be addressed. EPA representatives commented that the distinction between them would be addressed in the risk assessment.

Richard Kirchhoff, National Association of State Departments of Agriculture, inquired about how implementation of the new law will mesh with General Agreement on Tariffs and Trade (GATT) and other international efforts? Dr. Goldman felt that it will mesh well; however, she commented that there are concerns about how the special provisions for infants and children and Section 18 tolerances will impact the international market.

Carolyn Brickey, National Campaign for Pesticide Policy Reform, asked for clarification on how EPA was categorizing pesticides. Stephen Johnson responded that EPA was dividing the pesticides into the categories of those whose tolerances were expiring and those which EPA is about to make a decision on. He commented that EPA is trying to use the same criteria that were used in Section 18 evaluations: for those that clearly meet the new criteria they will make a decision; for those which require additional information, EPA plans to go back to companies for the necessary information; and, those pesticides which are in-between will be addressed on a case by case basis. Lynn Goldman added that it was important to emphasize that for the ones that cannot be addressed in the timeframe that EPA will continue to work on them and will make sure people understand the delay.

Jose Amador, Texas A & M University, wanted to know if the Right-to-Know Provision addressed worker protection standards? Jim Aidala responded that worker protection is not directly addressed in the legislation and that the Right-to-Know program will continue as it did before the new law passed. In addition, Lynn Goldman stated that there is a specific issue of worker Right-to-Know which the new law did not address. She noted that the Agency is evaluating the current program to decide if more should be done.

Michael Lesnick asked selected participants from diverse interests to reflect on priorities regarding implementation from their perspective. Their responses were:

Carolyn Brickey commented that she appreciated the opportunity to participate in this process and the level of awareness being given this issue. She recognized the amount of time the EPA staff and others have spent on the new law thus far. Of key concern to her was whether EPA has sufficient staff and resources to apply the new law effectively. She suggested that there is a need to develop a new priority list to achieve the goal of implementation. Ms. Brickey was interested in learning more about the criteria for protecting children, how tolerances are set, and how benefits are determined. She was also concerned about how gaps in data could potentially stall the process and suggested that the Agency address how they plan to continue to do the work they need to do around the data gaps.

Emilio Bontempo, Ciba-Geigy, was thankful to be given the opportunity to participate on the Committee. He appreciated the Agency's improved scientific approach and complimented them on their efficiency in processing registrations and reregistrations, especially for safer pesticides. He commented that he was concerned about the use of time-limited tolerances given the time it takes for registrants to produce the end product. He was also concerned that the limited resources available for implementation would increase the time required for new registrations, particularly for safer pesticides. He viewed EPA's job to be larger than before and suggested that efforts be made to insure that Congress provide adequate funds to support the volume of work and offered Ciba-Geigy's scientific resources. He urged that the focus be on getting the job of implementation done so that everyone can get back to the process of producing an abundant and safe food supply.

Dean Kleckner, American Farm Bureau Federation, stated that the Act was a great move forward. He commented that farmers were the first to be impacted and that the Delaney "train wreck" would have hurt many. He was optimistic that the Act will stop cancellations of uses on crops. He felt that the new standard was similar to the negligible risk standard used before the Delaney Clause. He hoped that EPA would stop pesticide cancellations immediately which were forced by the Delaney Clause, particularly for time sensitive crops in Florida.

Mr. Kleckner urged the Agency to scrutinize states' requests for more stringent regulations and expressed concern about the impact of the new law on minor uses. He commented that minor use farmers produce crops that are not minor to consumers. Mr. Kleckner stated that many farmers have already been hurt because of inadequate resources available for timely registration and reregistration.

In addition, Mr. Kleckner felt that it was unclear what the impact of the other major provisions of the Act, including cumulative effects and special provisions for children and infants would be. He wondered if the new law was too broad and therefore would invite challenges to maintaining the availability of crops specifically fruits and vegetables. He hoped that EPA would help to insure that future cancellations are based on reasonable risk, sound science, and peer review.

James Wells, California Department of Pesticide Regulation, applauded EPA for making the process of implementation transparent. He offered the perspective of a state with a mature regulatory program and experience in minor use issues. He cautioned that when focusing on risk there is a need to integrate worker protection. He commented that there is the potential to negatively impact integrated pest management programs. Mr. Wells also stated that the FQPA includes incentives for registering reduced risk chemicals and that the overall impact is reduced risk. He felt that EPA's efforts to make the process transparent will have a positive effect.

Al Meyerhoff, NRDC, characterized this process as "the dog that finally caught the car." He viewed the new law, which was passed unanimously by Congress and supported by many, as a major miracle. He also agreed that there are many issues associated with implementation of the new Act. He was particularly glad to hear concerns being raised about available resources for implementation of the Act because he feels that it will require a great deal of them. He commented that the key is public confidence in the government to do this right. He wants there to be agreement about how much money it will take to complete this process effectively in order to go to Congress to request their support.

Mr. Meyerhoff also expressed concern about the stake of workers in the implementation of the new law. He felt that organophosphates present a very serious exposure problem. He stated that he is glad to see representatives from labor taking part in this effort. He would also like to see the Farm Workers Union involved.

Michael Lesnick invited other participants to comment on priorities regarding implementation. Their responses were:

Jane Perkins, AFL-CIO, stated that she was happy to be part of the process as a representative of the AFL-CIO. She felt at a disadvantage because the AFL-CIO has not previously included the environment in its working agenda. She is interested in finding out how these issues fit into the labor context. She introduced as her alternate, Steve Berson, Altshuler, Berzon, Nussbaum, Berzon, and Rubin, as a resource who has participated in a related law suit.

Ms. Perkins expressed concerns about how worker protection will be addressed in the new law, and expressed her view that there was a lack of environmental justice representation and a lack of diversity around the table. She stated that she would like to see the interests represented at the table broadened by the inclusion of food and commercial workers, the Oil, Chemical and Atomic Workers, and the Teamsters. She feels this effort will be of interest to them because chemicals are high on their list of concerns. Ms. Perkins also felt that the question of available resources was key.

Ramon Llenado, Clorox, stated that he was concerned about how aspects of the Act would impact the use of antimicrobial pesticides, tolerances, risk assessment, registration and reregistration, and consumer labeling. He was concerned that the scientific basis for evaluating risk is not sufficiently developed to address endocrine disruptors and that the three-year timeframe specified in the FQPA may also not allow adequate time for sufficient development. In addition, he commented that new tolerances could easily lead to cancellation. Mr. Llenado hoped that consumer labeling which he feels is currently unfriendly, would become consumer friendly under the new law. He stated that he was pleased to be a part of this process and encourages EPA to do a good job implementing the new Act.

Jon Jessen, Gowan Company, stated that he represents the concerns of a small business focused on minor use crops that operates with limited overhead. He commented that they are particularly vulnerable to the cancellation of minor use pesticides because they may be integral to their crop production. He also observed that cancellation of minor use pesticides may also disrupt an effective integrated pest management (IPM) program where pesticides are rotated for resistance management. Mr. Jessen commented that small businesses are often economically fragile and marginally profitable. He fears that if available pesticide uses are narrowed and the cost of testing is too extensive, they will be driven out of business and crops critical to a healthy human diet will become scarce and expensive. He hoped that EPA would keep the implementation process transparent and provide growers with adequate time to respond to up-coming changes.

Luke Cole, California Rural Legal Assistance Foundation, was also disappointed to see the lack of environmental justice representation in this process. He commented that representation at the table of those most affected is fundamental. Mr. Cole stated that he hoped environmental justice and other groups which were under-represented, including farm workers, would be better represented in the future. He, too, recognized the need for resources to implement the recommendations from this process.

Mr. Cole was pleased to see the Act address less toxic alternatives, benefits criteria, and cumulative and synergistic effects. He suggested that implementation focus on common mechanisms of toxicity. He wanted clarification on how aggregate levels will be used in determining tolerances and how inhalation and drinking water will be integrated in these determinations.

Penny Fenner-Crisp, EPA, responded that a health benchmark is determined from toxicological data and used to compare against all exposures. She explained that for a dietary assessment, the combined exposures are determined and comprise part of the overall "risk cup." Aggregate effects from food and other sources are combined and compared against the health benchmark. If the combined risk exceeds the benchmark, then no tolerance is proposed. She commented that tolerances are driven largely by residue values.

Richard Rominger, US Department of Agriculture, was pleased that the Act was in the implementation phase because many people have worked on it for 20 years. He feels the federal government is responsible for delivering on the promise that farmers will have the tools to

continue producing food and consumers will have increased confidence in the safety of their food supply. He commented that the key is to get through the implementation phase. Mr. Rominger expressed concern with how EPA will coordinate with other agencies to gather the data necessary to set tolerances including the minor use Inter-regional Research Project No. 4 (IR-4) and the impact on IPM. He commented that he looks forward to working with EPA to help address these concerns.

Kathleen Merrigan, Henry A. Wallace Institute for Alternative Agriculture, inquired whether alternative models of agriculture were being evaluated in the implementation process. She shared that she has had success with alternative models through her work with grassroots farm organizations. Ms. Merrigan also acknowledged that resources represented a tough issue.

Richard Jackson, Centers for Disease Control and Prevention, was glad to see the connection made between worker safety and food. He commented on the need for a sophisticated risk benefit analysis to support decisions; he also noted that he feels EPA does not have adequate resources. For this reason, Mr. Jackson feels that EPA will have to prioritize its tasks.

Mark Atwood, American Cyanamid, commented that this group is looking at an enhancement of the risk assessment process and cannot hold up the registration and approval process for this purpose. He was concerned that more delays will cause more harm in the long run, particularly with Section 18's and Section 3's. He urged that EPA keep the Section 3 process going as they deal with emergencies.

Elaine Auld, Society for Public Health Education, Inc., commented on three areas of concern to her: (1) the challenge to develop and gather data to derive scientific certainty required to apply the new law; (2) the potential impact on the IPM process with the hope of continued progress; and (3) how Right-to-Know would be addressed. She noted that while EPA is working with good material, the law is too prescriptive on what and how to tell consumers. She felt that EPA needs to think more broadly to obtain a more accurate and culturally relevant, meaningful approach for reaching the general public to advise them about what is and is not known about pesticides and risk and what changes to expect over time. She does not want to negatively impact public health by decreasing the availability of fruit and vegetables.

Jan Relford, Gerber Products Company, stated that his focus was on children and infants. He commented that he was encouraged by the discussion thus far. However, Mr. Relford urged that the group not overlook the communications aspect of the law and the need for the public to understand what is sound science. He offered his help with communications.

Philip Barnett, Food and Drug Administration, was gratified when the law was passed. He commented that implementation of the law would be a big job and was glad to be a part of the effort.

Anthony Hepton, Dole Foods, commented on the number of environmentally conscious individuals present who were responsible for making environmentally sound decisions every day. He acknowledged that EPA has limited resources which will probably never be enough to do

everything desired. However, Mr. Hepton noted that with effective prioritization, the law will promote products which will provide greater safety and lower risk. He was impressed with what has already been done.

John Hagaman, DowElanco, agreed that resources are critical. Mr. Hagaman stated that he had experience with lengthy decision-making processes at EPA and cautioned that Section 18 tolerances could cause a loss of momentum in this process. To help achieve this end, Mr. Hagaman proposed that EPA address shorter term issues to allow crops to be planted. In addition, he suggested creating a support group of key individuals to address longer term issues.

William Kirk, DuPont Agricultural Products, was supportive of the progress shown in the new law, especially on new safer technology. He commented on improvements in the number of new products developed over the past ten years, the large reduction in waste generated, and in the expedited turn around time for registration/reregistration.

Dean Kleckner commented on the balance of representation around the table. He felt that farms and farm workers were well represented. Mr. Kleckner also commented that fruits and vegetables are important for a healthy diet; thus, there is a need to balance availability and cost of good food. He stated that one of the benefits of a diet which includes fruits and vegetables is prevention of cancer. Mr. Kleckner wanted clarification on whether an assessment of the eating habits and cumulative effects on children had been correlated with other dietary surveys, and whether children's' standards were consistent with EPA's current practices and the NAS report? In addition, he inquired how the standard would impact tolerances, especially for fruits and vegetables?

Dr. Penny Fenner-Crisp stated that the law is consistent with scientific procedures regarding effects. She added that scientists recommend an uncertainty factor of up to 10-fold. Dr. Fenner-Crisp commented that the law does change the way standards are set and requires a safety finding every time a tolerance is set. She suggested that if one were to go back through old tolerances, one would observe significant changes. Dr. Fenner-Crisp added that with the new process, the net outcome will be stricter standards for children.

Jean Pettibone, American Agri-Women, expressed concern about minor uses, establishing tolerances, and the language for the Right-to-Know literature. She hopes that the Right-to-Know language would not be alarmist, but rather factual and understandable. She commented on the concept of what "free to farm" means, proposing that it meant "free of subsidies and government interference." She was concerned about stricter requirements and the potential for total dependence on the export of products. Ms. Pettibone stated that growers may need help to deal with competition in the open market.

Daniel Botts, Florida Fruit and Vegetable Association, stated that implementation of FQPA was important. He suggested that the best case scenario was that three years from now EPA would be applauded for doing the right thing and that the proper pesticide and management tools were available for all crops. He suggested that the worst case would be that his industry will not exist

and that the tools will not be available to manage pests. Mr. Botts stated that this group is challenging the Agency to avoid the second scenario.

Steve Jellinek commented that the new law, in principle, represents good public policy and is an improvement over the last. Mr. Jellinek stated that additional resources are needed for implementation of the law through Congressional funding. He urged Fred Hansen to view the implementation of this law in the short and long term: in the short term, consider how to use the resources currently available; in the long term, consider obtaining additional Congressional appropriations.

Mr. Jellinek warned that there is a tendency for public policy officials to extend the scope of legislative authority and suggested resisting this tendency to help save the resources available. He also stated that priority setting will be necessary in view of how much there is to get done. He proposed that EPA may need to risk the potential for litigation in order to progress with implementation and maintain the morale of EPA staff.

Lynn Goldman thanked participants for their candor and their comments. She clarified that a Federal Register notice had been issued rescinding all of the pending Delaney actions at the time the law was signed. In addition, she commented that the new law should not compromise program improvements on safer pesticide registration, label changes, new way of doing business, and other efficiencies. She recognized that the Agency needs to make decisions in a timely manner to keep efforts on track.

Dean Kleckner stressed that it was important for the Agency to take worker protection standards seriously. Lynn Goldman commented that EPA does take these standards seriously. She noted that EPA just finished a series of eight field hearings to evaluate worker protection programs. She stated that EPA had heard the groups' concerns for farm worker protection and understands the need to involve the farm worker more directly. Ms. Goldman directed additional suggestions for individuals representing farm workers to Margie Fehrenbach, US EPA.

Fred Hansen commented that he wanted to chair this Advisory Committee because of how important he felt this law and process were to the Agency. He urged participants to think about the areas they want EPA to focus on and where participants feel they can be of most help. EPA looks to this group to help implement the law in the best way possible. He understands that there will be some tough decisions to make and that EPA will not be able to satisfy everyone.

PUBLIC COMMENT (Morning)

Dennis Avery, Hudson Institute

Mr. Avery stated that the topic of the Committee's discussion should be broadened to include how to get people to eat more fresh fruits and vegetables due to their ability to reduce cancer risk. He was concerned about driving some pesticides out of the market which will complicate the ability of achieving high yield production. Mr. Avery suggested that effective use of current lands being farmed is needed to protect other global resources such as tropical forests.

Jay Vroom, American Crop Protection Association (ACPA)

Mr. Vroom observed the progress the Agency has made in registering products. He feels that the Agency deserves much credit for having accelerated sound decision-making on new products and with the reregistration program. He sees the demise of Delaney as a continuation of improving technologies around the world. However, he cautioned that the replacement of Delaney could result in gridlock.

PRIORITIZATION OF KEY ISSUES

To initiate discussions on the key issues of concern related to implementation of the FQPA, Michael Lesnick presented a summary of the issues Keystone staff heard from participants in conversations held prior to the meeting. The concerns were organized and identified as follows:

I. What happens during the transition?

- How does the transition affect current programs? Are current programs on hold?
- What are the priorities during the transition? How will the priorities be established?
- Will the decisions become de facto new policy?
- What will the time-frame be for issuing regulations, policies, etc.?
- How will decisions be made in the context of existing data gaps and without the science necessary in place to fill those gaps?

II. How will EPA deal with the allocation of resources to implement the Act?

- How will the government ensure adequate resources in the short term? In the long term?
- What are the costs? (Full Time Equivalents, money)

III. Risk related issues

- What is the definition of "reasonable certainty of no harm"?
- How will the aggregate exposure/total exposure and safety of infants/children be determined?
- What are the implications of a 10-fold uncertainty factor?
- How will the cumulative effects/common mechanisms of toxicity be determined?

- What are the criteria for reduced risk pesticides?

IV. Minor Uses

- Will minor use pesticides continue to be available?
- What are the implications of the uncertainty factor for infants/children?

V. Right-to-Know Provision

- How will the relative risk/benefit to consumers be communicated?
- The tone and make-up of the Right-to-Know information disseminated is critical.

VI. Section 18

- How will Section 18 be addressed in the short term and long term?
- States need guidance on action levels/tolerances.
- How will growers know whether they can get a tolerance?
- How will time-limited tolerances be factored into exposure considerations?
- What will the timing on existing Section 18's be?

VII. Uniformity

- How will EPA/State regulations be harmonized?
- How will the need for international harmonization be addressed?

Dr. Lesnick then asked Advisory Committee members for their reactions to the summary of issues presented. While Committee members identified a number of issues, their discussion focused on several general areas:

- The extent to which the Advisory Committee will address scientific and technological issues;
- The extent to which the Committee will address strategic versus operational issues;
- The extent to which the Advisory Committee will address risk benefits and cost;
- How to balance long and short term issues; and
- How data gaps will affect the decision-making process.

Arnold Donald, Monsanto Company, asked the Agency how the list presented compares to the Agency's list. Dr. Lynn Goldman explained that many of the issues on EPA's list are the same as

those expressed by Committee members. She commented that EPA has already addressed some of the transitional issues related to risk, registration, and tolerances.

As Committee members began to evaluate the list of issues, they recognized that there were different types of issues and questions. For example, Jeff Foran, ILSI Risk Science Institute, noted that there are two different issues under risk: the social policy issue of "reasonable certainty of no harm" and defining aggregate or total exposure. He commented that this group may not have the expertise to answer technical questions but may be well suited to identify and prioritize appropriate research issues. Mark Atwood, American Cyanamid, characterized the issues as presenting strategic and operational choices.

Fred Hansen observed, based upon the list and the group's discussion, that the Committee may address important shorter term transitional issues, but suggested that they need to maintain a focus on longer term strategic issues of program development.

Richard Kirchoff, National Association of State Departments of Agriculture, was concerned about how the Act would impact international trade. He suggested that international concerns be added to issues listed under the category of Uniformity.

Carolyn Brickey, National Campaign for Pesticide Policy Reform, viewed the list as a good starting point which would help the group categorize the issues on which to focus. She agreed that this group should not focus on the scientific detail or get bogged down with transitional issues. Putting forth an alternative view, Jack Moore, Institute for Evaluating Health Risks, cautioned that, while he agrees that the Advisory Committee should make policy recommendations, the group is comprised of individuals with a broad diversity of intellectual resources and should not dismiss consideration of all scientific issues.

Lynn Goldman commented that information from the Agency's on-going work on the scientific issues may coalesce with policy development. Some of the transition and scientific issues, particularly risk-related issues which factor into Section 18's, such as a 10-fold uncertainty factor, may also be addressed by the SAP which is meeting in late October 1996.

Alan Meyerhoff, NRDC, stated that it is critical for this group to base its recommendations to EPA on priorities determined by concerns with high risk chemicals. He commented that once these priorities are set, EPA can focus on what he views as the core of the Act and address issues associated with implementation and allocation of resources. Lynn Goldman stated that EPA is currently engaged in developing a list of criteria which will be presented to this group for comment.

Cynthia Bearer, Case Western Reserve University, stated that, while she has concern about the criteria and the list, she is more concerned about where the data gaps are, particularly with respect to exposure to the developing fetus, infants, and children. She suggested the scientific community could provide guidance on prioritizing where the data gaps are. Fred Hansen suggested that FSAC evaluate how to implement the Act in a way that addresses data gaps.

While Jeff Foran agreed with the utility of addressing data gaps, he was concerned about the possibility of losing sight of where the data gaps are. He commented that the challenge will be to progress with implementation of the Act while considering data gaps and the evolution of the science to fill the data gaps.

Dean Kleckner, American Farm Bureau Federation, commented on the importance of transitional rules because they often become final rules. Of particular concern to him was the language in the special provisions for infants and children that may cause cancellation of pesticides currently in use, thus impacting the cost and availability of fruits and vegetables. Mr. Kleckner wanted to know if consideration of risk benefit, availability, and cost were outside the purview of the Advisory Committee.

Jane Perkins, AFL-CIO, was sympathetic to Kleckner's concerns which she viewed as choices about risks for people. She suggested that it would be appropriate for this group to address a wider scope of questions which might include financial considerations.

Steve Jellinek, former AA and ex-officio member, commented that, in the absence of science, the role of this group was to give EPA ideas about how to work around the data gaps. He felt the question for the Committee was to determine what approach to use: make worst case assumptions, ignore limited available information, or to use some approach in between the two extremes. Mr. Jellinek also agreed that transitional rules were of importance because they often become final. Additionally, he noted that they require resources that may be more appropriately spent on long-term issues.

James Wells, California Environmental Protection Agency, suggested that the Advisory Committee focus its efforts on somewhere between long-term and transitional issues. Cynthia Bearer commented that the group may similarly have to address issues that lie somewhere between the absence and availability of scientific data.

Emilio Bontempo, Ciba-Geigy Corporation, observed that operational issues are often strategic issues. For example, how to manage the size and allocation of resources within the Agency is a strategic issue which the Committee can address. Jack Moore suggested that the group focus its efforts strategically on evaluating how EPA can do its job differently. He recognized that EPA does not have the resources to do everything and proposed that EPA consider using a triage protocol to address multiple issues associated with implementing the Act.

To help frame the discussion, Lynn Goldman proposed that the Advisory Committee focus on broader issues which, when viewed ten years from now, would be used to judge if the implementation of the Act was successful. For example, she proposed considering four major issue areas in FIFRA for consideration:

1. Will we have protected the public health, especially children and infants?
2. Minor uses - Will there be adequate food available?
3. Will there be a safer array of pest control measures available?
4. Will we be able to say that we implemented a successful fifteen year renewal program?

She noted that EPA would like to say that they had done an effective, timely, well-managed job.

Richard Kirchhoff suggested that Dr. Goldman's list of criteria to evaluate the success of the Act in ten years include an evaluation of how the Act has impacted the viability of smaller but integral growers in the market. Will they still have farms and the money to farm? He reiterated that some consideration of finances be part of implementing the Act.

Daniel Botts, Florida Fruit and Vegetable Association, commented that Dr. Goldman's list of criteria for success in ten years is good in the context of the new law. However, he was concerned about how future definition of the criteria, goals, and guidelines for minor use pesticides would impact the growers and the market. Mr. Botts suggested the need for an accurate survey on dietary exposure and real risk to infants and children. He commented that transitional issues are just as important as long term issues. Dr. Goldman agreed that minor uses should be a major concern, both transitional and in the long term.

Jon Jessen, Gowan Company, expressed concern that, with implementation of the Act, effective IPM programs would be jeopardized. Mr. Jessen was particularly concerned that organophosphate pesticides, notably in the higher risk category of pesticides, would be arbitrarily banned from use because of low volume use and high risk categorization.

William Spain, Del Monte Foods, suggested that before the Committee identifies the questions that will help them think strategically or operationally, they start by clarifying the mission of the Committee. He proposed that the mission was implementing the law. He then suggested identifying the potential barriers to achieving the mission and determining what was necessary to achieve the mission (e.g., additional resources, what types of resources, what data). Mr. Spain commented that clear communication and agreement on definitions and interpretations was important to determining critical key strategic issues.

Anthony Hepton, Dole Foods, agreed with the importance of reaching agreement on definitions and interpretations. He commented that the law is addressing both the protection of individuals and the needs of crop producers. He noted that there is a good system in place today and supported EPA in their efforts to adjust the system to deal with the new set of regulations.

Alan Meyerhoff, NRDC, commented on the challenges posed by the intersection of reregistration with the new health-based standard and how to determine whether cumulative exposure to children is of no harm. He clarified that to him the real issue is addressing how we reduce the potential for cancer. He suggested that we add to the criteria for success in ten years, "did the process get strangled?"

Steve Berzon, Altshuler, Berzon, Nussbaum, Berzon, and Rubin, noted that the responsibility of the Advisory Committee is to address implementation within the context of the new Act, not to define the meaning of "reasonable certainty of no harm."

Genevieve Matanowski, John Hopkins University, recognized the need to reevaluate Dr. Goldman's list of criteria for success in ten years. She noted the criteria were not goal-oriented, and suggested that without a goal or goals, the group would end up with a series of cross-cutting issues. She also commented that Dr. Goldman's criteria were broad and it would be more effective to identify more focused, doable criteria. For example, Matanowski indicated it was unclear how to determine whether "the protection of public health" had been achieved.

Lynn Goldman responded that long-term objectives are necessary but acknowledged that there is also a need to break the objectives into achievable parts. She commented that this process will be a challenge.

REVIEW AND DISCUSSION OF FUTURE AGENDAS/NEXT STEPS

After discussing the prioritization of key issues, the group began to evaluate ideas for future agendas. As a starting point for the October agenda, Michael Lesnick proposed the following questions for the group to consider:

1. How to help EPA make difficult decisions about short and long term issues when scientific data are not available? What are the data gaps and do we know how to find the answers?
2. What are the criteria to develop the list of chemicals?
3. How should available resources be allocated?

Larry Elworth, US Department of Agriculture, stated that resources are of obvious importance to the successful implementation of the Act. He wanted clarification on the role of the Advisory Committee regarding the allocation of resources. He proposed that the Committee be used to provide strategic input about where to place resources.

John Hagaman, DowElanco, commented on how the group had characterized the focus of issues thus far: short- and long-term, strategic and operational, success after ten years, etc. He suggested that some issues may be more effectively evaluated at different time periods.

Jack Moore suggested that the group shift its focus from debate to viewing the risk related issues as basis from which to start to identify actions to take. He stated that Congress also wants EPA to prioritize what we have to do differently to effectively address the special provisions for children and infants and the new health-based standard.

PROPOSAL FOR ISSUES TO BE ADDRESSED AT FUTURE MEETINGS

Based upon the group's discussions, Fred Hansen and Lynn Goldman proposed a list of issues to be addressed at future meetings. They suggested that the group consider each issue in the context of: long term, transition, indices of success, and resources (e.g., money and lack of data).

For the October meeting they suggested the following topics:

1. Risk
   - Dietary Exposure,
   - Cumulative Exposures,
   - Multiple Exposures, and
   - Common Mechanisms of Toxicity

2. Minor Uses

3. Benefits
   - Where it applies and does not apply,
   - Statutory language regarding tolerance, and
   - Tradeoffs

4. Safer pesticides/IPM/Reduced use

5. Communication

For the November Meeting they suggested the following topics:

1. Risk
   - 10-fold uncertainty factor, and
   - In-utero cancer bioassay

2. Retroactive Review

3. Registration Renewal

The group evaluated the proposed plan for topics to be discussed at future meetings. Several in the group wanted some assurance that Section 18, Right-to-Know, and uniformity were included in the topics suggested. Lynn Goldman clarified that risk issues involved in Section 18 and other tolerance issues would be covered, but the nuts and bolts and time-frame for Section 18 would not be covered.

Some participants wanted to include a discussion of benefits to provide some perspective and context to address potential policy questions that may arise. They suggested that a discussion on benefits be added to either the October or November meeting agendas.

Several in the group noted that communications applies to all of the topic areas and represents a pervasive and on-going issue in this process at all levels: state, federal, and local. They proposed that it be added as an issue area.

The group discussed whether registration renewal was an appropriate topic area. Some felt that it was important because all of the other decisions will affect registration, but it was not seen as a

major issue area. The group agreed to drop registration renewal as a topic area as long as it was addressed within other topics of discussion. They agreed if, based upon the discussions from the October meeting, the group felt a subgroup on registration renewal was appropriate, a subgroup would be formed.

Others in the group were concerned that the ensuing discussions would also address how EPA planned to address the concept of the additional uncertainty factor of "up to 10-fold," substitution for canceled pesticides, cumulative exposures, and how Right-to-Know concerns would be carried out. EPA indicated that future discussions would address these concerns.

Following these discussions, a sign-up sheet listing five topic areas to be addresses in October: Risk Issues - Dietary Exposure, Cumulative, Multiple, and Common Mechanism of Action; Communications; Safer Pesticides/IMP/Reduced Use; Minor Uses; and Benefits was circulated for Advisory Committee members and their alternates to sign-up in their area(s) of interest.

PUBLIC COMMENT (Afternoon)

Michael Lesnick then invited members of the public to comment on the meeting.

Shelly Davis, Farm Worker Justice Fund

Ms. Davis noted that there are 2.5 million farm workers in the US and that it is important to protect their children who receive multiple exposures at home, school, and through contact with their parents. She commented that because they are most at risk, we must protect them. She stated that, while there is there is some data available on this population, there is a need for additional data. She urged the Agency to keep the process public.

Jay Feldman, National Coalition Against the Misuse of Pesticides

Mr. Feldman requested that the Agency keep the public informed about the level of protection provided and to avoid misleading them. He asked EPA to provide the public with information on what will and will not be done to get the necessary outstanding information, and to clarify what information is available now (e.g., FQPA children's section - residue levels in food; consumption patterns, etc.) He requested that this disclosure include information about the costs associated with obtaining the outstanding data.

Rick Hind, Greenpeace

Rick Hind asked the Agency not to repeat what happened with FIFRA in 1972. He expressed particular concern about synergistic or additive effects. He commented that the speed with which EPA is responding to new legislation is remarkable. However, Mr. Hind questions if the law will provide adequate protection for children.

Daniel Rosenberg, Public Interest Research Group (PIRG)

Mr. Rosenberg expressed concern about the law, especially the Right-to-Know provision. He commented that his organization is willing to help keep the public informed about the Act. He raised the question of how to determine if something is safe if there is a data gap?

Luke Cole, California Rural Legal Assistance Foundation & FSAC Committee Alternate

Mr. Cole expressed particular concern about some of the questions raised about cumulative risk exposures. He requested that EPA provide a listing of what information is and is not available to the Advisory Committee for their next meeting.

Bob McKenna, Office of the Deputy Under Secretary of Defense

Mr. McKenna suggested that the Advisory Committee address public health issues associated with minor use pesticide application in its discussions.

Rick Hind, Greenpeace

Mr. Hind spoke again and commented that 96% of all crop chemicals are based on chlorine chemistry. He noted that there are new types and groups of chemicals entering the market frequently and suggested that EPA look at synergistic effects. He also suggested that the Advisory Committee include people from outside of the Washington, DC area and urged that the process be open.

Jay Vroom, ACPA

Mr. Vroom expressed particular concern about the impact of the new law on farmers. He noted that additional resources will be needed by EPA to address this. He commented that ACPA is lobbying for more money to fill this need.

At the close of the public comment period, Mr. Lesnick invited Advisory Committee members to respond or provide any additional comments. Mark Atwood spoke first and stated that he supports the request for additional information from EPA, indicating that additional information would be helpful for discussions on how EPA approaches the risk management process. He noted that additional information could be of particular help in making decisions about how to protect public health.

Richard Kirchhoff wanted some clarification on how the Advisory Committee and others could provide additional input on the law to the internal EPA teams working on different aspects of the law. Jim Aidala suggested that, to manage the flow of information, input on the law be directed to Anne Lindsay or himself. In addition, Mr. Aidala stated that some of the EPA teams will be developing regulations which will require additional public outreach process.

Genevieve Matanowski commented that it would be helpful to this group to work through a realistic scenario of how the new law would impact a pesticide or group of pesticides. She suggested that the Advisory Committee could set up a decision-making framework using a case study provided by EPA.

CLOSING COMMENTS

Michael Lesnick thanked the Advisory Committee, their Alternates, and the observers for their active and constructive participation in the meeting.

Jim Aidala urged participants to use EPA as a resource in this process. He offered EPA resources to provide short training sessions on selected topic areas of interest to the group as they work through the issues associated with the law.

Lynn Goldman indicated that EPA would make its best efforts to provide people with any information requested, but cautioned that some of the information may not be readily available. She acknowledged that the meeting was scheduled with short notice and expressed great appreciation to participants for attending and committing their valuable time to participate. Dr. Goldman commented that the advice of the Advisory Committee is critical to carrying out the process effectively.

Fred Hansen stated that this meeting surpassed his hopes for accomplishments. He feels that the group generated a good outline of things to accomplish over the next few months. Mr. Hansen noted that the test will be to see if this broad-based involvement will move the process forward. He expressed much appreciation for all of the participants' time.

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October 22-23, 1996
Meeting Summary

FOOD SAFETY ADVISORY COMMITTEE
Second Plenary Session - Meeting Summary
October 22 - 23, 1996
Washington, D.C.

Chairman: Fred Hansen, Deputy Administrator, US EPA

Vice Chair: Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, US EPA

Members Present: Jose Amador, Texas A&M University; Mark Atwood, American Cyanamid; Elaine Auld, Society for Public Health Education Inc.; Cynthia Bearer, Case Western Reserve University; Daniel Botts, Florida Fruit and Vegetable Association; Carolyn Brickey, National Campaign for Pesticide Policy Reform; Kenneth Cook, Environmental Working Group; Jon Jessen, Gowan Company; William Kirk, DuPont Agricultural Products; Genevieve Matanoski, John Hopkins University; Gene McConnell, Scientific Advisory Panel; Kathleen Merrigan, Henry A. Wallace Institute for Alternative Agriculture; Jane Perkins, AFL-CIO; Jean Pettibone, American Agri-Women; Robert Rhodes, Holland and Knight; James Wells, California Environmental Protection Agency; Pete Wenstrand, National Corn Growers Association.

Alternates Present: Steven Balling, Del Monte Foods - Research Center; John Barnett, Ciba-Geigy Corporation; Philip Barnett, Food and Drug Administration; George Brennen, Dole Foods; Mark Childress, Environmental Working Group; Judith Conover, League of Women Voters; Larry Elworth, USDA; Wenonah Hauter, Citizen Action; Robert Hawk, Gowan Company; Rick Holt, DuPont Agricultural Products; Polly Hoppin, World Wildlife Fund; Richard Kirchhoff, National Association of State Departments of Agriculture; Ralph Lightstone, California Rural Leagal Assistance Foundation; Patrick Meehan, The Clorox Company; Elin Miller, DowElanco; Eric Olson, Natural Resources Defense Council; Nancy Rachman, American Cyanamid; Jan Relford, Gerber Products Company; Bob Schramm, Schramm, Williams and Associates; Dennis Stolte, American Farm Bureau Federation; Bill Tracy, National Cotton Council; Richard Wiles, Environmental Working Group.

Ex-Officio Members Present: Jack Moore, Institute for Evaluating Health Risks; Steve Jellinek, Jellinek, Schwartz, & Connolly Inc.

Congressional Participants Present: Eric Berger, US House of Representatives; Howard Cohen, US House of Representatives; Greg Dotson, US House of Representatives; Susanne Fleek, US Senate; Jean Fruci, US House of Representatives; Kay Holcombe, US House of Representatives; Curt Mann, US House of Representatives; Dale Moore, US House of Representatives; Terri Nintemann, US Senate.

Tuesday, October 22, 1996

WELCOME AND INTRODUCTIONS

Fred Hansen, Chairman of Food Safety Advisory Committee (FSAC) and Deputy Administrator US EPA, began the meeting by welcoming everyone and asking for introductions. He stated that he appreciates participants taking time to participate in this effort. He recognized that the participants have many other responsibilities and he appreciates the effort they have made, particularly their involvement with the task groups. He also commented that participation from everyone is critical so that EPA can be informed by the diversity of interests on the strategic choices they are considering as the Agency implements the Food Quality Protection Act (FQPA). Mr. Hansen then expressed his appreciation for the hard work being done by EPA staff.

Next, he introduced members who have been added to the Committee since the first meeting. Specifically, he welcomed Peter Winstrand from the National Corn Growers Association and Shelly Davis attending as an alternate for Arturo Rodriguez from United Farm Workers. He also stated his appreciation to Ralph Lightstone, California Rural Legal Assistance, who was attending the meeting for Ralph Abascal who has been ill and is in the hospital. Mr. Hansen noted that everyone's hopes for a speedy recovery are with Mr. Abascal.

In terms of overall participation in the FSAC, Mr. Hansen observed that there are many more groups who could be added, but participation in the FSAC is limited by the desire to have a Committee that is of a reasonable size. Additionally, he stated that FSAC has a limited life, four months, and there are several other means (e.g., Pesticide Program Dialogue Committee, Endocrine Disruptors Screening and Testing Advisory Committee, assorted workshops) for concerned citizens to use to provide input. He stated that he recognizes the potential for imbalance on the Committee especially from the environmental community since they have limited people and resources to apply to such efforts. It is his feeling that all stakeholders have full opportunity for participation both on this Committee and through the other efforts.

Mr. Hansen also wanted to clarify that EPA is seeking input from the FSAC and is not looking for consensus from the Committee nor seeking majority and minority opinions. He noted that if consensus arises during the discussions, the report will acknowledge such agreement, but, discussions will not be driven by a desire to achieve consensus. He also clarified that the summaries from the work group conference calls were essentially the facilitator's notes and were not consensus documents. The summaries reflect what issues were raised on the calls to jog the memory of the participants and prompt the plenary discussion on those topics.

Before moving onto the discussion of the issues on the agenda, Mr. Hansen wanted to respond to concerns raised at the first plenary session and in the conference calls about the adequacy of resources. He informed them that before Congress recessed, $30 million was added to EPA's appropriation to address the implementation needs of the FQPA and the Safe Drinking Water Act. The Committee will hear more about resources as it is the first substantive item on the agenda.

Mr. Hansen also stressed that in the discussions, the FSAC needs to focus on implementation of the issues, not re-debate what the law says. He recognizes that everyone is not in agreement with the outcome of law, but it is EPA's job to do the best they can to implement the law as written.

He noted that the next meeting, in November, will address issues associated with infants and children, tolerance setting procedures, and farm worker issues.

In conclusion, Mr. Hansen expressed appreciation to Larry Elworth, US Department of Agriculture (USDA), who will be leaving his job at USDA to work on a grant from The Pew Charitable Trusts. He stated that Larry has been a tremendous resource to EPA and has been constructive in the pursuit of achieving the goals of agriculture in a manner that is compatible with the need to provide a safe food supply. EPA staff will miss him and his contribution. He then asked Larry Elworth to say a few words.

On behalf of USDA, Larry Elworth thanked EPA and the people at this meeting for the opportunity to participate. He noted that how Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food and Drug Cosmetic Act (FFDCA) are implemented will have an effect on agriculture and need to be considered in a deliberate fashion. He hopes that this process starts an evolution towards sound pest management in the near term as well as in the future.

Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, spoke next. She joined Fred Hansen in welcoming everyone. She, too, expressed appreciation to Larry Elworth. She noted that his involvement on pest management issues in the past few years reflects the commitment of USDA to work with EPA to insure that the needs of farmers are addressed.

She then observed that from her perspective FSAC provides an opportunity for all involved to explore the diverse opinions that exist on the implementation of FQPA. She also reiterated her appreciation for the time and energy devoted to this task by the members of the Committee. She called specific attention to the effort put in by members to participate in the Work Group conference calls. It is her sense and that of EPA staff that the calls were very useful.

To address one of the specific issues that has arisen since the calls, she clarified the objective of the calls and the Committee. She noted that from the standpoint of the Pesticides Program, the objective of FSAC is to have an opportunity to air views. She observed that it is important that members state their views and have the opportunity to hear the concerns of others. She noted that the conference calls should be considered as a means of airing some of these opinions and to provide input to EPA on how they should move forward. She also noted that FSAC members should avoid debate over the specifics of the law as Congress has made decisions about what was included in the law. Next, Ms. Goldman restated that the FSAC is not aiming to achieve a consensus. She noted that EPA needs to get the program going and to make decisions. She noted that the Committee has an ambitious agenda to cover in its few meetings. As a reminder, she noted that the Committee will be addressing worker risk issues at the next meeting.

REVIEW OF GROUNDRULES AND AGENDA

Next, Michael Lesnick, The Keystone Center, reviewed the context for establishment of FSAC and the objectives. He stated that FSAC was established as a subcommittee under the auspices of the National Advisory Committee on Environmental Policy and Technology (NACEPT). The purpose of this Committee is to provide advice on implementation of FQPA of 1996, specifically at the policy and strategic level. He restated the three objectives of the Committee which are: help shape the strategic direction taken to implement the legislation; provide an opportunity for participants to inform and provide assistance to EPA on issues of concern; and, react to EPA proposals. The goal of the Advisory Committee is to provide input; it is not to develop a consensus, although if one emerges it will be documented. Procedural matters will be decided through consensus. The three former Assistant Administrators will serve in an ex-officio capacity; Congressional staff will participate as observers. He noted that as a committee established under the Federal Advisory Committee Act (FACA), the rules of FACA will apply; meetings will be open to the public; and, there will be an opportunity for public comment.

He explained that the Committee will operate generally as a committee of the whole. Sub-groups will be used as needed to develop materials for consideration by the Committee as a whole. He also noted that members have been selected to represent the diversity of interests concerned with FQPA.

He then reminded members of a key groundrule that addresses members' interactions with the media. It states that members are free to speak for themselves; however, they are asked to not characterize the opinions of others. They should suggest that the media go directly to those people to receive their opinion.

Dr. Lesnick stated that the next day's meeting of the FSAC would discuss what kind of report will be issued. He then reviewed the agenda. He reminded members that the first meeting had been primarily organizational in focus and a work plan for the FSAC had been developed. Based on that work plan, at this meeting, the FSAC will hear about resources needed and discuss communication and risk issues the first day. Two opportunities for public comment were provided during the day. On the second day, minor use, reduced risk/Integrated Pest Management (IPM)/pollution prevention, and benefits were discussed.

As a reminder, he noted that at the November meeting, topics for discussion will include the 10-fold uncertainty factor, in-utero exposure, tolerance reassessment, and farm worker issues.

He then went on to explain that the work groups held conference calls the previous week. These calls were intended to provide an opportunity for preliminary conversation to occur on complex topics. The result of these conversations would be used to tee up ideas for this Committee. He stated that the summaries, which were essentially the facilitator's notes, were intended to reflect the range of issues discussed. For each topic, there will be a brief presentation by a member who participated in the call. He noted that the call summaries and the background papers prepared by EPA will provide the basis for FSAC's discussion of these issues.

RESOURCES

Dan Barolo, Director of the Office of Pesticide Programs, spoke next. He began by adding a few additional words of thanks to Larry Elworth. He noted that Larry brought a sense of purpose and perspective to his work along with a sense of humor that helped in building a bridge between USDA and EPA.

As this was his first meeting of the FSAC, Dan also thanked everyone for participating in this effort. He then referred to two documents that present an overview of the Office of Pesticide Programs, including activities, resources, manpower, outputs, and program areas that will need additional resources for implementation of FQPA (Attachment A.) In summary, he explained that EPA overall is flattening its organizational structure. He also noted that the Office of Pesticide Programs (OPP) is a large, centralized regulatory program with a matrix organization, unlike most other EPA programs that are largely decentralized to the regions and states. He explained that they are responsible for implementing a risk/benefit statute. He noted that OPP makes more decisions annually than any other office in EPA.

The Office also runs the National Pesticide Telecommunications Network (NPTN) which is a hotline that responds to peoples' concerns about pesticides. They are also involved in the certification of applicators; over 2 million farm workers have been trained in pesticide safety.

He noted that the Office has six broad areas for budget purposes. The budget breakdown was presented in the handout. In considering manpower levels, Mr. Barolo explained that the Office had increased staff after the passage of FIFRA 88. However, they now have fewer people on board than they did in 1988, despite the fact that they have more to do.

To provide a sense of the number of tolerance decisions to be made, Dan Barolo noted that OPP averaged approximately 300 tolerances per year for the last few years. He observed that to comply with the new law, the OPP will need to complete 900 tolerances per year in order to complete the ten year review required.

He noted that in recent years, the Office has concentrated on bringing safer products into the Program. He is proud of the staff and their ability to continue to make decisions despite the government shut downs last year and the uncertainty associated with the new law. From his perspective, FY 1997 will be a transition year as the Agency determines new policies associated with implementation of FQPA.

He explained that as a part of its efforts to implement the law, the Office is focusing on re-registration of older chemicals where there are greater risks. He noted that allocating staff to that effort will mean that fewer new registrations will be completed.

Mr. Barolo then reviewed the resource needs associated with the new law. These include: tolerance reassessments; Section 18's; new sampling protocols; tracking registrations electronically; addressing endocrine disruptors; minor uses (specifically to expedite minor use

active ingredients and the registration of new uses); communications; Right-to-Know; and reduced risk.

In conclusion, Mr. Barolo noted that the Office is faced with unique opportunities and needs across its entire program. He and his staff will do the very best they can to increase efficiency and put resources in key areas. As he mentioned before, he sees 1997 as a transition year; the Office will adjust to the new law and seek needed resources. He noted that activities in some areas within the Office will be accelerated; others may not. He is confident in the long run that the activities will balance out and critical areas will be addressed.

John Ehrmann, The Keystone Center, reminded members that a number of issues to be discussed by FSAC relate to resources; thus, there will be numerous opportunities to discuss this further. He explained that this presentation was intended to provide an overview. With that in mind, he then asked for comments.

The first question asked by a FSAC member was whether OPP was considering the possibility of and impact of disruptions on growers. The speaker suggested that in considering which chemicals to address and in what order of priority, the impact on growers be considered.

Dan Barolo responded that he would like input from this group on how to set the priorities. He explained that it is the Agency's intent to focus on older chemicals. He is hopeful that an appropriate balance can be found between the needs of growers and the demands of the law. He noted that the need for better communication with growers and others is one reason for the environmental stewardship program.

Another member noted that EPA clearly has a need to improve information management systems. He observed that NACEPT already has a committee dealing with this issue which may be able to provide some assistance to the OPP.

A member then asked a clarifying question about whether the presentation on resources reflects the current allocation of money and whether this will change with the requirements of the new law.

Dan Barolo explained that the numbers provided are based on the 1996 plan; the real numbers will be slightly different. He expects the percent allocated to the different program components to change with implementation of the FQPA. In addition, he expects that by early next year, they will have a new distribution as well as new program elements to reflect responsibilities of the new law.

A member, concerned about minor uses, asked how the funding to implement this program is to be allocated. He pointed out that many growers had made planting decisions based on registration decisions that were expected prior to passage of this law. He commented that the subsequent delay has compromised their activities. He offered to provide a list of priorities from their perspective, if that would be helpful. He also suggested that time-limited tolerances for use this growing season would be one way to address the growers' concerns.

Lynn Goldman responded that EPA has been setting priorities. She noted that what growers need is an important factor in that process. She explained that EPA is also looking at reduced risk pesticides as well as those crops where there are limited alternatives as factors in setting priorities. In this process, they are working with USDA.

Another member asked if the Program's operating plan will be finished by the next meeting. Fred Hansen responded that he is responsible for the budget of EPA as whole. It is his expectation that in three weeks, the date of the next meeting, they will be very close to having the operating plan completed for submission. If it is done, he stated that they will provide it to the FSAC.

Several members emphasized the need to appropriate adequate resources for OPP to implement FQPA. It was noted that the law contains many new requirements along with tight time lines and that funds are needed across the entire Office whether for protection of minor uses or new opportunities for reduced risk products. It was suggested that all are part of insuring the safety of the food supply.

Other members encouraged EPA to allocate much of the new money to the registration of reduced risk products including reregistration and replacement by safer new compounds available. It was noted that the registration process is important to both the chemical and agriculture industry. Because of its importance, several members urged EPA to get the registration system running as soon as possible because of the time needed to make decisions. It was also suggested that Section 18's need to be addressed in a timely manner.

In terms of resources, a participant observed that a number of other offices in EPA, in addition to the Office of Research and Development (ORD), will be competing for the newly appropriated $30 million. He urged EPA to ask the other programs to look for savings and redirect funds within their own programs to help direct more money to OPP and, of course, the General Counsel's Office because decisions by the Program will result in lawsuits.

Several members stated that they were encouraged to hear that money was specifically being sought for Right-to-Know and other communication efforts (e.g., more money for the hotline.)

Observing that many of the members and alternates of FSAC have a great amount of skill and expertise related to the appropriations process, a participant urged them to pursue Congressional action to provide additional money to support the requirements of FQPA.

Fred Hansen elaborated on the budget process. He explained that he put out a request from all offices including ORD asking for their anticipated needs to implement the FQPA. He is looking at reallocation and new allocation; they are still in this midst of this process. In response to a question on research priorities, he noted that ORD has FQPA as a priority.

The importance of making food safe for children and infants as identified in the National Academy of Sciences (NAS) study was raised by several members. Two elements that the NAS had recommended be considered were: exposure for children; and, hazard. They wanted EPA to

clarify where in setting priorities is developing new information on sensitive sub-populations of infants and children. It was observed that such efforts had not been identified on the chart in the handout. The question was also raised whether EPA is updating old data bases and improving data on actual susceptibility of sensitive populations such as infants and children.

Dan Barolo explained that the charts present the broad areas that are the primary responsibility of OPP. It does not identify those areas which are covered by other agencies such as USDA and the Department of Health and Human Services (HHS). He offered that OPP can provide a matrix of recommendations from the NAS study and what OPP is able to do.

Penny Fenner-Crisp explained that the Program has undertaken multiple efforts to address the data base and sensitive populations since the release of the 1993 NAS study. For example, she noted that the Agency held a workshop this year to address age-related differences and consider some of the possible endpoints. The purpose was to get ideas for research topics. Over the last two years, $5 million has been spent on looking at children-related risk issues. She also explained that EPA is working with USDA and HHS to improve data on food consumption and pesticide residues on food.

Another participant expressed his surprise that Section 18 was not designated by FSAC members as a more important issue. He feels that in the next two years, the Agency will need to use Section 18 to address the concerns of growers. He observed that growers will feel the brunt of the program. He suggested that they will have to dedicate resources to Section 18's; he also noted that the Agency needs to devise an appeals process especially for those cases where there are no alternatives.

To summarize the discussion, John Ehrmann noted that participants were concerned with the overall money needed to implement the law and acknowledged the need to set priorities. They had provided a number of suggestions about where the money should be spent. He also commented that the suggestions made should be kept in mind since resources will drive implementation activities.

He concluded by reminding participants that several conference calls had been held in preparation for this meeting. Participants on the calls considered the questions raised by EPA in the background papers with the intention of further identifying and refining issues for discussion by the FSAC. He stated that the remainder of the day and most of the next would be spent exploring the issues discussed on the conference calls.

COMMUNICATIONS AND RIGHT-TO-KNOW PROVISION

Elaine Auld, Society for Public Health Education, Inc., provided a brief summary of the Communications conference call. She stated that the participants on the call were fairly representative of the FSAC; they included representatives from consumer, environmental groups, manufacturers, and growers. She felt that they had a good discussion of the four questions raised by EPA addressing how to inform/involve consumers without delay, dissemination of Right-to-

Know information, partnerships, and challenges associated with discussing benefit-based tolerances in the brochure.

Ms. Auld noted that during the conference call the point was repeatedly made that the message to be communicated needs to be tested. They also identified the need to determine, preferably using existing information, what the public wants to know; it was suggested that this information should be used in developing the brochure. Discussion also focused on the EPA hotline as a source of data for EPA about issues of concern; similarly, it was suggested that hotlines run by other entities such as companies could be a source of data. During the course of the conversation, it was noted that other means, besides the hotlines, would be needed to identify concerns of other populations, particularly those with lower income and education.

In terms of partnerships, Ms. Auld noted that it was suggested by a number of people on the call that partnerships were a mechanism to use to increase credibility and outreach. She mentioned, as an example, Hechingers, a local hardware store, that provides consumers with a brochure on lead paint and health issues. Mention was also made of using the USDA Extension home economists, FDA, etc., as a means to enhance credibility and use of the information.

She noted that those on the call also addressed the use of media as a means to disseminate information. It was suggested by several participants that EPA should do more to inform the media about food safety and pesticide issues. Examples given include the use of media round tables and media field tours.

Participants on the call also addressed the distribution of the consumer brochure specified in FQPA. It was observed that one group missing from the discussions was retailer groups that have experience in delivering information to consumers (e.g., the Five-a-Day Program that encourages the consumption of five fruits or vegetables per day).

In terms of the brochure's content, participants stressed that efforts need to be taken to not frighten the consumer. They urged that the document be balanced, factual, and science-based. They also addressed the question of how the brochure will be updated. The current requirement in the law is for the brochure to be updated annually. It was suggested that there may be a need for greater frequency in terms of benefit-based tolerances. Those on the call did not come to agreement on this, but suggestions were made for the use of libraries and the Internet as possible means to provide access to updated information. She concluded by noting that all members of FSAC and their respective organizations need to work together to inform the public. She observed that having a strategic communications plan to guide these efforts was important.

Before going to comments from FSAC members, Michael Lesnick asked Congressional staff if they had any comments.

Greg Dotson, Congressman Waxman's Office, stated that the statutory language on the Right-to-Know Provision was included to inform consumers so that they can make informed decisions. He supported the idea of using focus groups to test the content of the brochure. He noted that there are two key elements to the brochure: they are discussion of the safety standard,

specifically what is safe to children; and the need to provide suggested alternatives and discussion of risks and benefits associated with pesticide use.

Michael Lesnick noted that as he heard the comments from the call, the participants focused on two core topics: how should EPA involve the public and others in wide range of communication related to this law; and, given limited resources, what activities should be identified as priority?

In considering the question of how to involve the public, a participant raised questions about the effectiveness of a brochure as a means to inform the public. The question of whether direct labeling of food would be more effective was asked. A congressional staff member noted that the issue of labeling had been debated extensively on the Hill. The decision by Congress was not to ask for labeling. She observed that the point of the Right-to-Know Provision was to make the information available, but not to be punitive. The brochure was not intended to be a weapon used against producers of food. The brochure is intended to inform consumers about issues related to FQPA especially benefits and making choices on diet to avoid use of chemicals.

Lynn Goldman noted that the issue of labeling had been addressed during the crafting of the law. She urged FSAC members to focus their attention on how to implement those provisions contained in the law. It was noted however that EPA intends to pursue other means of informing consumers such as the World Wide Web.

Members also commented on the use of partnerships. It was suggested by many members that EPA needs to allocate sufficient resources to its hotline. They also encouraged EPA to pursue partnerships with various entities to increase the credibility of the message and increase dissemination.

Several participants cautioned that while partnerships with different organizations were desirable, the timeframe for preparing the brochure was so tight that it might preclude the use of partnerships in the initial effort. It was suggested that in considering potential partnerships, EPA would need to be sensitive to the balance of those involved. Members also cautioned EPA that the language used in the brochure needs to reflect the intent of the law and should neither frighten nor falsely reassure the public.

It was observed by several participants that there is a tension between ensuring that the public gets the necessary information and making the brochure attractive and "user-friendly." It was also noted that the intended audiences for the brochure will impact how the message is presented. Several participants emphasized the need for the brochure to be written in a manner that is appropriate for the general public. A number of members stressed the importance of targeting low income populations when considering the audience for the brochure. Another participant observed that they have found that partnerships have been an effective means to reach diverse audiences.

Other participants raised concerns associated with the variability of the food supply; products used in one region may not be needed in another. For example, while there may be a benefits-based tolerance for a particular crop, it may not be used. It was suggested that this may unduly

penalize specific crops. Concern was also raised about how alternatives for a specific food will be determined. Concern was also expressed abut the possibility of frightening the public. It was suggested that the limited exposure to pesticides that might occur does not outweigh the benefit of eating the product.

To put the discussion of benefits-based tolerances in perspective, Lynn Goldman noted that out of 9,000 existing tolerances, none have been approved based on a benefits analysis. She noted that the number of benefits analyses to be conducted in the future is unknown.

Another member observed that the legislation mandates that EPA consult with HHS and USDA and that the resources of those agencies may be used to inform the public. It was noted that cooperative extension service is present in every county; thus, they can assist in reaching and educating the public.

Another member suggested that EPA should learn from campaigns already being implemented by other federal agencies. The example given was the efforts by the National Heart Lung and Blood Institute (NHLBI) to reduce heart disease as the number one cause of death over last 20 years. Their efforts included pamphlets, partnering, and talking to the public about what they eat. NHLBI learned a lot about talking with different ages of consumers which may be applied to this effort.

At the end of this discussion, EPA staff noted that they welcomed information on what kinds of formats work best and with what frequency. It was stated that such advice will help EPA develop a feasible and effective brochure.

Next, the discussion turned to identifying what activities should be seen as priorities. Several participants urged the EPA to use their limited resources to focus on the brochure because it is required by FQPA. Other participants urged EPA to undertake selective activities such as partnerships to maximize the available resources as well as dissemination of the information. Still other participants recommended that there are many provisions within FQPA that should receive higher priority than communications.

To summarize the discussion, Michael Lesnick stated that it was useful to hear the results of the conference call and the ensuing discussion here. Many of the members had advised EPA to look at the law for a starting point and then consider how to develop the message. Various options were offered including the use of focus groups and working in cooperation with other organizations. He observed that members had identified both positive and negative factors associated with the use of partnerships. Michael Lesnick noted that members had made suggestions of other models of brochures and public information efforts that can be examined by EPA. Another message strongly stated was the need to reach additional audiences beyond those who are currently using the hotline. In trying to reach more people, numerous suggestions were made about possible mechanisms to use and the need to tailor them to the intended audience.

PUBLIC COMMENT (Morning, October 22, 1996)

Vern Highly, National Watermelon Association and a representative of the White Fly Management Committee, Imperial County, California, began by stating that he supports the comments made by FSAC member Dan Botts. He is concerned about minor use pesticides and how they will be treated during the implementation of FQPA. He stated his hope that FQPA will be followed as written and that there will be incentives for the development of new alternative products. He presented a story of farmers dealing with a white fly invasion. The fly was bringing massive destruction. The farmers worked with the University of California and USDA to address the problem by developing an IPM system. The farmers raised money to develop a program that concentrates on shorter seasons and the use of less toxic chemicals with parasites.

He then noted that the farmers he represents will need some help on Section 18s. He endorsed comments made about the need to balance the risk from pesticides with the risk of not eating a diet high in fruit and vegetables. In terms of the brochure, he suggested that EPA look to USDA for help as they are a tremendous resource when dealing with farmers.

Lynn Goldman explained what EPA has been doing to address Section 18s. She noted that they have shifted resources to the Section 18 process to expedite decisions on Section 18 requests. EPA is also working with states before they make a request to ensure that the applications are complete. She also explained that an appeal route for decisions on Section 18s does exist but observed that it is rarely used. Dan Barolo stated that there will be a workshop on Section 18s in mid-November; all are welcome to attend.

RISK ISSUES: AGGREGATE EXPOSURE & COMMON MODE OF ACTION

As the discussion moved onto issues associated with risk, John Ehrmann reminded members that they were not here to re-debate the statute. Jim Wells, California EPA, provided the summary of the conference call. He began by observing that the conference call participants had expressed polarized opinions on most of the issues discussed including cumulative exposure, common mode, aggregate risk, definition of subpopulations, defaults, etc.

He reminded members that EPA had presented three approaches in the background paper which call participants discussed. The approaches are as follows:

1. Requiring data that demonstrate common mode of action;
2. Using Structure Activity Relationships (SAR) to group chemicals; and
3. Grouping chemicals with the same or similar endpoints.

Some thought that all three should be used with the starting point being the one with the most information, while others thought that the default used should be the endpoint approach. Some of the discussion focused on whether sufficient data existed for these approaches to be used. Some participants felt that based on their experience, more data often exist than anticipated: thus, a tiered approach, using an interim default versus waiting for collection of data before making a decision, could be used.

While call participants disagreed on most points, there was general agreement on the use of defaults in the short term, however, they did not agree on what the defaults should be or how they would be determined. It was acknowledged that depending on how defaults are established, the resulting decision could result in either a loss of products or the continued usage of harmful products. Call participants recognized the potential for defaults to become de facto decisions. To address this concern, several participants suggested that a time-limited tolerance could be used while data gathering goes forward. Concern was also expressed that such a system could result in EPA having to make two decisions which would require additional money.

Also noted on the conference call were issues surrounding the quality of data. Specifically, the quality of data on the end of the curves where there are very few data points was raised. It was noted that EPA is still using old databases; this was of concern to some.

With the conclusion of the presentation, FSAC members began to address the issues raised. It was noted that in passing FQPA, Congress specifically used the word "available" in terms of data to eliminate ambiguity about what data was needed to make decisions. It was suggested by a number of members that defaults were necessary in the short term because there will be data gaps and this will enable the Agency to make decisions. It was noted that the use of defaults avoids the problem of no decisions due to lack of information.

Members had differing perspectives on the use of defaults and time-limited tolerances. Several participants stated that the FQPA establishes a new standard for setting tolerances and, in at least one case, establishes a Congressionally mandated default (e.g., 10-fold uncertainty factor for children). Concern was also raised that the use of time-limited tolerances will require EPA to expend resources as they have to visit decisions twice. It was suggested that it is more effective to encourage EPA to generate data for tough, sound defaults.

Some members noted that the gap between available data and conservative defaults was a fundamental issue. It was suggested that available data will remain limited as long as resources are scarce. From their perspective, the advantage to time-limited tolerances is that it allows crops to be put in. They reminded EPA staff that this is important because growing seasons do not wait for EPA to make decisions. It was their opinion that use of time-limited tolerances results in directionally correct decisions.

On the question of what approach to pursue, several members suggested that all three approaches need to be used and cannot be considered in isolation. Other members suggested that the third option of considering similar end points makes sense. From their perspective, the goal is to drive towards development of more data. They cautioned however that if the defaults selected are conservative, this data will never be generated.

Members recognized the need to make decisions. Some of them cautioned that there should be some level of insufficient information where a decision is not made until more data are collected. It was suggested that EPA develop a decision logic that will guide their decisions. Building on

these discussions, some members advocated that EPA needs to consider each case on its merits and subject that decision to internal and external peer review.

A member asked for clarification on the terminology being used. He wanted to understand how endpoint data are different from outcome data. In response, an example was provided. It was explained that kidney tumors are an endpoint, however, there may be different types of tumors with different mechanisms in terms of causation. The key is what the mechanism is, but, it must be looked at on a case-by-case basis so that scientists are not unreasonably limited.

To help focus the input from the members, Lynn Goldman presented a hypothetical example of a decision. In the example, a Section 18 emergency request for a pesticide applied to a vegetable crop was seen as legitimate. In looking at the pesticide, it clearly triggers risk to children resulting in potential birth defects. The pesticide is also a member of a class of related chemicals which are also registered. At this point in time, the EPA has not looked at cumulative risk for this chemical across the whole class. Because the request is an emergency, EPA will not have time to do a complex scientific evaluation and go to peer review. What does the Agency do, and how so, as not to compromise the overall reassessment process?

In response, some members suggested relying on key experts to assist in the decision. Other members proposed the use of a time-limited tolerance with a request for more data to be collected. Other members directed the discussion back towards the purpose of the legislation. From their perspective, one of the key purposes of the new law was to provide flexibility so that the Agency could do the logical thing. Other members noted that this discussion reminds them of the previous controversy associated with the Section 18 process where in their view, it was abused. During the discussion, it was also noted that the consequence of the risk associated with the use should be factored into the decision.

At the conclusion of the discussion, John Ehrmann summarized that members seemed to be suggesting that all three approaches be considered with the determination of exactly how to proceed being identified on a case-by-case basis. He also noted that members disagreed on how to determine defaults, but not on their use.

Several members noted that EPA faces a choice on where it concentrates its energies: looking at new compounds that do not currently have a full risk cup; or, on products with existing registrations and a full risk cup.

Concerns about the impact on minor uses were raised by some members, specifically concerns about the financial impact of EPA's decisions on farmers and companies, both small and large, who rely on the minor use pesticides. It was also noted that the issue of risk was not new. They wondered if anything from the discussion would change how the Agency is addressing risk.

Penny Fenner-Crisp responded that the Agency is using 20 year old data on food consumption and has not integrated the new data that are being gathered. She explained that the missing link is how to integrate the new data. She noted that models need to be developed that will fill in the real data gaps that allow EPA to make informed decisions.

In addition, it was explained by Lynn Goldman that EPA does not have a guarantee that data will be upgraded on an on-going basis. She explained that the source of data is the USDA human nutrition survey. EPA has been working with USDA to upgrade the survey using the questions raised in the 1993 NAS report on children. She noted that the USDA has not received funding to make these changes and collect new information. EPA is also working with the HHS on the national nutrition and health survey. It is an additional source of information but the resulting data are not in a format that is easily used by EPA. She observed that there is much uncertainty about how these programs will operate in the future due to decreases in appropriations.

Another participant commented that if there are cancellations of minor use pesticides, growers may substitute use of more higher risk pesticides. He wanted clarification on whether the risk cup will address this. He suggested that it is important to do so. He also suggested that such actions may penalize those farmers and growers who have been the most innovative with the development of IPM systems.

Lynn Goldman responded that EPA does consider competing risks when they make their decisions. If aggregate risk is too large, alternatives are considered and negotiations undertaken with the registrant to determine which uses will be dropped. She noted that the room for negotiation will be tighter now because FQPA establishes a tougher standard.

Several members asked for clarification on the ability of EPA to obtain information on the structural relationship between chemicals. They thought that such data should be easy to get, yet, the issue paper indicates the opposite. If this is true, they suggested that additional money needs to be put into getting structural data.

Lynn Goldman responded that registrants do provide structure data when they seek a registration. She explained that the focus of this discussion was on looking at structure as a means to determine structural similarities versus looking at endpoints. The latter requires more effort.

Some participants raised a procedural question. They wanted clarity on how EPA processes decisions and specifically wondered whether the degree of controversy affects the decision-making process. Dan Barolo noted that nothing is without controversy. He explained that EPA has been improving the process so that the analysis and decision-making are being made at the lowest level. He observed that 90 percent of the actions are routinely processed. Where there are problems with a decision, they are sent to the Assistant Administrator for decision. Lynn Goldman added that for Section 18 petitions, the states do much of the work.

Building on the comments about the decision-making process, another member urged EPA to establish a transparent process, specifically one that is transparent to growers. He also noted that much of the information about the way pesticides are actually being used is only available at the grower level. Thus, growers should be involved in updating this information. He further observed that if the data on usage are not good, then exposure information will be compromised. He suggested that growers should be involved in defining exposure concerns.

A few members voiced their interest in how cumulative effects are considered and how the data from studies with rats are relevant to humans. Lynn Goldman noted that FQPA does not change the use of data from rat studies as an indication of impact on humans. However, it does provide EPA with flexibility to decide whether to rely on the rat data or not. She explained that the Delaney Clause specified if there was a cancer impact on rats then it was assumed to impact humans in the same way. She did note that EPA would assume that the data are relevant unless there is evidence indicating otherwise.

Other members urged EPA to keep in mind that there are two different approaches that they could pursue in setting defaults: reasonable certainty of no harm or reasonable certainty of harm. Depending on which one is selected, a different test would be used.

Questions related to aggregate risk were also raised. From one perspective, it was suggested that the real issue is when you have different types of tumors, if you have ten different chemicals that cause same end point, is this cumulative? From their perspective the answer is yes.

Fred Hansen next noted that discussing a concrete example might be useful. It was his thought that it would give the group a chance to see what some of the choices would be, present views on them, and increase understanding of the decision-making process and decision logic.

Penny Fenner-Crisp and Margaret Stasikowski presented the case study. They focused on organophosphates (OPs) and carbamates. They began by explaining that in terms of a common mode of action, these chemicals are cholinesterase inhibitors. Thus, the first question to be considered was whether they should be split into subsets or addressed together. They noted that one possible split would be whether the effects were reversible or not.

Continuing, they stated the no one chemical exhibits toxicity with only one mode of action. Thus, it is necessary to look across the spectrum of toxicity. One will see different toxicity in different organs and other systems, so it is necessary to lay out a full toxicological profile for the 30+ OPs and find which share common endpoints. They suggested that most will be cholinesterase inhibitors, each with different potencies for having that effect. They then establish equivalencies by taking one chemical as a benchmark and comparing others against it.

Next, Penny Fenner-Crisp explained that they attempt to understand the exposure potential. Some may be substitutes for one another and thus would not be used at the same time and might be used in different proportions. Thus, the acute and long term toxicity potential may vary. One would also make distinctions based on food and non-food uses.

It was also pointed out that many have different intermittent exposures. How this variability is factored into the assessment of aggregate exposure is a question the Agency is addressing. It was suggested that this is where models need to be developed.

Lynn Goldman added that for many OPs, they are very close to 100 percent of the reference dose (i.e., the risk cup is almost full) under the old standard and for some of the OPs, the reference dose has been exceeded. Thus, when looking at them under the new standard, a number of issues

are raised (e.g., uncertainty factor for children.) She also commented that not all risk assessments are based on actual data; some of them begin by assuming that all food has residues at the tolerance level.

Penny Fenner-Crisp added that EPA has developed a standard methodology for determining exposure to food uses, but has not done so for other uses. Thus, they will have little to inform them when they consider exposure due to non-dietary exposures.

John Ehrmann then asked members for their comments on the case study, specifically that portion which pertained to the decision logic.

The first point made by a member was that such an approach will be problematic as the various chemicals come from different companies. In response, Dan Barolo stated that the Agency has an obligation to address the chemicals in a manner that is fair to all. He noted that they would not single out one chemical from one manufacturer, but would consider them as a class.

Several members noted that such an approach will require significant amounts of data and urged the Agency to get real data as the assumptions being made seem to be conservative. Other members noted that with increased data, it is likely that more effects will be seen. However, they observed that having such information will enable EPA to identify the value of information and how it is used in making a decision. With an increased understanding of the process, it was suggested that the members of this Committee will be more comfortable with the decision process instead of feeling that decisions are made in a black box. It was suggested by many members that the use of toxicity equivalents as outlined by EPA was an appropriate way to proceed.

Others urged EPA to consider the use of time-limited tolerances as a good compromise between overly conservative defaults and lack of data. It was thought that such an approach would be appropriate as it would provide growers with certainty and limit risk.

Lynn Goldman observed that there are 9,000 tolerances established; however all pesticides are not being used all the time. She explained that she understood that keeping them available is a option desired by growers as they are concerned about pests developing resistance. She asked for the Committee's thoughts on whether all of these uses were desired and if so, their insights on how to address aggregate risk given this reality.

Several members responded that they want the full complement of options available as their goal is to manage pest systems and, as many options as possible are needed to increase stability. From their perspective, diversity of products available connotes stability. It was explained that these products will not necessarily be used consistently, but having them available to address resistance issues is critical to the viability of pest management systems. Concern was specifically noted about pest management systems where only one pesticide remains. Concern was also stated about situations where the only efficacious product to address a new pest is an OP; it was suggested that such cases are difficult to factor into the Agency's decision-making.

On another line of concern, it was observed that the statute excludes calculation of occupational exposure; yet, farm labor camps are located within fields of crops and farmworkers and their families are heavily exposed. It was suggested that these types of exposures should be considered when determining aggregate exposure. It was also suggested that EPA consider that exposure may be intermittent, but that sometimes one exposure is enough, so immediacy of harm should be factored into the analysis.

Dan Barolo concurred that the statute does exclude occupational exposure for tolerance-setting purposes. He noted, however, that the Agency does have obligations under other parts of FIFRA to review worker exposure as well as ecological impacts.

Pursuing the questions of aggregate risk further, several members asked for clarification on how closely does EPA look at subgroups (e.g. children, workers with OPs on their clothes, etc) as a separate category when doing a risk assessment. They also sought clarification of how non-dietary exposures affects the definition of subpopulations.

Lynn Goldman noted that the questions of what is a subgroup is one that the Agency is addressing. Jim Aidala commented that the law identifies consideration for any "major identifiable subgroup of consumers" which can include more populations than just children (e.g., older people have slower metabolisms, thus might be considered a subpopulation).

In terms of subpopulations, several members asked EPA if a designated subpopulation was going to be farmworkers' children. Lynn Goldman responded that farmworkers' children would be considered as a subpopulation. She continued by stating that currently the identified subpopulations include: regions of the country, age categories, and ethnicity. She noted that the new law allows EPA to identify other groups (e.g., farmworkers, households that flea dip their dogs, etc.) She went on to explain that in terms of dietary risk, the Agency is limited to available data with its limitations.

Lynn Goldman elaborated further on the issue of subpopulations. She observed that when one is considering subpopulations, the attributes of that specific subpopulation affects what kind of information is needed on exposure. She then asked Committee members for their thoughts on the question that addresses the level of protection. She noted that assuming adequate protection for 90% of 23 million children - would mean 10% are not covered. She further explained that this issue raises questions about the quality of data as one gets to the extremes. Some members suggested that when considering cumulative risk and toxicological phenomenon, the Agency needs to look at it on a case-by-case basis. They suggested that the approach outlined by EPA is reasonable because of its flexibility.

Several members questioned if the Agency should be prepared to accept a protection level of only 99.9 % of kids which would leave some exposed. It was observed that the President, when signing FQPA into law, stated that we should put children first. Thus, their understanding is that if a pesticide presents a risk, it will not be used. It was suggested that EPA needs to protect all children.

Lynn Goldman commented that the Agency is hindered by the fact that it will not ever have all the data needed. She noted that they can improve from where they are today, but there are practical limitations.

Another member attempted to summarize the key points which he felt the law, FQPA, defined for the EPA. His summary of what the Agency has to consider under the FQPA is as follows:

- Make timely decisions;
- Attack the worst first; within three years, set priorities as to which chemicals should be considered first; and
- Protect the most vulnerable.

He went on to elaborate that making timely decisions is very important. He also noted that the Agency needs to establish a process that is clear and that they are going to have to make some tough decisions, but they will need to do this, by selecting defaults, where data do not exist. In conclusion, he urged the Agency to err on the side of safety.

Another member asked for elaboration on how EPA is looking at the agricultural system. As the most important risk may vary by crop, he wanted to know whether EPA is prioritizing risk crop by crop or on the basis of the active ingredient. Following up, the member noted that if EPA goes after an active ingredient with no other alternative, it may not be the highest risk pesticide in use on that crop. He suggested that they should adopt a crop approach to looking at risk and pesticides.

Several members noted that it is important that the Agency consider the whole picture when making its decisions. They suggested that the Agency look at other exposures in addition to the aggregation of risk from tolerances on food. It was observed that EPA has the tools to regulate other exposures so that the presumption should not be to reduce risk from the food side of the equation.

Another member stated that this group should not spend time on science; those issues should be left to other panels including the Scientific Advisory Panel (SAP) and Science Advisory Board (SAB). He noted, however, that a lot of what is being discussed is policy (i.e., how to deal with lack of data).

Several members raised concerns about the representation on the FSAC. They observed that the ratio of industry to public interest representatives is three to one or four to one. These members observed that the tone of discussion during the meeting has been one of EPA making industry jump through hoops and that through implementation of FQPA, industry would like to weaken the law. They urged that the representation on the Committee be changed so that more public interest groups and sustainable agriculture organizations are included, which would change the tone of the discussion. They also observed that the focus of the discussions assumes the continued use of pesticides. It was suggested that in its discussions, the FSAC needs to consider the overall direction of agriculture and whether the use and reliance on pesticides is appropriate.

Fred Hansen commented that EPA would welcome additional suggestions for representatives from the public interest and sustainable agriculture communities. He asked the Committee members to recognize that this Committee is not being undertaken in a manner where there will be majority/minority opinions produced in a final report. He further emphasized that the point of this Committee is to establish a process where the debate can be informed by assuring that all views are presented. The number of comments from any one perspective does not matter; what will be documented and heard is the diversity of opinions stated. He then observed that there are only two more meetings on the schedule for this Committee. He noted that EPA does recognize that public interest, environmental, and environmental justice organizations are stretched thin and that participation in efforts such as this can be a burden for them.

John Ehrmann noted that the Agency faces tough decisions when convening meetings of this type He observed that the good news is that the Agency is trying to open up the process and that meetings such as this offer an opportunity to address fundamental issues about what the statute is and what are the fundamental issues. He explained that the Agency has established parallel fora to deal with technical and scientific issues. These fora are addressing policy as best they can; not everyone will be satisfied. In terms of the issues around representation, the Agency is open to additional representation while balancing the need to have a workable number of people on the Committee. The balance, in terms of perspectives represented, will seem different depending upon the issue. As mentioned by Fred Hansen, this is not a consensus process and EPA will not tally how many people held a particular view.

PUBLIC COMMENT (Afternoon, October 22, 1996)

Jay Vroom, America Crop Protection Association (ACPA), spoke. He stated that this had been a productive day for science and souls. He stated that most of us walk away from this meeting with a better understanding for the real responsibility faced by the Federal Agency who will implement the FQPA. He noted that in the risk arena, much has been heard about the importance of using the new law to benefit society. He concurred with the statements by Jack Moore and Kay Holcombe that acknowledge that the Agency must get on with developing a decision process matrix so that they can make decisions, and decisions need to be made based on available information. He stated that a one-size-fits-all approach to risk management is not acceptable or necessary; EPA has real science expertise in the SAB and SAP which will provide guidance. He also observed that three time-limited tolerances are already a reality.

He stressed the importance of the Agency having adequate resources to implement FQPA. He shared a letter from fourteen organizations including grower organizations and others, that urge Congress to provide additional resources. Congress has now given EPA additional money. It is now up to Administrator Browner and Deputy Administrator Hansen. He encouraged the Agency to maximize the amount of money allocated to this effort for greatest effect.

Bill Tracy, National Cotton Council of America, expressed appreciation to EPA for bringing this group together. He spoke of the real work of agriculture which requires the availability of an array of pest management tools. He noted that, if decisions can be made now then they can

continue to farm wit' IPM and address resistance management. Having the tools will also make growers more efficient and help to maintain the agricultural base.

He continued by noting that as an agriculturist, he believes that the wealth of the nation comes from its agricultural base. He stated that he is a father of four and has a few employees. Farming is one of the only professions where one has to get a bank loan in order to undertake the work of the year and, at the end of the year, one gets paid. And he noted some years one does not get paid. In those years, one gets another loan to pay yourself and banker. He concluded by thanking them for the opportunity to make a statement and urged EPA to consider the letter mentioned by Jay Vroom.

With the conclusion of the public comment, John Ehrmann noted that if anyone wanted to submit additional comments the docket number is OPP00450.

OCTOBER 23, 1996

Fred Hansen opened the second day of the meeting. He commented that building on yesterday's discussions, he would like to engage the Committee on policy questions. He noted that EPA would like to present a proposed decision logic that identifies points where policy choices need to be made. He noted that some of the issues raised such as tolerances and subpopulations will be taken up in more detail later. He asked Dan Barolo to present this decision logic and to engage the Committee in a discussion of the policy choices that underlie it.

MAJOR GOALS AND POSSIBLE DECISION LOGIC

Dan Barolo presented the decision-making logic for risk decisions under the FQPA. He qualified his presentation by noting that this was a preliminary draft and would be refined further. At the beginning, he explained that the goals of the Program are to make timely decisions, attack the worst first, and protect the most vulnerable populations. He observed that if EPA can meet these goals, they will have addressed the goals of the Act. (The proposed decision logic is attached in Appendix A.)

As presented, the decision-making logic has three main steps: inventory the Agency's data base on all 600 active ingredients and 20,000 products; group pesticides in broad classes based on structural similarities or similar health-effect endpoints triggered (e.g., organophosphates); and. assess and manage the risk.

As part of the inventory process, the Agency will look for critical data gaps. He explained that he expects there to be relatively few critical data gaps because of recent reregistration efforts. Where critical data gaps are identified, Barolo stated that EPA will apply conservative assumptions to be used in the decision-making process.

He explained further that at the risk assessment and risk mitigation phase of the logic, EPA would conduct individual chemical evaluations applying the standards from the new FQPA and FIFRA. If the standards are not met, mitigation measures such as the suspension of the registration will be

sought. In evaluating a specific chemical, EPA would determine the uncertainty factor for sensitive subpopulations using a weight-of-evidence approach. As a part of this analysis, aggregate exposure, both dietary and non-dietary, will be considered as well as whether there is a common mode of action.

In terms of common mode of action, EPA will determine if there is one. If not, then the Agency can make a regulatory decision on the chemical to approve or not. If the chemical has a common mode of action, the Agency will conduct an integrated risk assessment. If the assessment suggests that there are no problems, the Agency can proceed to make a regulatory decision. If problems are identified, the Agency would consider actions such as suspension.

Dan Barolo noted that this decision-making logic will allow EPA, in three years, to make tolerance reassessments and reregistrations on chemicals such as OPs, carbamates, etc., including those chemicals registered since 1984 and pre-1984. He explained that such an approach folds in uses approved in prior regulatory decisions. It also allows them to address chemicals which have higher risk and provides a means to process Section 18's, use of time-limited tolerances, and consider reregistration decisions. He stated that newer safer pesticides would follow the same process for decision-making.

After concluding the presentation, the question posed to Committee members was "What is your reaction to the overall decision logic and flow?"

As members began to react to the decision-making logic presented, John Ehrmann reminded them of the ground rules, specifically that the goal is not to seek consensus. He restated that EPA is looking to the Advisory Committee to provide their views and perspectives.

A member suggested that EPA needs to add a fourth goal to the three listed: registering new and safer products, as this is key to users. Dan Barolo noted that the decision-making logic presented only addresses the risk aspect. He explained that other aspects are considered elsewhere.

Several members noted that the presentation had provided clarification on how decisions are made. Some noted that as always the devil is in the details. They noted that it appears to be a good logical approach. Looking for some additional definition of the process, they questioned how the uncertainty factor is applied to a chemical.

Lois Rossi, EPA, explained that the first step in the normal assessment of chemical is to do a risk assessment. Now with the passage of FQPA, the factors specified within that law (e.g., aggregate exposure) are taken into consideration. She explained that in the first step uncertainty is identified and it is addressed further in step 3.

Several members wondered why the number of Section 18's has been increasing. They had thought that the intent was for Section 3's to be sought instead. It was explained that due to the potato blight, there have been more Section 18s granted. Barolo noted that the overall trend is towards less Section 18s. He further noted that Section 18s only apply for one year. As a part of the Section 18 process, progress needs to be shown towards getting a Section 3 registration. It

was further noted that substances which have been receiving Section 18s have been given priority in the queue.

Several members suggested that they find it hard to imagine that there are pesticides for which there are no data. It was suggested that in such cases EPA should look at similar products for data. Dan Barolo explained that no new product or use is permitted without data and that EPA staff are looking at those products or uses where there are outstanding data and taking more aggressive action on them. He went on to state that FQPA requires the Agency to look at subpopulations which creates a need for even more data. He also observed that the common mode evaluation is a new process for EPA staff and is likely to require more data.

A few members stated that they were still mulling over the presentation. They wanted to be clear as to whether this logic differs from what was done prior to passage of FQPA. Several participants observed that the logic presented was a good start. It was suggested that a flow chart of the process would be helpful. Dan Barolo explained that they are looking at existing data in new ways as the focus is now on classes of active ingredients. He went on to explain that EPA has been acting on individual applications and making decisions. This gives EPA an opportunity to look at three broad areas: sensitivity of subpopulations; determining aggregate exposure including non-dietary exposures; and common mode of action.

He also clarified data gaps by explaining that EPA has guidelines for over 150 tests which are required for registration or reregistration. He also noted that there are not any older chemicals where broad pieces of information are missing; however, he explained that additional information is likely to be required for new chemicals.

Following up on their question, several members observed that there are key areas for which there are gaps and no mechanism for filling them (e.g., nondietary exposure). They suggested that there may be ways to come up with reasonable conclusions. The idea of using defaults was raised again and concern was expressed about the use of automatic defaults. They suggested that the Advisory Committee should explore the idea of reserving some of the risk cup. It was noted that this is clearly a policy call this group should consider.

Other members wanted to know more about data gaps. Of specific concern was who declares there is one? When is the toxicity review done? Dan Barolo responded that the Program defines the data gaps and makes the regulatory decisions. As a part of that process, they have an intensive internal peer review process. As a follow-up, several members wanted to know to what extent does EPA look at pre-natal and peri-natal exposure when looking at risk. It is their understanding that data are lacking in some of these areas.

Building on the discussion of subpopulations, some members requested that EPA provide the Committee with a list of the subpopulations they have identified at the next meeting. Dan Barolo agreed to provide such a list to the Committee.

Another member queried if EPA could provide a similar decision-making logic for devising mitigation efforts. Lynn Goldman responded that the risk management process is the last step of their decision process and they will present a similar logic illustrating it.

Other members raised the question of resources again. It was observed by several members that implementing the requirements of FQPA will require more resources. Specifically, they wanted to know if EPA has requested additional staff to do this.

Mr. Barolo explained that a great deal has been invested in the re-registration process and evaluating risk. He observed that 187 reregistrations have been completed and more are expected soon.

Fred Hansen responded that EPA will be able to provide a flow chart of the decision logic and the other items requested.

A member raised questions about how data gaps will be filled. He noted that information is better for toxicological effects than for exposure. He also raised questions about field worker exposure data. He observed that such data often do not reflect the actual exposure workers receive because potential exposure varies from crop to crop.

Dan Barolo explained that EPA has been working on this issue. They have a task force that is attempting to generate data on residential, worker, and other sources of exposure. He noted that decisions will have to be made, and, if there is a gap, the Agency will make conservative assumptions. He stated that he hopes that the Committee will provide input on whether they should add additional subpopulations and/or if they should add additional safety factors. For context, EPA indicated that they would provide Advisory Committee members with a current listing of subpopulations by the November 14-15 meeting.

In response, several members noted that the Agency needs to be careful when considering risk mitigation from the worker exposure side. They suggested that care be taken when considering theoretical versus actual values. They noted that studies may not correspond with what happens in the real world. Other members pointed to the lack of data about incidents and associated exposures to workers. They felt that the lack of data in this area needs to be addressed.

Fred Hansen commented that having the decision-making logic outlined and receiving input on it has been useful. He reminded everyone that the process outlined is preliminary and still needs to be refined.

Several participants wanted to know how the decision logic presented applies to Section 18s, safer new registrations, etc. Dan Barolo explained that the Agency has an obligation to apply the FQPA factors to determinations and decisions being made and that the proposed decision-making logic applies for Section 18 and/or new classes of products. He went on to state that EPA is encouraging others to be more active in their consideration of the Act's requirements when they consider submitting Section 18 requests and applications for the registration of new products.

Lynn Goldman explained further that the 50-day review period for Section 18's still applies; the timeframe for decision-making is the same, but the way decisions are made will differ.

After hearing the presentation on the proposed decision logic, some members suggested that it will be more difficult and time consuming for EPA to make a decision on an entire class of chemicals than on an individual chemical. They raised this as a concern and suggested that EPA consider the ramifications.

Several members wanted to know where and how EPA will use their science advisors (i.e., the SAP and SAB) overall, but with specific concern in terms of considering factors for minor uses. Dan Barolo responded that the Program will consult with the SAB and SAP on science and science policy decisions.

Penny Fenner-Crisp explained the structure of the SAP is defined in FIFRA. Seven individuals are on the Panel at one time, however, membership can be supplemented to bring in additional expertise. It was noted that the October meeting would have 20 additional people involved. She explained that the SAB is an Agency-wide effort that has a number of subcommittees that examine the implications of specific substantive decisions by other Agency program offices. The upcoming SAP meeting will involve a number of people from the SAB.

A member asked that in terms of worst first, to what extent does the Agency consider identifying tolerances out of "whack" with the reference dose. Dan Barolo responded that the list of reference dose exceeders has only six products remaining. The Agency has been aggressively working on them; thus, they do not anticipate having many products to address where the tolerances are out of "whack."

Penny Fenner-Crisp explained that there are a number of tests that are conducted to address pre-natal and post-natal exposure. Lynn Goldman noted that these issues will be discussed with the SAP next week. She also stated that the means to test for developmental toxicity has been under revision since the release of the NAS study in 1993 with the involvement of many scientists. She specifically noted that a critical policy question facing the Agency is how to make decisions while in transition between the old and new tests.

Several members noted that this discussion had been helpful. They then observed that EPA also needs to make timely decisions. This led to a re-statement of concerns expressed earlier about the need for adequate resources including staff, so that the Agency can make timely decisions. It was also observed that even once the Agency has adequate staff, it will take time to get them integrated into the Program and making decisions.

Fred Hansen replied that in terms of resources, the question facing him is not whether there will be resources but the amount of additional dollars that will be committed to this program.

Several members wanted to know whether farmworkers were on the Task Force dealing with field exposures. Dan Barolo clarified that the Task Force is only dealing with data generation at this

time. Issues associated with application will be addressed later. Thus, farmworkers are not currently involved.

MINOR USE PESTICIDES

The discussion of Minor Use pesticides began with a presentation summarizing the task group's conference call. Rick Holt, DuPont, began by noting that fruit and vegetable growers will clearly be impacted by FQPA. The conference call discussion did not focus on the new language contained in the law; instead it centered on three main topics: how minor use growers can be informed as early as possible about potential cancellations; how to involve minor use growers in decision-making as they are the repository for much on-the-ground information; and, the potential impacts from the loss of products.

Rick Holt noted that those on the call clearly expressed the desire and need for increased communication about affected products. They noted that the sooner they were informed of possible loss of a chemical, the sooner they could begin to look for alternatives. During the call, the potential for products put on a potential loss list to result in a de facto loss of use was raised. This resulted in a discussion of ways to inform minor use growers such that a "list" did not have to be generated. Ideas suggested include holding annual meetings with growers to discuss concerns, use of mailing lists possessed by organizations such as ACPA and USDA, and increased informal stakeholder involvement efforts by the Agency.

Those on the call recognized that the primary parties involved in discussions over continuing uses are the Agency and the registrant, but many urged that growers be included because of their knowledge. During the conference call, EPA staff encouraged growers to provide information to them about actual usage to be used in risk calculations.

As the discussion continued, the EBDC Task Force was cited as an example of an effort where growers had been involved. Those on the call who had been involved with the Task Force agreed that overall the effort had been a good way to proceed, but, they cautioned that it was expensive and time-consuming.

Conference call participants also raised a number of short term issues including concern that EPA not make decisions before the science is known, the need to include minor uses in the risk calculation, and impact on USDA's IR-4 program.

In terms of setting priorities, it was suggested that EPA should consider what products are in the pipeline. In response, EPA asked for suggestions of other mechanisms for allocation of risk. Ideas discussed briefly included prescription use, (e.g., use only in IPM programs), pilot projects, reserving a portion of the risk cup for minor uses, etc.

Rick Holt reported that at the end of the call, several participants had raised the possible consequences of conservative actions by EPA. From their perspective, such actions could result in fruit and vegetables being produced off-shore.

With the conclusion of the summary, a member added that the discussion of minor uses needs to consider the roles of other agencies. He suggested that the minor use community needs to see the guidelines EPA will use before they will know what the impact will be on them. Continuing, he urged EPA to consider all aspects of risk mitigation associated with the use of a product. He also observed that future negotiations on uses will become contentious because of what is at stake. He encouraged EPA to do what is necessary to insure that uses are retained or modified to allow production. He also noted that minor use growers have already been impacted because of delays with new products due to the lack of guidelines following the passage of FQPA.

Several members echoed the comments made on the conference call. They stressed the importance of trying to make sure that minor use growers have adequate amount of time to make adjustments for cancellations.

Other members stated that they were intrigued by the idea of reserving part of the risk cup for minor uses. They noted that more time is needed to think about the implications. However, it was observed that it would put more policy focus on sharing risk, whereas, currently, the process has lacked incentives to involve minor use interests up front.

Several members observed that there are two broad issues: data - particularly for registering products or keeping products registered; and, risk management. They wondered how different FQPA will be for chemicals that already exceed the daily amount, and similarly, how the Agency is going to make decisions about which uses are safe and which are not.

Dan Barolo noted that the law provides incentives to encourage an accelerated pace, but the process is also more complicated. One example is in risk management; the new law does not recognize benefits except for non-threshold effects. It was suggested that this will complicate matters for minor uses.

Several members then sought to better understand this. They asked what will the Agency do when faced with a decision where there are 15 uses of the product, but, only 10 can be used to meet the tolerance. How would the Agency decide which uses are eliminated as they reduce uses from 15 to 10. How would they consider benefits as a part of that decision? Additionally, other members wanted to know what kind of information is used to make these decisions and how it is applied to minor uses?

Dan Barolo stated that the Agency is trying to establish a policy on this matter. He and others at EPA welcome the members' thoughts in this area. He noted that historically it has been the registrant who decides which uses to retain. He went on to note that in the last two years, the Agency has been engaging users more often. They recognize that the decision should not be made by EPA or the registrant solely. He stated that the Agency is wrestling with how to insure broader input. The Agency would also welcome the members' thoughts on how to get USDA to play more of a role.

Another member suggested that EPA look at use patterns, alternatives such as IPM, worker safety, and other issues and involve those concerned with those issues at that point. He suggested

that whether USDA ultimately assists or not, EPA will have to make the decision and that it is a risk/risk process. He urged EPA to make their decisions based on the good information available from the user community as well as others.

Several members stated that farmworkers and organized labor need to be included when the Agency makes these decisions as minor use crops are labor intensive. From their experience, farmworkers have been omitted. They urged the Agency to identify users, such as farmworkers and include them. They also noted that in terms of residue data gaps, many of the efforts are driven by research on food tolerance residue that remains if the chemical is used. Also, they wondered if there are data on dislodgeable residue that workers are exposed to in handling, and urged the Agency to look at both consumer and worker exposure.

A number of members noted that the statute allows for an extension to be granted for limited types of data, but observed that there are big gaps on consumption and exposure and environmental effects for some pesticides. They also asked about the quality of the data for individual crops. How will EPA make determinations on who collects the data? Second, what is the obligation of EPA and USDA? Is EPA supposed to alert growers, others, and registrants early when minor use products are in trouble? They suggested that USDA needs to look for alternatives in advance by looking ahead for products that may be considered for cancellation.

Building on an earlier comment, several members observed that from their perspective, responsibilities for minor uses fall to USDA. Others observed that the responsibility is not only on USDA and EPA, but also on states when companies cannot afford to collect the data. They also asked for clarification of the roles in relation to minor uses for each of the agencies, EPA and USDA. It was suggested that without clarity as to roles and responsibilities, uses could be lost because it would not be clear who would be responsible for a public benefit evaluation which would include an assessment on alternatives and benefits.

Members then queried Larry Elworth from USDA on what they are doing and how they are insuring that alternatives will be available. He responded that USDA has a process for looking at what is likely to be regulated and going back to users to see if they have alternatives and if they have the research capacity to look for alternatives. He observed that most of the crops with few alternatives, identified by USDA and EPA in their review, were minor use products. He also noted that voluntary cancellations affect minor uses. He stated that a key question to consider is the availability of resources for special reviews and voluntary cancellations.

Larry Elworth continued by observing that more than just the availability of alternatives needs to be considered. He noted that they need to ask if safety is being addressed as well as the needs of the growers. Is the system going to give growers products that they can use or leave them without alternatives? He concluded by stating that to do such will require Congressional support.

Several members commented that it is incumbent on EPA and USDA to look ahead. Larry Elworth observed that it raises an important process question: Should the Agency act as if the registration schedule is to be used as a mechanism for looking at a two year time frame? He

noted that the agencies and growers should know enough to avoid the dilemma of leaving growers without any products.

Other members observed that such efforts will need investment of money from USDA on this process. It was noted that if the agencies cannot get money from Congress, they need to find the money elsewhere to avoid risk to the food supply.

It was also suggested that the idea of reserving part of the risk cup for minor uses up front is worth discussion. It was suggested that such a system would mean that the Agency would not have to always wait for a registrant to act.

Other members noted that the Agency cannot tell the registrant who to sell products to. However, they noted that it is important to bring growers into the process sooner to increase understanding of the implications and actual use of a product. Over time one can move to a new system that is technology forcing. It was also noted that registrants do not know how products are used; users do.

One of the members who is a registrant agreed with the need to involve users and other stakeholders early in the process. However, he noted that in the end, registrants as owners will make decisions as it is the responsibility and right of the owner. He suggested that he is uncomfortable with the concept of reserving part of the risk cup. It is his feeling that the registrant and EPA need to be the ones who decide which uses make up the cup. It was his thought that the up front decision to preserve part of the risk cup would not prove to be an effective incentive to protect minor uses. It was suggested by other members that the new law has incentives for the registrant such as the exclusive use of data for a period of time if they develop a chemical for use with minor crops. It was suggested that before taking an action like reserving part of the risk cup, they should see how this plays out first.

Other members also agreed with the idea of involving stakeholders and growers early in the process. It was noted that when referring to minor uses, lots of foods fall into this category. They suggested that other means should be considered other than just eliminating some uses. Ideas presented include selective use, restrictive use, etc.

A number of members felt that additional lead time was needed for involvement of the user community. It was suggested that the additional time may force communication between USDA and EPA. Other members suggested that the claims about losing food products from the market due to the loss of minor use pesticides are exaggerations. Previous statements have not turned out to be true; it was observed that we still have good food.

As mentioned previously, some members wanted EPA to consider the addition of a fourth goal - the need to provide for safe uses. It was suggested that there had to be some alternative between allowing unsafe products on the markets and decisions made based on worst case assumptions. It was suggested that all should be concerned. It was explained that minor crop growers have been among the most progressive and creative and may be the hardest hit; it does not seem fair to them.

Another member noted that the discussion is reminiscent of discussions held during the Carter Administration. It was observed that most chemicals currently of greatest concern are fungicides Attempts were made to address them in 1977, yet they are still around. He explained that growers in 1977 had the clout to stop action by the government; he noted that if this perception remains, support will lag and the seriousness to look for alternatives will not be there. He suggested that there needs to be real commitment and realistic perspective that all can work towards.

In response to previous comment, it was observed that the industry has spent money looking for new fungicides over the past 20 years and is still doing so. However, it was suggested that efforts for growers to work with industry should be encouraged as should the search for means to undertake risk mitigation in terms of exposure. In terms of the concept of reserving a portion of the risk cup, it was suggested that it will not work to maintain uses; it was his feeling that it will result in an increase in cost for marginal uses.

Another member raised the concern identified in the conference call about the implications of the loss of minor use products. He stated that the result will be to drive fruit and vegetable production offshore. He also observed that imported crops will then be brought into the country with illegal residues on them since imports are not totally sampled. Steve Johnson noted that the tolerance levels are the same for imported foods. The assumption made by EPA is that 100 percent of imports are treated.

Another member wondered if the FQPA can be used as an encouragement for the development of reduced risk pesticides and is this is one of the goals seen by EPA? Lynn Goldman responded that it is anticipated that FQPA will encourage the development of reduced risk pesticides and it is a goal embraced by the EPA.

Another member restated a common theme - minor uses are not used on minor crops in terms of what people eat. She also noted that alternatives just may be too expensive. She noted that there needs to be incentives for minor uses to be maintained. She thought that the idea of reserving part of the risk cup may make sense.

Fred Hansen summarized the morning's discussion by observing that it had been very valuable. The clear message about insuring input from all concerned on which decisions need to be made was heard as well as the need for a more proactive nature in the minor use area and to think about alternatives. He noted that he was not sure whether government can do a good job of making choices between competing interests. He noted that the Agency often undertakes individual discussions with registrants about alternatives rather than seeking the input of diverse interests. In concluding the morning session, he requested input on the concept of reserving a portion of the risk cup from growers and others.

REVIEW OF FUTURE MEETING AGENDAS

After the lunch break, Fred Hansen requested input from the Committee on issues to be discussed at the next two meetings, November 14-15 and December 4, 1996. The Committee members agreed with the issues that had been identified previously: risk; 10-fold uncertainty factor for infants and children; in utero exposure; worker safety; and, tolerance reassessment process. As they had done for the October meeting, EPA promised to provide background information to help frame the discussions.

In terms of the December 4 meeting and as appropriate for the November meeting, members suggested that the addition of the following issues be considered:

- How statistics will be used and what percentiles are planned for use?
- Reports on the discussions held by the SAP;
- Section 18's;
- How to reduce use of pesticides and still maintain a balanced food supply?
- How EPA will decide what is worst first?
- Resource allocation including consideration of the nature of delivery system; and,
- Presentation of options being considered to implement the law; where will resources be put - towards safer products or those with slightly less risk?

The identification of reduced use pesticides as a possible topic for one of the next two meetings elicited discussion from a number of members. They urged EPA to focus the available resources on looking for safe alternatives rather than just less toxic alternatives. Others felt that the reduction of pesticide use was not part of the goals identified in the FQPA.

REDUCED RISK/IPM/POLLUTION PREVENTION

Steve Balling reviewed the discussions that occurred on the conference call. He noted that this group could be labeled the "buzz word" working group. He also noted that the discussion had been quite wide ranging. He stated that call participants recognized that FQPA does require development of procedures to expedite development and registration of reduced risk products. He noted that EPA had started such efforts in 1993 and that the law codifies what was being done. He explained that the most important aspect of the discussion was the group's analysis of what is safer. The participants identified two distinct definitions of safer. One is an absolutely safe product. The other is relatively safer (e.g. product A is safer than product B). As the discussion proceeded, it was suggested that maybe EPA should develop a separate program for relatively safer products.

During the call, participants recognized that if too many products fall within the boundaries of the reduced risk pesticides program, the program will be overwhelmed, thus, an expedited process would not result. It was observed on the conference call that if the program currently receives more than two applications, it is overwhelmed. It was acknowledged that resources associated with this program would be critical to the Agency's ability to expedite the review of reduced risk

pesticides. Also, during the call, the importance of considering the needs of agriculture in considering products was noted.

Those on the call also considered possible measures of success for a reduced risk program. Suggestions included looking at the number of registrations, market penetration, membership in the pesticide environmental stewardship program, and monitoring key pesticides critical to IPM programs.

They also discussed incentives for adoption of IPM and safer compounds. Ideas included use of a safer designation on labels advertising the product as a green compound, provide labeling of products' impacts to growers, and IPM certification. The issue of how to accelerate adoption of IPM in general was also discussed. Many of those on the call raised questions about the implications that enactment of FQPA is going to have on the adoption of IPM systems. Many thought that there was much potential for the law to slow adoption of IPM. One mechanism suggested to reduce the potential negative impact was the use of time-limited tolerances which would help growers transition to new IPM systems. Another suggestion was the use of state-specific registrations of products for use in IPM systems.

Many of those on the call also noted that FQPA will place an increased burden on growers to collect information that reflects how products are actually being used.

With the conclusion of the summary, Mike Lesnick asked members if the EPA proposal, presented in the background paper, to use a weight-of-evidence approach made sense. Several members suggested that the weight-of-evidence approach makes sense because of the complexity

Reiterating a point made on the conference call, several members pointed to the confusion surrounding the apparent inclusion of both safer and incremental reduction products in the discussion of reduced risk pesticides. They urged EPA to separate the two types of products. Other members raised the question of where would the line be drawn. They observed that if the line is drawn to include only absolutely safe products, very few would qualify.

Members also queried about the situation where the risk cup is almost full. How would the Agency deal with the new product and its likely substitution for other more risky products.

Lynn Goldman noted that reduced risk process is not a panacea. She observed that the Agency has received 27 applications to date. She explained that one half of them passed the safer screen. EPA would not have been able to handle more than that.

Several members identified the current condition of limited resources as being problematic. If the Agency gets large numbers of safer product applications, it will slow down the process and it will take longer to get them on the market, yet, one of the incentives for safer products is an expedited process which is supposed to place them at the front of the queue. Other members questioned the proper allocation of resources; they were concerned that if too many resources are allocated to the safer program, other products which are less risky but do not qualify for the safer queue may be slowed down.

Dan Barolo stated that the Agency has processed more active ingredients over the past few years, with exception of this year; more than 50% of them were safer.

Reacting to the suggestion of using labeling as an incentive for the development of safer products, several members noted that the Agency would need more elaborate criteria. They observed that in other arenas labeling has proven to be quite complicated to do.

Many of the members saw having their product put at the front of the queue as a good incentive They recognized the need for more resources. Several members noted that if such products are developed, the market would reward the manufacturers. This led to a discussion of the need to get information out to growers about the new products so that they can make informed decisions It was suggested that this needs to be done in a manner that is distinct from the label. A few members specifically called for the need to consider a variety of incentives. Others pointed to the need for having the appropriate infrastructure for getting information out to growers.

Several members observed that many safer pesticide pose greater resistance problems. Thus, they encouraged EPA to look at this in making decisions so as to prevent resistance problems.

In terms of the impact on IPM, several members suggested that EPA has a role but more of the responsibility lies with USDA. Some suggested that given EPA's limited role, they would rather see the money spent on the registration of safer pesticides. They also suggested that in making decisions EPA needs to understand the need for transition time to deal with changes especially in specific locations. They also encouraged EPA to consider expanding the use of the states to demonstrate IPM programs.

Other members urged EPA to encourage the development of bio-intensive IPM. They also suggested that it would be helpful if EPA could identify chemicals that appear to be in trouble early in the process so that USDA has time to develop alternative methods.

Speaking as the representative from USDA, Larry Elworth stated that most progress in IPM has not been in the traditional programs because adequate funding has not been available. He observed that there has continued to be a disconnect between authorizations and appropriations He observed that they are seeing changes in non-appropriations programs. For example, the Forest Service has made advances, crop insurance is being used as a way to mitigate risk, new technologies being identified by ARS, and areawide programs through ARS and its technology transfer program are being implemented. So, many of the non-traditional ways are advancing the adoption of IPM. He then asked how one can create incentives for the private sector to do what the Extension Service used to do.

It was observed by several members that research has been the stepchild of agricultural policy. However, it was noted that the 1996 Farm Bill provides increased flexibility for research and that gave the Secretary of Agriculture funds to spend on research. It was also noted that the House Agriculture Committee plans to evaluate agriculture research and refocus and re-allocate resources.

Another member noted that IPM program successes have happened where problems had been identified and growers have been at the table since the beginning of discussions. Other members noted that the success of IPM is difficult to measure. It was observed that there is more than a disconnect; there have been active efforts to squelch the adoption of IPM. Other members stated that there is much being done outside of formal IPM programs; the example given was the increased use of crop consultants. Another member noted that one of the limitations on the national application of IPM is regional variation.

BENEFITS

Larry Elworth provided a summary of the conference call held on benefits. He began by noting the distinction between benefits as discussed in FIFRA and FFDCA. Big "B" benefits is the law in FQPA. Under FQPA as it amends FFDCA, eligible tolerances do not consider the benefits if the risk exceeds the threshold. An exception where benefits may be considered over the tolerance is allowed if there is a "significant disruption of the food supply." This raised the question of what is a significant disruption of the food supply? Little "b" benefits falls under FIFRA and is the information traditionally considered in assessing whether uses will be allowed, impacts on risk reduction, and changes in use patterns, alternatives, and resistance.

Some members wondered about the congressional intent in terms of benefits? A congressional staff person stated that the intent was to give flexibility to EPA in terms of the definition of significant disruption. The intent was to have the consideration of big "B" benefits be used in special circumstances. It was understood that with the shift from Delaney, there would not be a risk/benefit consideration. However, little "b" benefits would still be considered. The Hill tried to come up with a common sense approach. They are aware that the language in FQPA does not satisfy many people. The staffer advised EPA to start with a common sense approach to what the law means. He also observed that benefits had been used rarely in the past; but, he is uncertain how much it will be used in the future.

While there had been much discussion of the definition of a disruption on the conference call, the Committee as a whole did not spend much time discussing it. A member suggested that it will vary regionally.

Another member observed that the previous benefits provision, Section 408, had not been taken seriously; no determinations had been made to register a product that exceeded negligible risk. He observed that FQPA has limitations on benefits and when they will be considered but they expect it to be used. From their perspective it is a mitigation provision in the law to help address the down sides of the law. He stressed that one is talking about benefits for consumers with regard to disruption in food supply.

Steve Johnson, EPA, noted that in considering the many applications received, all have been within the acceptable risk standard --"reasonable certainty of no harm." He observed that the benefit side of the equation has not come into play and where there have been questions, the Agency has entered into conditional registration decisions.

NEXT STEPS

With the conclusion of discussions, the agenda for the November and December meetings were reviewed. The November meeting will address:

- children's issues (10-fold uncertainty factor, in utero exposure)
- tolerance evaluation
- Section 18
- decision logic on risk assessment
- introduction of decision logic on risk management
- worker issues

The December meeting will address:

- refinement on risk assessment and management papers
- resources

Fred Hansen asked Larry Elworth if USDA could provide some background on its role vis a vis FQPA. Larry Elworth agreed to request such information from the appropriate staff at USDA

In terms of the final report from the Committee, it was suggested that it consist of a compilation of the meeting summaries and that it would not represent a consensus of the Committee. Rather, the report would reflect the different perspectives raised. Committee members agreed with that suggestion.

PUBLIC COMMENT

Ken Wolmart, Enviro Corporation, began by observing that the state of science is ripe for policy discussion. He urged EPA to consider the differences between chemicals and to maintain flexibility to look at them individually and not always as a group. He cautioned the Agency to not make the process too linear.

Jay Vroom, American Crop Protection Association, spoke next. He commented that he was disappointed at number of empty chairs in the audience. He expressed concern about the apparent lack of concern by the public. He suggested that a few years from now, one may look back at 1996 as a hallmark year for IPM due to the commercialization of precision agriculture which enables pesticides to be delivered selectively and the increased viability of biotechnology and its ability to engineer crops. Both will enable IPM to be adopted by more growers.

Tom Van Arsdall, National Council of Farmers Cooperatives, was the last speaker. He noted that it was important for staff from the Appropriations Committees be involved in discussions about the implementation of FQPA. EPA staff commented that they had been invited to participate

Fred Hansen closed the meeting by observing that the two days had provided good discussion on the topics of concern. Lynn Goldman observed that based on the quality of the discussions, the Committee is beginning to work together well and she and Fred appreciate the effort everyone made both at the meeting and during the preparatory conference calls.

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November 14-15, 1996
Meeting Summary

FOOD SAFETY ADVISORY COMMITTEE

Third Plenary Session - Meeting Summary
November 14 - 15, 1996
Washington, D.C.

Chairman: Fred Hansen, Deputy Administrator, US EPA

Vice Chair: Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, US EPA

Members: Mark Atwood, American Cyanamid; Emilo Bontempo, Ciba-Geigy Company; Daniel Botts, Florida Fruit and Vegetable Association; Carolyn Brickey, National Campaign for Pesticide Policy Reform; Kenneth Cook, Environmental Working Group; Shelly Davis, United Farm Workers; Jon Jessen, Gowan Company; Ramon Llenado, The Clorox Company; Genevieve Matanoski, John Hopkins University; Gene McConnell, Scientific Advisory Panel; Kathleen Merrigan, Henry A. Wallace Institute for Alternative Agriculture; Jane Perkins, AFL-CIO; Jean Pettibone, American Agri-Women; Robert Rhodes, Holland and Knight; Richard Rominger, US Department of Agriculture; Alan Tracy, WI Department of Agriculture, Trade, and Consumer Protection; James Wells, California Environmental Protection Agency; Pete Wenstrand, National Corn Growers Association.

Alternates: Steven Balling, Del Monte Foods - Research Center; Philip Barnett, Food and Drug Administration; George Brennen, Dole Foods; Mark Childress, Environmental Working Group; Tom Carato, Monsanto Company; Jennifer Curtis, Natural Resources Defense Council; Larry Elworth, USDA; Benjamin Gitterman, Physician; Anthony Hempton, Dole Foods; Rick Holt, DuPont Agricultural Products; Lynn Jenkins, National Institute for Occupational Safety and Health; Richard Kirchhoff, National Association of State Departments of Agriculture; Jim Lamb, Jellinek, Schwartz, & Connolly Inc.; Mike McGeehan, Centers for Disease Control and Prevention; Patrick Meehan, The Clorox Company; Elin Miller, DowElanco; Jan Relford, Gerber Products Company; Bob Schramm, Schramm, Williams and Associates; Bill Tracy, National Cotton Council; Bob Vice, California Farm Bureau.

Ex-Officio Members: Jack Moore, Institute for Evaluating Health Risks; Steve Jellinek, Jellinek, Schwartz, & Connolly Inc.

Congressional: Greg Dotson, US House of Representatives; Curt Mann, US House of Representatives; Dale Moore, US House of Representatives; Terri Nintemann, US Senate.

Tuesday, November 14, 1996

OPENING REMARKS AND OVERVIEW OF AGENDA

John Ehrmann, The Keystone Center, welcomed participants to the meeting and initiated brief introductions around the table. Following the introductions, Fred Hansen, Chairman of the Food Safety Advisory Committee (FSAC) and Deputy Administrator, US EPA, welcomed participants back and thanked them for their continued interest in the process. He noted that the focus of this group was to provide input to critical public policy and a strategic direction for the new law. He also recognized the growing need to make critical decisions within the constraints of the new law.

Mr. Hansen then observed that FQPA raises thresholds and fundamentally changes the processes for registration, reregistration, and determining tolerances. To support these changes, he noted that approximately half of the $30 million added to EPA's supplemental appropriation to address the implementation needs of the FQPA and the Safe Drinking Water Act will go towards implementation of the FQPA. In addition, Mr. Hansen noted that he had requested that Office of Office of Pesticide Programs (OPP) reserve additional resources to support the implementation of this law in 1997.

Next, Mr. Hansen requested that throughout the meeting participants comment frankly on the various proposals made by EPA so that the Agency can make necessary regulatory decisions and proceed with implementation of the new law. He also wanted the group's assistance in developing an agenda for the final December meeting.

Mr. Hansen noted that there are other public fora that address the implementation of the new law including the Pesticide Program Dialogue Committee which met earlier in the week, and the Endocrine Disruptors Screening and Testing Advisory Committee. In addition, he called attention to the Scientific Advisory Panel (SAP) established under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Agency's Science Advisory Board (SAB), the Section 18 workshop to be held on November 20 - 21, 1996, and the Antimicrobial workshop scheduled for January 1997.

Mr. Hansen then introduced Shelly Davis, Farmworker Justice Fund, as a formal member of the FSAC. He also welcomed Richard Rominger, Deputy Secretary of Agriculture, US Department of Agriculture (USDA), who attended the meeting to answer questions about how the USDA will contribute to this process. Mr. Hansen concluded his introduction by thanking the group once again for their participation and he commented on the importance of the group's input. He concluded that he looked forward to continued input from the group.

Lynn Goldman, Vice Chair of FSAC, and Assistant Administrator for Prevention, Pesticides, and Toxic Substances, joined Fred Hansen in welcoming everyone, and thanked them again for their very useful input. She commented on the ambitious agenda for the next two days and observed the challenge the group will face in balancing discussion on the issues raised by the Committee and the need for EPA to obtain input from the group on additional critical issues. She indicated that the agenda will include:

- a presentation on USDA programs;
- tolerance reassessment;
- discussion on risks to agricultural workers;
- the human health risk assessment process and an update from the SAP on uncertainty factors affecting children and in-utero exposure;
- the decision-making process (modified based upon discussion at the October meeting); and
- the December meeting agenda.

Dr. Goldman called attention to the background material supplied for the meeting which included an example of how EPA communicates with the public, glossary of terms and definitions, a chapter from the National Academy of Science (NAS) 1993 report on Pesticides in the Diets of Infants and Children, and a summary of the recommendations from NAS.

John Ehrmann then reminded the group of the groundrules for the meeting. He commented that, while areas of agreement will be recognized, the Advisory Committee is not striving for consensus. Rather, the Committee is encouraged to express differing views to provide the Agency with input on the various issues. Mr. Ehrmann also noted that there will be opportunities for public input at specified times throughout the meeting and invited individuals to provide EPA with additional input outside the meeting.

Next, Mr. Ehrmann introduced the Congressional staff in attendance. He noted that the Congressional staff had a key role in making the new law happen and invited the group to ask them questions. Mr. Ehrmann then introduced Richard Rominger, Deputy Secretary of Agriculture, USDA, for opening remarks on the USDA programs.

USDA PROGRAMS PRESENTATION

Mr. Rominger expressed his thanks for the opportunity to speak to the Advisory Committee about USDA's role in the FQPA. He noted that the FQPA amended FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA) both of which specifically involve the Department of Agriculture. Mr. Rominger expects to continue to cooperate with other federal agencies to ensure the effective implementation of FQPA. In this spirit, he noted that EPA and USDA were in the process of amending the Memorandum of Understanding (MOU) that addresses some aspects of the Act which were not covered effectively before.

Mr. Rominger highlighted some of the aspects of FIFRA and FFDCA that had the most significant impact on USDA. He noted that the changes associated with FIFRA had the greatest impact on USDA through the Minor Use Pesticide Program (IR-4) and resistance management, Integrated Pest Management (IPM), growers registration of minor uses, and assistance with the Minor Uses program to develop a data base on public health pesticides. Mr. Rominger then commented on some of the impacts of FQPA on FFDCA. He focused on Special Provisions for Infants and Children and made specific reference to Public Health Subtitle C for the identification of pests of significant risk to children and infants, Title III Sections 301 (a)(c) on data collection of pesticide residues on food which are most likely consumed by infants and children, 302 on data

collection survey in coordination with EPA, 303 on IPM research and education, and 305 on evaluation of pesticide use and effectiveness. He also called attention to the consumer "Right-t Know" provisions. Mr. Rominger closed his opening remarks by noting that funding is critical to the success of all of these programs. He then introduced his associates from the National Agriculture Statistics Survey (NASS), Economic Research Services (ERS), Agricultural Research Service (ARS), and Agricultural Marketing Service (AMS).

Sam Rives, Chief of the Survey Administration Branch, NASS, provided the group with an overview of the role of NASS in FQPA (Attachment A). He explained that since 1990, NASS conducted chemical use and ecological statistical surveys to provide comprehensive, reliable data on the use of pesticides and fertilizer on the farm for a large percentage of fruits and vegetables. Mr. Rives noted that a working group with representatives from USDA and EPA planned the surveys and also solicited help from the grower community. He summarized by stating that they planned to expand their coverage in the future and will continue to solicit input from the grower community to provide the most useful data. He thanked everyone who contributed to the surveys for their cooperation.

Margo Anderson, Deputy Director, Natural Resources and Environment, ERS, explained that ERS is the economic and social science research agency at USDA whose primary role is to provide comprehensive and reliable information for policy decision-making (Attachment B). She then provided an overview of core ERS research activities:

- Performs joint surveys with NASS to estimate pesticide use and pest management practices;
- Examines the economics of pest management alternatives; and
- Examines consumer's dietary intake of pesticide residues using recent food consumption data and Pesticide Data Program data.

After briefly describing each of these areas of research, Ms. Anderson elaborated on how ERS collaborates with NASS and EPA in the review and analysis of trends in pesticide use in agriculture based upon the comparative analysis of EPA data and data from USDA to help develop good pest management strategies. She closed by stating that ERS looks forward to continuing to work with EPA.

Edward Knipling, Acting Administrator, ARS, referred to the handout on the background and role of ARS in the implementation of the FQPA (Attachment C). He described ARS as the intramural research arm of USDA with a focus on farm production and natural resources. Mr. Knipling noted that there were 100 laboratories across the country through which ARS collaborated on joint research with other USDA and federal agencies and state institutions on the following areas of research:

- Continuing Survey on Food Intake by Individuals (CSFII);
- Integrated Pest Management (IPM);
- National Agricultural Pesticide Impact Assessment Program (NAPIAP); and
- Minor Use Pesticide Program (IR-4).

Mr. Knipling explained that the first of the four areas of research, CSFII, was extensive and integrated dietary intake from various agencies and the private sector nationwide. He noted that the data are used to assist in policy formulation. Mr. Knipling then explained that the latter three research areas focus on pest control. After a brief description of each of the three pest control areas, he noted three specific smaller programs which are coordinated with EPA:

- Inter-Regional Committee # 4 (IR-4) - focus on the industry of minor use crops and expanding the associated registration process;
- Decision Support System - computerizing the data necessary to prioritize research needs and provide a source for research guidance; and
- Health Environment Safety Education - focus on expanding good pesticide handling practices and protect human health through programs such as the Pesticide Applicator Training Program.

Following Mr. Knipling's summary of the ARS, Lon Hatamiya, Administrator of AMS, provided the group with a brief background on AMS and described the role of AMS in the implementation of FQPA (Attachment D). He explained that there are 50 programs in AMS that were designed to enhance domestically grown products. He identified the Pesticide Data Program (PDP) as one of the key programs that has been responsible for performing data collection which has allowed EPA to make more refined decisions about dietary risks from pesticide residues. Mr. Hatamin explained that PDP was a voluntary federal-state cooperative effort that will also play a significant role in determining cumulative and multiple exposures to pesticide residues and will provide a statistically reliable database on endocrine disruptors. He noted that there are 21 commodities that are in the testing program through FY 1996, all of which are high consumption products by American consumers, 16 of which are high consumption commodities for infants and children. Mr. Hatamin concluded his remarks by noting that while program operations were suspended due to funding uncertainties for FY 97, EPA and USDA are working together to find a way to fund participating states and federal agencies to resume program operations as quickly as possible.

John Ehrmann then invited Committee members to pose questions of clarification to representatives of USDA.

Some Committee members wanted to know how IPM surveys compared to Crop Practices Surveys (CPR). Margo Anderson responded that preliminary data showed an increase in IPM, particularly for fruits and vegetables. However, she noted that it was premature to determine trends at this point because of insufficient data and the definition of IPM varies from product to product. Other Committee members wanted clarification on what IPM data indicated about the risk of pesticide use. Ms. Anderson responded that the data showed mixed results on adopting IPM and the effect of pesticide use.

Several participants wanted clarification on whether children and infants were adequately represented in the studies evaluating dietary risk. They wanted to know about the number of younger individuals tested and their demographics, particularly in the ARS study as compared to the NAS study. Mr. Knipling responded that half of the 16,000 individuals sampled in the ARS study were children and that data from the NAS study are being refined to obtain additional

information on the children tested. He suggested that once these data are refined, statistics on social demographics can be determined. He commented that there is still need to test a larger number of individuals in the younger age groups.

Dr. Penny Fenner-Crisp, Deputy Director, OPP, added that, based upon the NAS study, the Committee recommended expanding the subgroups of children considered. Currently, she explained, children are subdivided into ages of less than one, one to six, and seven to twelve years. Data is insufficient at this time to further subdivide children in the age range of one to six years, as recommended by the Committee. Dr. Fenner-Crisp then noted that the residue data base provided by PDP was expanding, and, with continued funding, the capacity to develop a database on dietary exposure will increase.

Many Committee members stressed the importance of obtaining the data necessary to run the new program effectively. They felt that resources should be allocated for data collection, particularly on consumption. Some participants referenced the 1990 implementation of Organic Standards and the survey of user records as a potential data resource. It was clarified that a proposed rule on the Organic Standard is pending and that more data may be forthcoming. In addition, once data gaps are clarified, some industry representatives volunteered to try to address data gaps with commercial data.

Some participants commented on the absence of a sustainable agriculture program, and wanted clarification on the role and budget of the Sustainable Agriculture Research and Education (SARE) program. They felt that supporting a program on sustainable agriculture was important, possibly using Funds for Rural America. Fred Hansen recognized the importance of the SARE program, particularly as a model for other programs. However, he clarified that the use of Funds for Rural America is restricted to addressing issues that are not the emphasis of other programs. He noted that the funds may be applied to address the intersection of human health and environmental resource management issues.

Several Committee members expressed concern about how the diverse USDA programs would be coordinated, particularly after the departure of Larry Elworth. Secretary Rominger clarified that USDA programs would continue to be coordinated through his office. Fred Hansen thanked USDA representatives for their contributions.

TOLERANCE REASSESSMENT

John Ehrmann initiated discussions on tolerance reassessment by referring participants to the staff paper on Proposed Tolerance Reassessment Program (Attachment E.) He asked participants to think about critical questions as they evaluated the paper. Mr. Ehrmann then turned to Jack Housenger, SRRD, OPP, to provide an overview of the paper.

Mr. Housenger summarized FQPA requirements on tolerances and exemptions to be reassessed:

- All tolerances and exemptions are to be reassessed within ten years;
- "Riskiest" pesticides addressed first;

- 33 % of all existing tolerances and exemptions reviewed within three years; and
- 66 % reviewed within six years.

He noted that the new law requires that EPA consider aggregate exposure, cumulative effects from other pesticides with a common mode of toxicity, increased susceptibility of infants and children, and whether the pesticide produces endocrine effects.

Mr. Housenger then described the plan for tolerance reassessment. He explained that the primary regulatory programs that will be used to achieve tolerance reassessment and complete the reregistration of older pesticides would initially be the reregistration process, followed by registration renewal. Mr. Housenger indicated that EPA would first identify the chemicals for which tolerances were established prior to the enactment of FQPA (subject to reassessment). EPA would then separate these chemicals/tolerances into four groups (differentiating between chemicals for which Registration Eligibility Decisions were issued before and after the new Act, chemicals registered after November 1, 1984, and chemicals considered inert which are registered for food and have tolerances,) and then schedule the remaining chemicals, including all other chemicals that share a common mode of toxicity, to address cumulative effects for reregistration. As an example, Mr. Housenger indicated that OPP would schedule as many carcinogens as possible, all of the organophosphates, and all of the carbamates within the first three years.

Dan Barolo, Director of the OPP, spoke next. He emphasized that FQPA will reorder priorities which will result in a revised schedule for tolerance reassessments. Mr. Barolo noted that the workload will also increase from producing 300 tolerances per year to 1,200 tolerances per year, in addition to addressing the Section 18 emergency requirements and temporary tolerances on the books. Mr. Barolo called specific attention to the group of synthetic pyrethroids for which the tolerances expire in the Fall of 1996. He indicated that aquatic studies are underway and will be submitted to EPA for review upon completion. Registration will therefore be extended for a year to allow EPA to reassess in the Fall of 1997.

Mr. Barolo then stated that EPA plans to meet the broad work schedule discussed above and intends to continue to advance public health and protection domestically and internationally. He requested that, when reacting to the Tolerance Reassessment Program, Committee members consider the following questions:

- Does the general approach make sense?
- If it does not, how could the approach be improved?
- What are the strengths and weaknesses of the approach?

Many Committee members felt that the approach generally made sense, but felt that the "devil was in the details" of the approach. Some of their particular concerns were:

> ***How will "worst first" be interpreted? In addition to carbamates and organophosphates, what other pesticides might be included?***

Dr. Lynn Goldman invited the group to comment on the proposal and to suggest additions or alternatives to the proposed "riskiest" pesticides.

How will latent risk chemicals that turn out to be more important in the future be addressed?

Dan Barolo commented that the importance of integrating future findings will be stressed.

Why are the triazines and methyl bromide not listed?

Jack Housenger clarified that the triazines are in the special review process. The special review process will include a tolerance review against the new standard. Dan Barolo indicated that methyl bromide would be reviewed and folded into the schedule for reassessment.

How will pesticides be addressed that are not carcinogenic but impact development and reproduction? Will they be classified as "riskiest"?

Dr. Penny Fenner-Crisp indicated that, if the impacts were shown to be acute, the pesticide could be added to the list.

How will data gaps and defaults be addressed? Many participants were concerned that, when assigning defaults, EPA maintain the incentive to collect outstanding data.

Dr. Lynn Goldman commented that defaults will be used only if actual data are not available. She noted that incentives to collect outstanding data are established, especially for conservative defaults. She stressed that it is essential for EPA to be able to make decisions with defaults until data become available.

Some participants felt it was dangerous to use defaults when mechanisms are assumed to be the same. In general, they felt that defaults were conservative and would result in limited use of the product and lack of incentive to provide the missing information.

Mr. Barolo acknowledged these concerns and indicated that they would be addressed in greater detail tomorrow in the Process Flowchart Discussion. Dr. Penny Fenner-Crisp also commented that, while OPP has not dealt extensively with risk assessment of multiple sources of exposure (e.g., food, residence, lawn), other parts of the Agency have and their resources are available to OPP.

The user/grower community requested that EPA give them as much advance notice on decisions that could impact pesticides in use to enable them to plan accordingly. They suggested that EPA prioritize the registration of new products to help with this.

Several Committee members were concerned about whether there would be adequate funding to implement the program in the future and what the impacts of future funding deficiencies might be.

Some participants observed that the strength of the approach was that it was a beginning. The weakness of the approach was in the details (e.g., how data gaps and defaults would be addressed.)

Several participants observed that, under this plan, EPA will be moving quickly over the next three years. They suggested that EPA be realistic in its approach over that period of time. Congressional staffer Dale Moore also noted that a lot of the provisions in the new law were meant to be evolutionary. Specifically, there was recognition on the part of Congress that the budget for the program would evolve. He suggested that EPA focus on picking its issues and concentrate on them.

John Ehrmann closed the discussion by reassuring the group that defaults would be discussed tomorrow. He then invited the public to provide comments to the Advisory Committee.

PUBLIC COMMENT

There was no public comment during this period.

WORKER RISK ISSUES

Cathy Kronopolus, FOD, OPP, presented background and a brief overview on EPA's efforts to protect agricultural workers from exposure to pesticides (Attachment F). She highlighted the core requirements for the Worker Protection Standard which was revised January 1, 1995: unacceptable to spray fields when the worker is present; post information about pesticide applications; provide basic pesticide training; provide clean, operating, personal protective equipment for employee use; provide decontamination supplies for use in case of pesticide exposure; and provide emergency transportation when needed.

Ms. Kronopolus indicated that as a result of on-going outreach, compliance assistance and enforcement efforts, her organization has held many field hearings with farmworkers, growers, physicians, state regulators, and others. She indicated that they were also working with a stakeholder group to evaluate training and certification programs. She commented that she has learned a great amount from these individuals and processes, and welcomes additional comments from the Advisory Committee.

Some Committee members observed that, with all of these efforts, there are still many job-related worker injuries and elevated rates of cancer. They suggested that some aspects of the worker protection plan are not applied effectively, particularly for protection from drift and pesticide use. Some members identified language as one of the barriers to effective worker protection. In addition, several participants indicated that some workers are afraid to go to the doctor for work-related illnesses for fear of being released from the job. They suggested reducing risk to workers by restricting the use of dangerous pesticides and requested that worker safety be kept at the forefront when decisions are made in the future.

In addition, several participants recognized that farmworker children were particularly vulnerable to pesticide exposure. They wanted to know if EPA planned to identify these children as a sensitive subpopulation in the risk assessment process. Dan Barolo commented that EPA has an obligation to look at the potential for farmworker children exposure very carefully. He indicated that it may be possible to address their specific concerns in studies on farmworkers which are presently taking place across the country.

Other participants felt that farmworkers were well trained and protected and that the amount of their exposure to pesticides was minimized as a result. They stressed that education and training works to prevent unnecessary exposure. In addition, some participants noted that the trend towards using professional custom application services further reduces the potential for risk to farmworkers and their children.

In response to some of these concerns, the group requested more information on the scale of the worker training program. Ms. Kronopolus indicated that the training budget for this year was 2 million dollars and several thousand dollars for in-house evaluation. Other participants commented that, in addition to EPA efforts, many states have significant resources committed to training and there is a substantial private market in training. Also, they commented that there is significant work going on between the U.S. and Canada to develop registrant information on exposure.

Several participants stressed the importance of maintaining some means to evaluate the effectiveness of the worker safety program through on-going evaluation and enforcement. The noted the value of learning from past experience. Lynn Goldman called attention to some of Ms. Kronopolus' earlier comments on EPA's efforts to obtain and integrate feedback on their programs and specifically noted EPA's efforts to work with National Institute for Occupational Safety and Health (NIOSH) to look at incidents of exposure and reporting to help refine worker safety protection efforts.

Dale Moore reminded the group that, while worker protection is of critical concern, it was not addressed as a specific issue in the new law. Worker safety issues are addressed more directly in HR 1627 and may be better addressed in a different forum.

John Ehrmann brought a close to the discussion by suggesting that some of the concerns about children's safety may be further addressed in the next discussion on the Human Health Risk Assessment Process and the additional 10-fold uncertainty factor for children. He suggested that the group keep in mind the purview of this legislation in this regard.

HUMAN HEALTH RISK ASSESSMENT PROCESS

Dr. Penny Fenner-Crisp introduced Margaret Stasikowski, HED, OPP, to present an overview of the Human Health Risk Assessment Process. A copy of the slides on her presentation is presented in Attachment G. Margaret Stasikowski summarized what EPA defines as a risk assessment and described the evolution of EPA's risk assessment process. Dr. Stasikowski explained what toxicity data requirements are and described the process of toxicity testing to evaluate the effects

of in-utero exposure. She then explained how EPA evaluates toxicity data and defined the concepts of no observable effect level (NOEL), uncertainty factors, and reference doses. Dr. Stasikowski closed her presentation with an explanation of the FQPA requirement of "...an additional 10-fold margin of safety ... for infants and children ..." She noted that the Administrator may use a different uncertainty factor if reliable data show it to be safe for infants and children.

At the conclusion of Dr. Stasikowski's presentation, Dr. Fenner-Crisp introduced Dr. Gene McConnell, Chair of the Science Advisory Panel (SAP), to provide an overview of what the Panel is and to provide preliminary comments on how they evaluated the safety factors affecting children (10-fold uncertainty factor) and in-utero exposure for carcinogenicity.

Dr. McConnell explained that the SAP is comprised of a core group of five to seven scientists with diverse experience in toxicology, neurotoxicology, immunology, and clinical epidemiology. He explained that additional scientists were invited to advise the Panel on the 10-fold uncertainty factor and in-utero exposure. Dr. McConnell stated that the expanded Panel was then asked to review and discuss background material on these topics.

Next, Dr. McConnell summarized the Panel's findings. He stated that the Panel found EPA's review of the data on in-utero exposure to be adequate. In general, they agreed that the data do not support increased risk of cancer with prenatal exposure. He noted that the exception would be if there were a unique circumstance of in-utero exposure.

With regard to the 10-fold uncertainty factor for children, Dr. McConnell stated that the Panel agreed with EPA's finding of the need for an additional uncertainty factor for children. In addition, they agreed that using a "weight-of-evidence" approach is appropriate and that the 10-fold factor should be applied based on science on a case-by-case basis. Dr. McConnell indicated that the results of the Panel discussions should be available to the public after Thanksgiving.

At the conclusion of Dr. McConnell's presentation, Committee members were invited to ask questions or comment on the presentations.

Some Advisory Committee members questioned the terms "reliable data" and "unique circumstances." They wanted to know what the SAP would propose for EPA to use as criteria to judge what "reliable data" and "unique circumstances" were. Fred Hansen responded that the SAP did not meet long enough to address this level of detail.

Several participants were supportive of a conservative uncertainty factor because there may not be an adequate uncertainty factor for the protection of children. They were concerned about the potential for the uncertainty factor to be lessened, and felt that the uncertainty factor should be lessened only based upon scientific proof. Lynn Goldman clarified that the uncertainty factor shall apply unless reliable data show otherwise.

The group requested clarification on whether EPA would evaluate foods which are likely to be eaten by children and what the hazard and rate of consumption are when applying the additional

safety factor. Lynn Goldman clarified that the law requires EPA to look at both toxicity and exposure.

Several participants expressed concern about whether EPA had the resources to perform the additional testing required to assess in-utero exposure and accelerated reviews of antimicrobial pesticides, etc. Dan Barolo indicated that EPA has been authorized to increase its staff to address some of these challenges.

In a similar context, some Committee members wanted to know if EPA planned to consider the harmonization of testing guidelines for cancer, neurotoxicity, and reproduction. Penny Fenner-Crisp responded that this was on the SAP agenda for discussion at their last meeting.

Several participants complimented EPA on the amount of work they had done in preparation for this meeting.

PUBLIC COMMENT (Afternoon, November 14, 1996)

Philip Glase, Apple Grower from Winchester, VA, stated that, while it is also his goal to insure safe food and protect workers, he is fearful that the new law will interfere with the flexibility his industry needs to implement effective IPM. He commented that if, as a result of the new law, pesticides used by his industry are taken abruptly from the market, the critically timed pest management scheme will be set off-balance and may jeopardize apple production. He stressed the need for EPA to seek input from the grower industry to prevent unnecessary market loss. Mr. Glase also stated that Section 18 registrations are important because it is critical for a grower to be able to respond to emergency circumstances.

Jay Vroom, American Crop Protection Association (ACPA), complimented Dr. McConnell on his presentation. He asked EPA to take care when prioritizing and allocating resources to implement the new law. He suggested that resource priorities be given to product registration and label changes for existing and new products. In addition, Mr. Vroom suggested that EPA make decisions using time-limited approval mechanisms.

Chris Wilkinson, Technology Science Resources Group, requested confirmation that EPA will determine the additional uncertainty factor for children based on both toxicity and exposure. He commented that, if this is so, it will be a deviation from the past. Lynn Goldman responded that exposure is referenced in the law and that the challenge will be to take the intent of the law and apply the best available science to that. She commented that EPA will use this Committee for policy advice on how to do this.

FRIDAY, NOVEMBER 15, 1996

Introductory Comments

The second day of the meeting began with Lynn Goldman welcoming and thanking everyone for their efforts. She stated that she recognized that there are benefits and costs for everyone to participate in such a process. However, she believes that this is the right way; the Agency needs to involve everyone as they attempt to implement the FQPA. She noted that the amount of work in preparation and level of participation evidenced by Committee members is impressive. Ms. Goldman also observed that members seem to be listening to each other at this meeting and engaging in constructive dialogue; it is much appreciated and she feels that it will advance EPA's efforts.

Next, Lynn Goldman briefly discussed the confidential business information issue in the Toxics Program. Dr. Goldman indicated that she also intends to have an audit done of the FIFRA program to determine if there are any problems with its document tracking system. She feels that knowledge of how the system is working is necessary if one is to do business effectively.

Next, John Ehrmann reviewed the agenda for the day. He noted that discussions will begin with Section 18's, consider next steps, and then review the decision logic and decision flow together. He also noted that the Committee will also talk about the format for the final summary of Committee deliberations.

Section 18's

Stephen Johnson, Director, Registration Division, OPP, made a brief presentation on Section 18's. He wanted to review four items: the overall Section 18 program; the Section 18 process; EPA's review process; and, a comparison between activities undertaken by the program in the 1980's and 1990's. He also introduced Jim Jones who is head of the Branch that carries out the Section 18 process.

In the overview of the Section 18 process, Stephen Johnson explained that it is a process that authorizes the states to request an emergency exemption for use of an unregistered pesticide. Such use and exemption are sought if the conditions growers face are urgent, non-routine, and it is an emergency. When faced with such a situation, a problem with a pest that is unable to be controlled with available tools, (i.e., no currently registered pesticide can be used), growers and commodity groups ask the state for relief through a Section 18. It was observed that these situations are typically caused by weather. If the state believes the situation is an emergency, they will submit a petition to EPA. In most states, the lead agency for these actions is the State Department of Agriculture. Typically, the petition is for a food use.

Stephen Johnson stated that upon receipt of the petition, EPA reviews the document. Under the law, no time frame is required. He indicated that the Agency's target is 50 days. Within that timeframe, the Agency makes an assessment of the situation and the pesticide based upon best

available information. It was noted that in considering the petition, the Agency examines dietary occupational, and ecological risks as well as an assessment of the emergency. Based on this analysis, the Agency makes a decision to accept or deny the petition.

It was explained that occasionally during the time it takes EPA to consider the petition, the emergency goes away (e.g., the weather changes or the pest goes away) and the state withdraws the petition. It was noted that at other times the petition is withdrawn because EPA determines that there is inadequate information for acceptance.

Stephen Johnson also explained that if the situation is such that the state cannot wait 50 days, the state has the authority to make a crisis determination that allows the pesticide to be used immediately; the state then submits a petition. The state contacts EPA prior to the making a crisis determination. It was noted that if a state uses the crisis authority too frequently for unfounded crises, EPA has the authority to revoke the state's authority to petition.

Stephen Johnson provided a historical context for the Section 18 program. He explained that the risk assessment process in the 1980's looked at ecological effects, environmental fate, and dietary exposure. It included a simple review of dietary exposure for the general U.S. population which was based on limited data. In the 1990's, the Agency is undertaking more extensive analysis. Now the analysis, the Dietary Risk Evaluation Standard (DRES) includes acute dietary risk and the consideration of sensitive populations, (e.g., children and infants).

He then referred the members to the table that presents Section 18 emergency statistics contained in the briefing paper. He explained that in 1982, a large number of Section 18 petitions were submitted to EPA and not many were denied. He noted that the perception of Section 18's being heavily used lives on today. Except for 1982, he observed that the numbers of denials, revocations, incomplete applications, and crisis uses, are consistent. He also noted that the table presents the statistics for the Agency's ability to meet the 50 day timeframe.

He also explained that FQPA requires that the Agency establish tolerances for all Section 18's granted even when faced with a crisis situation. He went on to note that under FQPA for a commodity to enter commerce, the tolerance given has to meet the same standards as for a regular registration - "reasonable certainty of no harm." He pointed out that the statistics reflect the effect of the recent blight on potatoes, tomatoes, etc., specifically in the 1996 numbers. He noted that the Agency issued 109 Section 18 approvals to address this specific problem.

When considering Section 18's, Stephen Johnson noted that concerns are often raised that Section 18 petitions are used to circumvent the "normal" registration process. In response to that concern, he commented that one of the provisions required by the Agency for receipt of a Section 18 is that the product is making progress towards meeting the requirements to receive a Section 3 registration. From analysis of previous chemicals considered for Section 18's, he noted that 48% of the chemicals that received Section 18's are now registered.

As a final point, Stephen Johnson noted that FQPA, as it relates to Section 18's, raises a question about resources. He stated that in 1996, the Agency received 478 Section 18 petitions. It is his

estimate that roughly 200 tolerances will have to be established for Section 18's. However, they will not know how many applications they will receive for the 1997 growing season until early 1997 as the busy time for submission of petitions is January to May. The time and energy to establish those tolerances will take additional resources. To put this in context, last year, EPA OPP issued 150 tolerances for OPP overall. With an anticipated workload of 200 tolerances just for Section 18's, it is his fear that all of OPP's resources will be devoted to Section 18's rather than to the registration of new products which generally pose a reduced risk.

In closing the presentation, Stephen Johnson reminded those present that EPA is sponsoring a workshop on Section 18's during the week of November 19, 1996. The goal is to provide an opportunity for stakeholders to give early input on the Section 18 rulemaking process being considered for setting Section 18 tolerances. It was stated that interested people were welcome to attend.

A state member of the Committee pointed out that there is also a state component to the Section 18 process. He commented that states are very involved and concerned about these situations and the process for granting exemptions. He explained that the states screen petitions before they are sent to EPA to ensure that the request is warranted and that the petition contains all of the relevant information. He noted that the petition must document the pest problem and explain why it is an emergency situation that will have economic consequences. It was explained that if one looks at previous years, EPA has rejected over one-third of the applications submitted. Thus, prior to issuing a crisis determination decision, many states contact EPA by phone to "pre-clear" their assessment of the need for a crisis determination. He explained further that the states usually go to the cooperative extension service for supporting documentation for the need to make a crisis determination. He explained that states take the extra steps because they are concerned about the potential for embarrassment if their decision is turned down by EPA. He noted that the states are concerned that FQPA does away with crisis determinations. He strongly noted that states cannot plan for emergencies; thus, how crises will be handled is of utmost concern to them.

Building on the comments about the states' role, Lynn Goldman observed that the federal/state relationship seems to be working well. She noted that states exercise quality control as does EPA. With the changes due to FQPA, she commented that the Agency will need to communicate the new requirements to the states so that petitions submitted will be complete. It is her feeling that such clear communication will alleviate loss of time due to the need to provide additional information. She reiterated the earlier points made that Section 18's require a balancing of risk. To do this properly, EPA needs confirmation that it is a crisis and that the product is making progress towards registration. With the passage of FQPA, she noted that the burden of proof shifts toward protection of the public; thus, the level of effort in assessment increases.

In terms of planning for emergencies, Dr. Goldman stated that to some extent it can be done, (i.e., problems can be anticipated). She gave the example of the recent potato blight and cotton problems. She suggested that a certain amount of upfront work can be done as a number of Section 18's are repeats. She observed that it is critical that EPA provides guidance on the process to the states and growers.

A participant commented that Section 18's are critical to growers' ability to deal with the risks associated with crop production (e.g., specific crisis situations). He suggested, however, that growers and the states will have problems anticipating crises eight months ahead of time in order to get through the Section 18 decision-making process. He noted that many of the Section 18's they seek are due to the weather which cannot be determined that far in advance. He concluded by stating that he does not know how to advise the growers in his state on how to proceed given the uncertainty associated with Section 18's. He encouraged EPA to look at different approaches that can be used to address time-limited situations.

Other participants suggested that one way to address these problems is to give the states the authority to grant Section 18's which would reduce the time needed to make a decision. They also proposed that the Agency consider approaches such as tiering decision logic with pre-approval for a product's use being granted dependent on a specific situation (e.g., a certain level of insects present in the crop).

Several participants observed that the EPA staff responsible for emergency exemptions do a great job. They commented that there has been significant evolution in how petitions are handled. They explained that in some minor crop situations, one time approvals are needed. It was noted that many of the pesticides approved under Section 18 are also used on other crops. To address the greater amount of time needed for Section 18 petitions, it was suggested that for permanent crops (e.g., tree crops) that they be able to submit Section 18 petitions months in advance. They also suggested that EPA tell commodity groups that if they see evidence of a new pest that they should go ahead and submit a Section 18 petition in anticipation of the problem. It was observed by a Committee member that such an approach will result in an increase in the number of Section 18's submitted.

In response, Stephen Johnson noted that the Section 18 Workshop will address these issues in greater detail. He noted that the Agency does have some concern about encouraging the submission of Section 18's in advance. They do not want to encourage Section 18's for "might happens" versus situations where there is clear evidence of a looming emergency (e.g., potato blight) where major potential losses would be incurred. The Agency encourages submission of the latter type. They also recognize that there is a large gray area in the middle.

Some participants asked for further clarification on the relationship between Section 18's and Section 3 applications. They desired a better sense of the number of products which have received repeat Section 18's. Stephen Johnson responded that EPA now requires that states identify if there has been progress towards registration. He noted that for some minor use products, movement towards registration is difficult.

Following up, a participant asked what percent of the products given Section 18's are IR-4 and what percent are from companies? Jim Jones responded that approximately one-third are IR-4. He also commented that denial of a Section 18 petition can be based on no progress in the Section 3 process. He explained further that it is the second most used reason for denial.

A Committee member representing a company commented on the new requirement that a threshold be established for Section 18. He stated that in some cases the company had not submitted an application because the chemical was at a threshold level. He indicated that it is a clear issue of allocating limited resources. He questioned the need for all of the additional information requested. He asked if it has changed the approval process and as a result are we making better decisions that improve health and protect crops. Stephen Johnson responded that better decisions are being made, especially in terms of acute dietary risk and protection of sensitive populations. He reiterated that these considerations were already being factored into decisions prior to the passage of FQPA and are explicitly required by the new law.

Several participants observed that with the new requirements, a Section 18 cannot be considered an emergency exemption since it takes about six months to submit the necessary paperwork and receive a decision. It was also noted that products that receive Section 18's are often not used since the cause of the emergency dissipates. EPA staff were asked for the statistics on Section 18 approvals that are never used. They also asked for the statistics on Section 18 approvals not used due to the amount of time it took for a decision.

Other members asked for clarification on the difference between Sections 18 and 24? They suggested that Section 18 rewards those who wait until an emergency arises. In response, Stephen Johnson noted that Section 24 allows a state to issue a state registration to meet a state/local need. However, the chemical must have an existing registration and tolerance and it cannot be used in an imminently hazardous situation. Lynn Goldman elaborated further; she explained that a Section 24 requires a complete data package for the chemical whereas, for a Section 18, the data package may not be complete. Thus, the two approaches are not equivalent.

Another member reminded the Committee members that in terms of the state issue, minor crops are minor in acreage only. These crops are of great importance to the states. He observed that states do not pursue either Section 18 or Section 24 as a means of circumventing the registration process. He noted that they represent two different processes with different incentives and rules. He also noted that the new law exacerbates the difference between the two since the cost of registration is increasing. He also pointed out that costs of submitting Section 18 petitions is also increasing. He suggested that it is important to streamline the Section 18 process as it is a necessary alternative.

A member suggested that there will be a significant reduction in Section 18 petitions because of the resource demands on EPA as well as the change in the equation of what is considered. He observed that benefits do not carry as much weight. He suggested that the result will be fewer Section 18 petitions that fulfill the technical requirements. Stephen Johnson indicated that they will know soon, once they start acting on Section 18 petitions.

Another member stated that he echoes the concerns raised earlier about major and minor crops; from his perspective, Section 18 is necessary to production agriculture. He also noted that in the field, growers face major losses if there is not a quick response. In the past, the EPA procedure has been workable since it allowed growers to anticipate problems, seek pre-approval, and get a

decision. He urged EPA to come up with a similar process under the new law. He concluded by stating that whatever EPA does with Section 18 must be workable.

Other members pointed out that the requirements in the law in terms of Section 18 were intentional; thus, they suggested it is incumbent on EPA and the grower community to learn how to deal with the changes. Another member disagreed about the intent; he suggested that, while the changes included in FQPA were not intended to slow down Section 18's, that is what seems to have been the result. A congressional participant followed up by noting that the goal of the legislative language was to make sure FDA had an enforcement standard for a tolerance level that could be used to protect public health. Seeking to clarify the discussion further, another member noted that the impetus for including the Section 18 language on tolerances was FDA's concern about adequacy of tolerance levels.

Continuing the discussion, it was observed that this time next year, Section 18 decisions or lack thereof will translate to crop damage. He suggested that Congress did not mean to limit responses to emergencies or paralyze EPA from doing anything else. He wanted to know how EPA will prevent this from happening.

Another member raised a question about prescription use for some chemicals; it was suggested that such a program would alleviate some of the pressure on the Section 18 process. In response, Lynn Goldman noted that the Administration's proposal had included prescription use of chemicals. The Administration had thought such an approach made sense. The approach was seen by some as threatening as they interpreted it to apply to all pesticide use. As a result, the language was not included in the legislation. She also commented that FDA's desire for establishment of a tolerance arises from both domestic and international concerns related to GATT.

Decision Logic

Next on the agenda, Dan Barolo presented the revised decision logic flow chart for registration and reregistration. In considering the chart, he stated that the shaded boxes, aggregate risk and common mode, represent areas of change due to the passage of FQPA.

After the presentation, as members began to address the chart, Lynn Goldman pointed out how things have changed. She noted that a portion of the first shaded box, "Dietary, Aggregated" (for each subpopulation), has always been there; however, the second box, Consider Common Mode(s) of Toxicity, has not. In considering how benefits are addressed, it was noted by several members that a benefits test has always been part of the decision process. Several comments were made that the FQPA benefits provision may or may not be used in the future.

A member asked about how with the FIFRA standard where there is significant risk, where are benefits considered in the determination of whether the FIFRA standard is met? It was explained that under FQPA, if a determination of significant risk is made, then ways to mitigate are considered. With interim risk mitigation measures, if the chemical meets the FQPA standard, common mode is evaluated. If the chemical does not meet the standard, then the threshold effect

is considered. If the threshold effect does not apply, the benefits are considered and regulations issued.

Several members noted that it would be useful if the flow chart indicated where input to the system occurs. It was observed that much of the input occurs prior to the risk assessment box. A member suggested that the diagram, specifically the FQPA threshold, be clarified to show that it does not apply to new active ingredients. Several members stated that the FQPA benefits test box includes consideration of common mode chemicals. Thus, the benefits assessment will be based on multiple chemicals and overarching risk on crops. It was noted that it is complicated, but the assessment will be used to decide which uses of which chemicals to leave on the market.

Building on the theme being discussed, Lynn Goldman referred to the previous meeting where benefits had been addressed and a distinction had been made between big "B" and little "b" benefits. It was explained that the box on the flow chart represents big "B" benefits where tradeoffs are considered. She noted that benefits will play an important role in the decision process.

A participant asked how, under FQPA, the Agency would deal with a class of chemicals found to have a common mode. For that class of chemicals, risk is exceeded and the registrant withdraws the chemical. Does EPA continue to look at risk? Dan Barolo explained that as part of the tolerance reassessment process, EPA will be looking at classes of chemicals.

He observed that the decision process explained earlier is the legal framework for decision-making and is derived from FIFRA and FFDCA.

PUBLIC COMMENT

R.G. Schultz, AgTech, introduced himself and explained that he has worked on many aspects of agronomics including involvement with a minor crop consortium that was formed to address registration and reregistration under contract with EPA. He has expertise in economics and biology and has worked on precision agriculture. He wanted to comment on the use and economic importance of minor crop products to production agriculture. He noted that there is a repeated constant omission of the lack of dietary exposure considered in the calculation of the risk formula. He suggested that dietary exposure needs to be done by crop and region. He suggested that the private consortium can help individually with specific minor use products. In conclusion, he observed that precision farming is a technology that allows variable rate application for management. It will alter pesticide use.

Interim Decision Logic

After lunch, Fred Hansen initiated the discussion on the interim decision logic. He observed that the discussion reflects a key point where the Agency desired input from the Committee. He noted that the handout presents different scenarios for decision-making that the Agency will need to make in a relatively short timeframe with a lack of information. (See handout on Interim Decision Logic for more details.) He urged members to focus on the broad philosophical issues.

Dan Barolo then introduced the Agency's rationale for having an interim decision logic. Key is the Agency's need to make decisions in the interim where lack of data is an issue. He explained that in making a decision, the Agency must look at aggregate risk defined as exposure associated with food, water, residential and lawn, and other. He noted that aggregate risk is hazard multiplied by exposure. It is his sense that the Agency has good information on the hazard side of the equation, especially with regard to older chemicals. On the exposure side, the Agency has relatively good information for food and water, but is deficient for residential and lawn exposure. He explained that the Agency is trying to assess these types of exposure now. They are testing models and have active task forces focused on these topics. He also observed that in determining aggregate exposure, they need to address both chronic and acute exposure which may require them to use different approaches and that it will take some time to refine them. He also observed that the tolerance reassessment process which was discussed the previous day will be the driving engine for determining the priority for consideration of specific chemicals.

Additionally, he noted that the ability to make decisions in the short term will allow for the Agency to take further mitigation measures to affect interim risk as needed. It will also allow the Agency to make decisions on suspensions and cancellations. Building on the previous discussion, he reminded members that the basis for making these decisions is derived from FIFRA and FFDCA.

Given that the Agency will be making decisions based on an interim decision logic, Barolo emphasized that all decisions will be time-limited or conditional (except cancellation). Thus, the Agency will be able to revisit the interim decisions, if necessary. It is the Agency's expectation that they will refine the decision logic in three months.

Dan Barolo then briefly outlined each of the options (see handout on Interim Decision Logic). Option 1 has EPA establish and reserve a percentage of the risk cup for water and residential uses. The amount allowed for food uses would be a specified percentage of the total RFD. The dilemma with this option is determining what the percentage should be. As a point of further explanation, it was noted that if a chemical was not used for all types of uses, only those that are relevant would be considered.

Option 2 would establish a process for highly hazardous pesticides that would lump significant pathways and would determine a risk value for each of them according to type of use (water, residential, and lawn). The risk values generated would be combined and the remainder of the risk cup would be allocated for food uses. Other active ingredients would be treated as a single category and given a risk value of Y%.

Option 3 would use a weight of evidence approach. Each chemical is ranked as to whether it is a high, medium, or low risk for lawn, residential, and water. Based on the level of risk, each is given a weight (e.g., one is low, three is high) which are added up to determine the amount of risk to be allocated to food in the risk cup. (e.g., 7-9 = x%, 4-6 = y%, and 1-3 = z%). It was noted that the criteria used to determine whether a pesticide is a high, medium, or low are critical to this option.

After presenting the three options, Dan Barolo asked Committee members for their reactions and suggestions as to which option to pursue and factors to consider. In terms of factors, Dan Barolo noted that on page five of the handout, they had outlined a list of decision factors which the Agency has identified including mobility, persistence, use, detection, etc. How to weight these factors is a question the Agency is addressing.

He also explained that on page six, they had considered how to address the issue of common mode. It stated that if one seeks a new use and sees similar end points and/or similar chemical structure, then assume a common mode. Once a mode of action is defined, a common mechanism determined, and cumulative risk assessment determined, the Agency will calculate the risk and revisit the decision.

As the discussion of the options proceeded, Dan Barolo noted that there is a tension between pursuing the more complicated options which more accurately reflect the risk and the fact that they will take more time to apply.

Asking for further clarification on Option 1, a member asked if the process for determining the amount of risk reserved is arbitrary or determined on a chemical-by-chemical basis. Dan Barolo responded that it is not arbitrary; chemicals would be considered by class of active ingredients where possible. EPA would assume a conservative reserve for each use.

Other members observed that while overall there seems to be a lack of data on the exposure side, for some products there may be good available data. They asked how these situations would be handled. They wanted to know whether the simple assumption would be followed or would the Agency use real data. Dan Barolo stated that real data would always "trump" or be used instead of assumptions. The approach presented in Option 1 presumes the absence of information, but would use real data when available.

Several members wondered how the Agency would treat modeling results that use some real data. EPA staff noted that data from validated models could also be used.

Some Committee members wanted to know what process will be used to determine which factors will be considered. Dan Barolo noted that EPA will seek a process for additional input on factors to consider including consultation with the SAP.

A Committee member asked for clarification on Options 2 and 3; it was not clear to them how common mode was integrated. Dan Barolo explained that Options 1-3 only address aggregate risk; common mode is considered subsequently.

Several members noted that the logic presented is reasonable. They were still unclear, however, on the process for determining the other percentage values. Barolo noted that the Agency will utilize a number of means including the use of surrogate data. He continued by noting that the presumption is that applications for new uses of an active ingredient are complete. To the extent that surrogate data can be used, they will be.

From a broad perspective, a member asked if it was correct to assume that with each more complex option, the assessment of the risk is more accurate. Dan Barolo noted that if one applies the decision factors consistently, that is a correct assumption. It was further noted by the member that with the more complex options, there would be fewer changes in the decisions when real data are acquired. EPA staff agreed but reminded members that there is a trade off: with an increase in accuracy, more time and effort is needed prior to making a decision. It was further observed by Fred Hansen that the tendency is to move towards Option 3 because of its increased refinement, but the more time the Agency spends on these interim decisions, the less there is available for other activities such as Section 18's.

Several members asked for clarification of a few terms. One asked for clarity on the term reference dose and risk cup. Another sought an explanation of how the 10-fold uncertainty factor is considered. In response, it was noted that the reference dose, defined as a 70 year burden, determines the risk cup for long-term exposure. In terms of the 10-fold uncertainty factor for children, Dan Barolo stated that it changes the size of the overall cup.

Several members wanted to know if EPA had any idea on how much time would be required for each option. They indicated that there is a bias towards the more accurate options, but they recognized that it may not be best.

Fred Hansen noted that EPA staff have indicated that Option 2 reflects a reasonable level of work as it allows them to consider various factors without requiring too much scrutiny. Dan Barolo expanded on Fred Hansen's comments and stated that the Agency could do Option 1 tomorrow. Option 2 could be done relatively quickly. Option 3 would require more time. He reiterated that all three options consider the same factors.

As an additional point of clarification, it was noted that if a new chemical had no lawn or residential uses, those portions of the risk cup would be available for the other uses.

A number of members noted that the approaches presented by EPA are a good beginning. Several of them urged EPA to use as simple an approach as possible. They suggested that if more data are available for a particular chemical, the Agency could then use one of the more sophisticated approaches.

Stephen Johnson restated the concern about resources and the need for decisions. He reminded members that the tolerance reassessment process will be driving this decision process, consideration of new uses, Section 18's, etc. If tolerance reassessment for a specific chemical does not show up until 2005, what will be done in the interim? He observed that there are more than 300 applications in the queue and hundreds that will have registrations expire in the next three years. Thus, he urged that the process selected be simple, otherwise EPA will be paralyzed and the registration gate will not be open for years.

Fred Hansen concluded this discussion by noting that the Agency welcomes members' thoughts on these options. The Agency has not yet decided how to proceed.

Next Steps

Lynn Goldman reviewed the agenda for the next meeting to be held Thursday, December 5, 1996 Based on the Committee's discussions at previous meetings as well as the issues raised during this meeting, further elaboration of the following issues were identified as possible topics:

- Approach to science assessment;
- Interim Decision Logic;
- Tolerance Reassessment;
- Communications;
- Minor Uses; and
- Other Areas including Endocrine Disruptors.

Given that list, she asked the Committee for their thoughts on what topics they would like to discuss at the last meeting of the Advisory Committee. Lynn Goldman noted that the first three topics are important to her as they are critical to the Agency's ability to move the Program forward. In response, several members of the Committee observed that they felt there should be additional discussion of resources and their allocation to support the implementation of FQPA. They felt that the Committee should have another opportunity to provide input on priorities. Additionally, some members stated that they felt that part of the discussion of resources should include projections from EPA on the number of activities that the Program expects to accomplish in the next year given funding constraints.

In response to a question, Lynn Goldman clarified that the discussion of endocrine disruptors would be an update on the activities being undertaken by the Endocrine Disruptors Screening and Testing Advisory Committee.

Other members noted that the discussion of topics related to the National Academy of Sciences Report could be a very long discussion unless the intent is to provide an update. Lynn Goldman responded that the intent would be to provide an update and to seek input from the Committee on the associated policy questions.

Another member observed that much of the discussion had focused on how to manage risk from the assessment side. It was suggested that the December meeting should include a discussion of recent data and what can be done to mitigate risk, (i.e., on the risk management side).

Another member noted that there is potential for states to assist with Section 18 petitions. He proposed that an expanded role by the states will further leverage efforts by other federal and state agencies in facilitating the process with limited resources and that such an approach should be discussed further. It was suggested that this issue could be addressed within the discussion of resources.

Following up on USDA presentations earlier in the meeting, it was suggested that the Committee request that USDA compile a joint paper with EPA that will consider how the two agencies will

work together. It was observed that based on the earlier discussions, it is clear that both Departments have an interest in coordinating better.

Next, John Ehrmann presented a suggestion for the final summary of this Committee's efforts He explained that the plan is to draft an executive summary which will be a narrative description of the objectives of the FSAC and will outline the main topics discussed. Attached as appendices will be the individual meeting summaries.

In his concluding comments, John Ehrmann stated that the comments provided on the proposed agenda will be considered and incorporated into the agenda for the December 5 FSAC meeting He pointed out that in many situations, the Agency seeks input when it has already determined the answers. In this case, he observed, the Agency is seeking input from the Committee as it ponders how to proceed with the implementation of FQPA.

PUBLIC COMMENT

No one asked to give public comment.

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December 5, 1996
Meeting Summary

FOOD SAFETY ADVISORY COMMITTEE
Fourth Plenary Session - Meeting Summary
December 5, 1996
Washington, D.C.

Chairman: Fred Hansen, Deputy Administrator, US EPA

Vice Chair: Lynn Goldman, Assistant Administrator for Prevention, Pesticides, and Toxic Substances, US EPA

Members: Jose Amador, Texas A&M University; Mark Atwood, American Cyanamid; Elaine Auld, Society for Public Health Education, Inc.; Cynthia Bearer, Case Western Reserve University; Emilo Bontempo, Ciba-Geigy Company; Daniel Botts, Florida Fruit and Vegetable Association; Carolyn Brickey, National Campaign for Pesticide Policy Reform; Kenneth Cook, Environmental Working Group; Shelly Davis, United Farm Workers; Arnold Donald, Monsanto Company; John Hagaman, DowElanco; Jon Jessen, Gowan Company; Kathleen Merrigan, Henry A. Wallace Institute for Alternative Agriculture; Jane Perkins, AFL-CIO; Jean Pettibone, American Agri-Women; Robert Rhodes, Holland and Knight; James Wells, California Environmental Protection Agency; Pete Wenstrand, National Corn Growers Association

Alternates: Steven Balling, Del Monte Foods - Research Center; Judith Conover, League of Women Voters; Larry Elworth, Program for Strategic Pest Management; Wenona Hauter, Citizen Action; Antony Hepton, Dole Foods; Rick Holt, DuPont Agricultural Products; Richard Kirchhoff, National Association of State Departments of Agriculture; Mike McGeehan, Centers for Disease Control and Prevention; Patrick Meehan, The Clorox Company; Erik Olson, Natural Resources Defense Council; Jan Relford, Gerber Products Company; Bob Schramm, Schramm, Williams and Associates; Dennis Stolte, American Farm Bureau Federation

Ex-Officio Members: Linda Fisher, Monsanto Company; Jack Moore, Institute for Evaluating Health Risks; Steve Jellinek, Jellinek, Schwartz, & Connolly Inc.

Congressional: Howard Cohen, US House of Representatives; Greg Dotson, US House of Representatives; Kay Holcombe, US House of Representatives; Curt Mann, US House of Representatives; Dale Moore, US House of Representatives

WELCOME, INTRODUCTIONS, AND OVERVIEW OF AGENDA

Fred Hansen, Chairman of the Food Safety Advisory Committee (FSAC) and Deputy Administrator US EPA, welcomed members and thanked them for attending the last of the series of meetings. He recognized that it was not an easy time to travel due to the upcoming holidays, and expressed appreciation for Advisory Committee members' extra effort, time, and commitment.

Mr. Hansen then reflected on the initial intent of the Food Safety Advisory Committee which was to provide an opportunity for members to comment on the implementation of the new law. He noted that the input received to date had been remarkably helpful, particularly on the general framework and the proposed decision logic presented by US EPA. While Mr. Hansen acknowledged that this was the last meeting of the Advisory Committee, he commented that there had been a greater level of stakeholder involvement as a result of the meetings; he hoped that the connection with the stakeholder community would continue. He also reminded members that other fora would provide additional opportunities for public input (listed on Attachment A).

Next, Mr. Hansen commented on some follow-up activities that occurred after the last meeting. He explained that, based upon concerns expressed by this group, a series of meetings were planned between himself and Mr. Rominger, Deputy Secretary of the U.S. Department of Agriculture (USDA), to discuss children's food consumption and other issues so that EPA can make more informed decisions. He commented that this series of meetings was the beginning of what he hoped would be an on-going relationship between US EPA and USDA.

In addition, Mr. Hansen noted that $16 million of the additional $30 million budgeted for 1997 was committed to implementation of the Food Quality Protection Act (FQPA), while $14 million was committed to the new Safe Drinking Water Act (SDWA). He explained further that an additional $5 million dollars has been set aside to insure sufficient resources to achieve the requirements of both FQPA and SDWA. Mr. Hansen's final comment regarding the budget for implementation of the new Act was that, with the endorsement of the President, EPA was continuing discussions with the Office of Management and Budget (OMB) on the importance of adequate funding for FQPA in 1997 and in future years.

Mr. Hansen closed his comments by thanking members once again for their commitment to this process. He also thanked the Congressional staff for taking part in the meetings; their presence provided direct and real-time explanations about the intent of the law.

Lynn Goldman, Vice Chair of the FSAC and Assistant Administrator for Prevention, Pesticides, and Toxic Substances, joined Fred Hansen in welcoming members to the last meeting of the FSAC. She reiterated that it was very helpful to have the participation of Congressional staff and commented that their advice was invaluable. She extended particular thanks to the EPA staff who helped to organize and run the meetings. Dr. Goldman then summarized the following agenda for the meeting:

- Recap of Previous FSAC Meeting Topics;

- Discussion of Draft Implementation Plan Outline;
- Minor Uses and Section 18 Program; and
- Public Comments.

Next, John Ehrmann, The Keystone Center, reminded members of the meeting's groundrules. He clarified that the goal of the Advisory Committee is to provide EPA with input on the implementation of the new law and not to develop consensus on related issues. He reiterated that input provided to EPA thus far has aided the process of implementation, and that EPA plans to continue to use their input in the future. Mr. Ehrmann explained that summaries of each meeting will be made available to the public in a final report. He then introduced Martha Tableman, The Keystone Center, for the recap of previous FSAC meeting agenda topics.

RECAP OF PREVIOUS FSAC MEETING AGENDA TOPICS

Martha Tableman referred members to the *Food Safety Advisory Committee Summary of Main Points Covered at the First Three Meetings* (Attachment B) for her recap of previous FSAC agenda topics. She characterized the first of the four meetings which was held on September 26. 1996, as an organizational meeting at which EPA outlined the objectives of the Advisory Committee and reviewed the major provisions of the FQPA. Members also identified a series of issues to be addressed at subsequent meetings. Dr. Tableman explained that at the second meeting, held on October 22 - 23, 1996, members discussed: resources; communications and Right-to-Know; risk: aggregate exposure and common mechanism of toxicity; minor uses; reduced risk pesticides; and benefits. They also provided preliminary comments on EPA's proposed interim decision logic for how an application for a chemical may be handled under FQPA. In closing, she explained that the third plenary session addressed topics including: worker issues; human health risk assessment; tolerance reassessment; Section 18; and the proposed decision-making process. In addition, she noted the staff of the USDA summarized their programs that address pest management and information collection.

DISCUSSION OF DRAFT IMPLEMENTATION PLAN OUTLINE

Following Dr. Tableman's recap, John Ehrmann introduced Anne Lindsay, US EPA, OPP, to present an overview of the Draft Implementation Plan Outline. Ms. Lindsay referred Advisory Committee members to *the Draft Implementation Plan Outline* (Attachment C), for her presentation. She explained that the plan provides:

- An overview of the FQPA;
- The guiding principles for implementation; and
- A description of the implementation process.

In addition, Ms. Lindsay stated that the plan provides:

- Guidance on the approach to risk assessment;
- A summary of the requirements that relate to minor uses and reports on plans for meeting those requirements;

- A description of other regulatory requirements;
- A summary of plans to produce a brochure;
- A plain English guide and other public access resources; and
- A table of milestones on major issue areas and sources for additional information.

At the conclusion of her presentation, Ms. Lindsay asked members for comments on the outline by December 20, 1996. She explained that EPA expects to use the interim decision logic until April 1997, unless the Scientific Advisory Panel (SAP) requires additional information and time to assess it.

Approach to Science Assessment

Following Ms. Lindsay's overview, Dr. Margaret Stasikowski, Director, Health Effects Division, OPP, US EPA, referred members to a document titled, *Approach to Science Assessment* (Attachment D) for her presentation on where EPA stands on risk assessment policy changes to comply with the new law. She explained that there are four major issues addressed in this assessment:

- Protecting Sensitive Sub-populations, Including Children;
- Aggregate Exposure (e.g., Dietary and Non-dietary or Residential and Drinking Water);
- Common Mode of Action; and
- Endocrine Disruptors.

Dr. Stasikowski provided additional details on the first three issues, but explained that she would not address endocrine disruptors because the issue is being addressed by a separate advisory committee. She then invited questions from members.

Several members wanted an explanation for EPA's choice to use "common mode of action" versus "common mechanism of toxicity (or action)" and expressed concern that the choice be consistent with the meaning of the law. Lynn Goldman explained that "common mode" was used because there is generally insufficient data to evaluate a pesticide at a cellular level as would be required for identification of the "mechanism of toxicity". She clarified that there are three ways to look at the issue of chemicals acting with a common mechanism: at the molecular level; by grouping chemicals with the same endpoint; and, by aggregating chemicals with a common mode of action. She explained that the latter of the three ways was chosen by EPA as the middle ground as sufficient data are available.

As a point of clarification, some Congressional staff members noted that in terms of drafting FQPA, Congress used "common mechanism of toxicity" to address the concept of similarities to the other pesticides that make it appropriate to consider the risks posed by the different pesticides together. Another Congressional staff member urged that EPA should be cautious in their approach because "mode" and "mechanism" of toxicity may not necessarily be equivalent.

How the additional 10-fold uncertainty factor for infants and children is being interpreted was identified as a concern by many members. Some members stated that the FQPA language clearly

states that the presumption is that a 10-fold uncertainty factor is used unless there is reliable data indicating that the value should be higher or lower while still ensuring that there is a reasonable certainty that no harm will result to infants and children. Other members presume, based on FQPA's legislative history, that the risk assessment begins with EPA scientists' best judgment based on reliable data to determine whether an additional margin of safety of up to 10 is required. From their perspective, an additional uncertainty factor , between three and ten, is used when data is incomplete. The value of the additional factor is dependent on how much information is incomplete. During the discussion, it was noted that the latter interpretation reflects the approach used by EPA prior to FQPA's passage. EPA clarified that they begin with a 10-fold uncertainty factor unless reliable data indicates otherwise.

Many Committee members wanted to know whether they would have additional opportunities to evaluate and comment on these and other issues. Representatives of EPA reiterated that there were additional opportunities for the public to comment, as discussed earlier in the meeting. They reminded members that the information on which EPA based its decisions is and will continue to be part of the public record. In addition, they clarified that information about the uncertainty factor would be available soon, subsequent to the Agency responding to the review by the SAP.

Interim Decision Logic for Screening Risks

Daniel Barolo, US EPA, presented an overview of the interim decision logic for screening risks. He referred the group to the following three handouts for this purpose (Attachment E):

- A diagram of the *Proposed Registration/Reregistration Decision Process*;
- *Interim Decision Logic*; and,
- The revised risk cup options diagram (options 1 - 3).

Mr. Barolo referred members to the updated diagram of *Proposed Registration/Reregistration Decision Process*. He explained that, while EPA was developing the full decision-making process, the interim decision logic was necessary to address the issue of making protective decisions now, that meet the "reasonable certainty of no harm" standard in the absence of complete data and fully developed exposure and risk assessment methodologies. In addition, Mr. Barolo stated that decisions made based upon the interim logic would be time-limited and would be revisited as additional knowledge/capacity were obtained.

Next, Mr. Barolo described three options to determine the percent of risk to reserve in the risk cup. He provided some background on how the options were developed and summarized the distinctions between the options as follows:

- Option 1 - represents the simplest approach to reserving a percentage of the risk cup for future drinking water/residential/lawn use. The option does not allow for distinction between high and low risk ingredients.
- Option 2 - is a more flexible option which allows the categorization of active ingredients based upon the level of hazard as high and low.

- Option 3 - represents the most complex of the three alternatives which would enable a greater degree of distinction between levels of hazard; high, medium, and low. Option 3 would also require more time and resources.

Mr. Barolo stated that EPA preferred Option 2 because it allowed for some distinction between the level of hazard but, in comparison to Option 3, did not require many more resources than Option 1. He then invited members to comment on the interim decision logic.

Several members wanted to know if there were empirical data to evaluate how realistic the options were. Mr. Barolo responded that EPA tested the options by evaluating 18 registered chemicals which had the potential to contaminate groundwater. He offered to provide additional information at an information-sharing meeting on the interim decision logic to be held on Thursday, December 12, 1996 from 10:00 a.m. until 12:00 p.m. at OPP's offices in Crystal City.

Some members were concerned about the use of defaults to determine the percentage of the risk cup reserved where data were not available, particularly for residential and lawn exposure. They wanted to know how EPA planned to integrate exposure data where it existed, especially when exposure data supplied by a grower suggested a risk allocation that differed from an EPA-determined risk allocation. Representatives from EPA clarified that they would base their decisions, including the determination of defaults, on scientific data when they are available. They commented that EPA does not limit itself to its own data and that, under the Act, anyone can petition EPA with new information. Fred Hansen then asked Advisory Committee members to consider, if information supplied by the grower community or others opened up space in the risk cup, how they would prefer to allocate the additional space? He stated that EPA wants guidance from the Advisory Committee on how to allocate the risk cup fairly.

Several Advisory Committee members wanted clarification on how this process would apply to non-food uses. Dan Barolo explained that the intention was to address the aggregate exposure, and that non-food uses would be addressed specifically where sensitive populations could be affected.

Many members were concerned about what and how subpopulations would be addressed. In particular, several Committee members wanted to know if EPA would address farmworker children as a subpopulation. Dan Barolo explained that EPA addresses 22 subpopulations, including infants and children when conducting dietary risk assessments. He commented that sensitive subpopulations are generally the driving force when allocating risk. Mr. Barolo commented that non-dietary information is generally lacking, including such information on farmworker children. Lynn Goldman acknowledged this point and committed to follow-up on the concern raised.

Some members felt that, because some subpopulations were more vulnerable than the general population, they should have greater statistical significance in the allocation of risk. Other members disagreed with this concept and felt that it contradicted the purpose of statistical evaluation.

Following this discussion, many in the group supported the use of Option 2. They acknowledged that there were still some concerns and unanswered questions about the details of the Option, but suggested that EPA get started with the process of risk allocation by using it.

Fred Hansen stated that, based upon the number of questions and concerns, the information-sharing meeting on the methodology for determining the percentage contribution from water, residential, and lawn exposure next week was essential and he hoped members would seriously consider attending the meeting. Lynn Goldman supported Mr. Hansen's suggestion, but also reminded members that EPA also needs to make decisions. She asked the group to remember that the interim logic is conditional and time-limited.

PUBLIC COMMENT

Melanie Scott, Pesticide and Toxic Chemical News, asked a clarifying question on whether pesticide lawn use was addressed directly in the risk cup calculations. Representatives of EPA clarified that data on lawn application are limited but were considered in the calculation.

DISCUSSION OF DRAFT IMPLEMENTATION PLAN OUTLINE (CONTINUED)

Tolerance Reassessment Program

Lois Rossi, US EPA, summarized the *Proposed Tolerance Reassessment Program* (Attachment F.) She explained that the FQPA requires all tolerances and exemptions from tolerances to be reassessed within ten years and that the most risky pesticides must be addressed first. Ms. Rossi noted that the reregistration program will initially drive tolerance reassessment, after which time the required registration renewal program will drive the process. Dan Barolo added that the proposed Tolerance Reassessment Program fundamentally redirects the priorities of the Pesticide Program which were formerly based on a "data complete" basis. He explained that the proposed program bases the priorities on a chemical class approach.

Some members were concerned about the amount of resources required for the proposed plan and wanted to know if EPA had an estimate for this. Dan Barolo explained that, at this time, EPA did not have an estimate for the amount of labor that would be required.

Several Advisory Committee members asked EPA to address what happens to the pesticides for which reregistration is close to completion at this time. Ms. Rossi explained that pesticides which are close to completion will be addressed in 1997 - 98. Dan Barolo added that if there are no food uses, reregistration will proceed. Lynn Goldman stated that EPA will publish a revised tolerance reassessment schedule in 1997, particularly to address older pesticides.

Other members wanted to know if EPA had considered the amount of time that it may take to reevaluate some of the time-limited decisions made during the interim. They suggested that EPA may want to consider alternative strategies to address this concern. Dan Barolo acknowledged the concern and suggested that the group continue its discussion on how this might be achieved

through promoting coalitions in the user community, in the discussion of minor uses, and the Section 18 program.

DISCUSSION OF MINOR USES AND SECTION 18 PROGRAM

Steve Johnson, US EPA, initiated the presentation on minor uses and the Section 18 Program. He introduced Hoyt Jamerson, Minor Use Officer, Registration Division, and Robert Forrest, Section Head, Emergency Response and Minor Use Section. Mr. Johnson then presented an overview of the minor use provisions (Attachment G) and Section 18's. He addressed the overall implementation plan of the minor use program, the results of the Section 18 workshop, the status of Section 18 activities, and current Section 18 decisions facing EPA.

Mr. Johnson first summarized the proposal for implementing the provisions of the FQPA relating to minor use pesticides. He explained that the proposals will be published for public comment in June 1997. Mr. Johnson then summarized the six major components of the proposals:

- Clarification of the definition of minor use including use on less than 300,000 acres, identification of major crops to aid in identifying minor use crops, economic criteria for minor use crops, and significant public health pests;
- Procedures to identify, validate, and track exclusive use of data for minor use pesticides;
- Procedures and tracking systems for minor uses and public health pesticides during reregistration, registration, and tolerance reassessment;
- Prioritization of minor uses within the system;
- Recommendations for minor use program organization within the program; and,
- What US EPA, in coordination with USDA and Health and Human Services (HHS), can do to help the minor use program.

Representatives of the grower community thanked EPA for developing these proposals and commented that they provided a good safety net for minor uses. They explained that they were also working on ways to improve the process and invited other members to join them in their efforts.

Several members expressed interest in learning how EPA planned to involve the grower community in the minor use program. Some of their concerns included:

- How EPA would address crop size;
- Expediting reduced risk pesticides;
- Whether the use of weight-of-evidence is sufficient to address worker safety concerns; and,
- The criteria for risk allocation and the resulting impact on risk cup allocation for minor uses.

Some suggested that the grower community could help EPA by providing data for the program. Others proposed that EPA plan to have structured conversations with the minor use industry and work closely with other appropriate agencies.

EPA was supportive of additional input from these communities. In particular, Fred Hansen requested that the registrant community, grower groups, and USDA staff get together and recommend to EPA what criteria they should use to allocate risk and how to allocate minor uses within the risk cup. He commented that, if the group reached agreement on the process for risk allocation, EPA would seriously consider the recommendation. A number of people from the environmental and minor use community felt that this was a good idea. Mr. Hansen then asked USDA to help convene this group effort and move the process along.

Next, Mr. Johnson discussed the results of the Section 18 workshop, the status of Section 18 activities, and current Section 18 decisions facing EPA. He explained that the workshop was well attended and the group addressed questions on the interim process and how to proceed with the list of pesticides issued prior to FQPA (Attachment H). He noted that the results of the Section 18 workshop will be available by the end of December.

Mr. Johnson then walked the group through an example of a Section 18 pending a decision on two unregistered fungicides on seed corn. He explained that the risk assessment was done on both fungicides assuming the risk cup was overflowing prior to the assessment. The result for both pesticides was no approval of a Section 18 because EPA could not issue a tolerance showing "reasonable certainty of no harm."

Many members felt that the example of seed corn was not a good one because seed corn is not a food, thus pesticides used on it should not be subjected to the requirements of Section 18 and establishing tolerances.

Members urged EPA to use common sense when assessing risk and to apply the interim decision logic to get the program back on track.

PUBLIC COMMENT (Afternoon, December 5, 1996)

Jay Vroom, American Crop Protection Association (ACPA), cautioned EPA that time was at a premium and they should focus their efforts on transparent implementation of the law. He stressed that, to insure the safety of the food supply, EPA not delay decisions on pesticides, make interim decisions if necessary for new product labels, reopen the acceptance of new tolerance applications, apply the interim decision logic cautiously, and allocate limited resources effectively He closed his comments by stating that he looked forward to working with EPA in the future.

Jim Cranney, US Apple Association, stated that EPA did a good job with the FSAC meetings. However, he commented that EPA had not fully addressed the immediate problems for growers caused by insects and diseases. He stated that growers need to be able to deal with these problems flexibly and with available tools. He expressed concern that the new law could adversely impact growers by placing moratoriums on new product registrations. Mr. Cranney observed that EPA has the discretion and talent to implement the new law without negative impact on industry. He closed with the comment that he looks forward to working with EPA as they move forward with the implementation of the new law.

Jere Downing, Cranberry Institute, expressed concern about FQPA because of the potential for products critical to his industry to be canceled. He commented that his industry is small and vulnerable and that any cancellation will be disruptive. Mr. Downing explained that his industry is looking at risk reduction programs like IR-4, but is not finding many alternatives quickly. He stated that they are also trying to address risk through a partnership with EPA through the stewardship program. In closing, he requested that EPA make the transition to the new law seamless and that they look at the percentage of the crop treated and how the crop is processed in comparison to the whole crop when evaluating risk.

Vern Highley, National Watermelon Association, stated that the FSAC meetings provided a good dialogue. He supported EPA's common sense approach and stressed the need to use this approach to battle pests which come back in force. Mr. Highley commented that the community needs to trust EPA to do its job and requested that EPA keep it simple and avoid hold-ups.

Tom Van Arsdale, National Council of Farmer Cooperatives, noted that agriculture is vital to the well-being of our society and that crop protection tools are essential to agriculture. He expressed concern about how the transition between the old and the new law may affect the application of these tools and stressed that the new law can work without seriously disrupting agriculture. He suggested that the community work together and let EPA do its job.

Bob Lake, Food and Drug Administration, commented on the challenge to EPA presented by the transition between the new and old laws. He offered FDA's assistance, particularly with enforcement actions to address unintended uses of food such as the illegal use of seed corn as food.

Heidy Davis, Keller & Heckman, asked a clarifying question on the difference between how benefits apply to Sections 18 and 3. EPA staff explained that additional information was required for response to the question.

CLOSING REMARKS

Fred Hansen thanked everyone for their participation. He commented that input received throughout the process was valuable. He urged people to take advantage of the additional opportunities in the future to share opinions and information on aspects of the new law. Mr. Hansen stressed that this series of meetings had an unprecedented impact on EPA's thinking and ideas, and that he was glad to have had the opportunity to take part in the process.

Following Mr. Hansen's closing comments, Lynn Goldman reiterated that the process had accomplished much for EPA. She stated that EPA was appreciative of the views expressed, and they found the input on the implementation framework very helpful. Dr. Goldman encouraged members to remain actively involved in the process and to participate in future opportunities to provide input.

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