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

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

When FQPA took effect, EPA was immediately faced with having to implement new standards and requirements. The Agency established the Food Safety Advisory Committee (FSAC) as a subcommittee of the National Advisory Council for Environmental Policy and Technology to assist in soliciting input from stakeholders and to provide input to EPA on some of the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs.

The interim approach developed through discussions with FSAC has allowed the Agency to make regulatory decisions that met FQPA's standard but that could be revisited if additional information became available or as the science evolved. As EPA's approach to implementing the scientific provisions of FQPA has evolved, the Agency has sought independent review and public participation, often through presentation of many of the science policy issues to the FIFRA Scientific Advisory Panel (SAP).

Although the Agency has sought independent review and public participation, the Agency has decided that the implementation process would benefit from a more thorough process of notice and comment. As directed by Vice President Albert Gore, EPA has been working with the U.S. Department of Agriculture (USDA) and the TRAC, chaired by EPA Deputy Administrator Fred Hansen and USDA Deputy Secretary Richard Rominger, to address FQPA issues and implementation. TRAC comprises more than 50 representatives of affected user, producer, consumer, public health, environmental, states, and other interested groups. The TRAC has met five times as a full committee from May 27 through September 16.

With the TRAC, the Agency has been working to ensure that our science policies, our risk assessments of individual pesticides, and our process for decision making are transparent, open, and based on sound science. An important product of these consultations with TRAC is the development of a framework for addressing key science policy issues.

The TRAC identified nine science policy issues key to implementation of FQPA and tolerance reassessment. The framework calls for EPA to provide for notice and comment on

each of the nine issues over the course of the next several months. For each of these policies, EPA will issue Federal Register notices announcing the availability of appropriate science policy documents for comment. Other opportunities for public involvement in the refinement of these policies will also be available, depending on the current status of the individual science policy. Each of these issues is evolving and in different stages of refinement. Accordingly, as the issues are further refined by EPA in consultation with USDA and others, they may also be presented to the SAP. For some of these issues, the Agency may also hold workshops. This framework notice briefly summarizes each of the nine science policy issues, the efforts underway to refine them, plans for notice and comment, and the timelines for completing refinements.

(1) Applying the FQPA 10-fold safety factor - FQPA requires EPA to use an extra 10-fold safety factor when assessing a pesticide's dietary risk to take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children. A different safety factor may be used only if, on the basis of reliable data, it will be safe for children.

The 10-fold safety factor is not simply a matter of uncertainty but is also a way of assuring an extra measure of protection for infants and children in cases where special sensitivity or exposure is identified. In assessing risk, OPP assumes retention of the 10-fold safety factor unless, based on a weight-of-the-evidence evaluation of all reliable, applicable information on toxicity and exposure, it can be reduced or removed.

The major issues involved include: (1) what are the appropriate criteria for deciding

whether the safety factor should be retained, reduced, or removed; (2) the need for improved consultation outside of OPP in decision-making; and (3) the need for improved clarity and transparency of our policy and process.

Three major efforts are underway to address these issues. (1) In July 1998, the Agency updated the SAP on its progress in responding to the issues raised by the SAP in March 1998, on the OPP Health and Effects Division (HED) draft guidance on the application of the FQPA safety factor. (2) An Intra-Agency workgroup is addressing general considerations regarding safety factor decisions such as procedures for consistency and documentation, as well as ensuring the adequacy of the data set for decision making. This workgroup includes representatives of the Office of Research and Development, the Office of Children's Health Protection, as well as the Office of Prevention, Pesticides, and Toxic Substances. (3) OPP has completed a draft Standard Operating Procedure addressing safety factor determination issues at the working level.

EPA will complete two final guidance packages based on these efforts and other information consisting of (1) a general guidance document, which includes the scientific basis for the 10-fold safety factor policy, and (2) a working level guidance document, which will provide the process to be used by those who are working on 10-fold safety recommendations. Completion of these draft documents is expected in December 1998. The documents will become final in March 1999 after a 30-day Notice and Comment period, and 30 days for incorporation of comments. EPA has also committed to discuss the 10-fold safety factor at

the SAP meeting in December 1998.

(2) Dietary Exposure Assessment - Whether and How to Use "Monte Carlo" Analyses - EPA assesses dietary exposure using two distinct pieces of information: the amount of pesticide residue that is present in and on food (i.e., the residue level) and the types and amounts of food that we eat (i.e., food consumption). In the past, EPA has used the Dietary Risk Evaluation System (DRES) to combine the residue and food consumption information with data on a pesticide's toxicity to calculate acute and chronic dietary risk.

Over the last few years a different technique has been applied to estimating risk - the use of a probabilistic evaluation called Monte Carlo analysis. Monte Carlo analysis uses the entire range of data from controlled field residue studies. DRES analysis typically uses only the tolerance level, which is the regulatory level and is generally higher than the highest level found in controlled field studies. Monte Carlo assessment has the capability of using all available data (i.e., not just tolerance level) and of better estimating the distribution of exposure to the residues over the population of concern.

The major issues associated with the current approach include: (1) Monte Carlo analyses may overestimate or underestimate risks at the extremes of the distribution; (2) Disagreement exists regarding the most appropriate percentile of exposure for use in regulatory decisions (e.g., 99.9th percentile?); and (3) There is concern over statistical treatment of data inputs into the Monte Carlo model, e.g., use of USDA's high-end consumption estimates and how these combine with using a 99.9 percentile output.

The following steps have been taken to address these issues: (1) In July 1998, the Agency took draft guidance on policies for Monte Carlo analysis to the SAP for comments. (2) USDA is addressing the issues of accuracy of the reported high-end consumption. (3) The issue of the appropriateness of using the 99.9th percentile was taken to the SAP; SAP comments are being considered. (4) In a related effort, the Agency is working on statistical methods for effectively using composite data to estimate exposure from single-serving-sized food items.

SAP comments and related policy issues will be incorporated into the Monte Carlo draft guidance in October 1998. Final guidance will be issued in January 1999 following a 60-day Notice and Comment period and 30 days for incorporation of comments. In addition, the Agency is developing a guidance document on statistical methods on single serving food items. EPA will issue this document for a 60-day public comment period in November 1998 and will issue a final in March 1999. USDA is reviewing its food consumption data to ensure accuracy. This process will be complete in October 1998.

(3) Exposure Assessment - Interpreting "No Residues Detected" - Under the requirements at 40 CFR 158.240, the pesticide manufacturers (i.e., registrants) are required to submit data on the level of pesticide residues that remain on food. Often, instrumentation in the laboratory is not able to detect any residue below a specified level, which is called the 'limit of detection' or LOD. However, even though the laboratory instrumentation cannot detect a residue, a residue may be present, at some level below the LOD, which may still present a

potential concern to human health. Current EPA policy is a treated commodity with non-detectable residues will be considered for purposes of exposure assessment to contain residues at ½ the level of detection.

Issues involving non-detectable residues include the following: (1) There is a common belief that if no residues are detected, no residues are present (i.e., "zero is zero"); explaining the issue of non-detectable residues potentially leading to unacceptable risks is difficult. (2) There are potential trade and market impacts if the Agency assumes that there is risk associated with a use based on non-detectable residues so the use is canceled in the U.S., while other countries allow that use and then those crops are imported into the U.S. legally because residues cannot be detected. (3) The Agency's method for incorporating non-detectable residues into its risk assessment (½ LOD) may lead to inaccurate estimates of risk. (4) A use could pose a significant risk even though residues are not detected.

Although this is not a new issue, FQPA requirements to add risks from all sources (i.e., food, drinking water, and residential) and from all chemicals with a common mechanism of toxicity greatly magnifies the problem, showing much higher risk estimates even when residues are all below the level of detection.

The Agency has two workgroups addressing the above issues. (1) An EPA workgroup is working on a paper to broaden the definition of "no reasonable expectation of finite residues" as discussed in 40 CFR 180.6(a)(3). With sufficient data and clearer guidelines, uses whose residues are insignificant could be assumed to have no risk associated with them. This would

also improve international harmonization. (2) Another Agency workgroup is examining the availability of better statistical methods for assessing data sets that contain both detectable and nondetectable residues.

Products resulting from these workgroups include: (1) a paper to better define "no expectation of finite residues" (i.e., when is zero actually zero?); (2) a paper describing appropriate statistical methods for incorporating non-detectable residues into risk assessments (i.e., where zero may not be zero, what is the appropriate method for incorporating a value in the risk assessment?); (3) a paper describing use of limit of detection versus limit of quantitation in dietary exposure assessment. These three papers will be released for a 60-day public comment period in October 1998, with final guidance to be issued in February 1999.

(4) Dietary Exposure Estimates - EPA assesses dietary exposure from food using two distinct pieces of information: the amount of pesticide residue that is present in or on food (i.e., the residue levels) and the amount and proportion of food that we eat (i.e., food consumption). In assessing dietary risk, EPA starts out with 'worst-case' residues, which are the tolerance level residues that are developed from the crop field trials. Tolerances are regulatory levels, which are set to accommodate the highest residue level found in crop field trials.

Dietary exposure assessments can be improved with information on actual pesticide use, agricultural practices, and processing practices. This type of information includes data on pre-harvest intervals, actual application rates, application frequency, cooking and commercial

processing studies, and other related information, as well as with more comprehensive monitoring data for food and water. To estimate actual residue levels, the Agency also needs certain supporting residue data or procedures to translate or model residue data for typical use practices.

Assuming that residues are present at tolerance level and that 100 percent of the crop is treated allows cost-effective decision making in many cases where risks are low. In these cases, there may be no need for registrants to collect data or for the Agency to use resources to review additional data.

USDA provides the Agency with extensive information on pesticide use, food consumption data, and pesticide residues. The USDA information and information from other sources is key to the preparation of realistic risk assessments. USDA and EPA work to ensure that the needed information is identified, collected, and used appropriately in the risk assessment. USDA and EPA have and will continue to obtain use information from growers. When the Agency meets with the registrants early in the reregistration process, this information is reviewed and supplemented, as needed. EPA recently acquired the capability to perform exposure assessments using state-of-the-art software and the most recently available USDA food consumption data (1989-91). The Agency has been working to complete the National Pesticide Residue Database (NPRD), a comprehensive database that will contain information about actual pesticide residues in foods.

Issues associated with dietary exposure estimates include: (1) Dietary risk estimates

may be unrealistically high when typical use practices have not been factored in. (2) Monitoring data are not available for all commodities, resulting in use of significantly different quality data in risk assessments for different chemicals and/or foods, and unrealistically high risk estimates for those pesticides and crops that lack monitoring data. (3) Information on actual pesticide use may be available but residue levels resulting from this use cannot be calculated without certain residue testing or modeling efforts.

To resolve these issues, USDA and EPA are working together to ensure that data important for accurate dietary risk assessments are collected, and used appropriately and that growers have opportunities to contribute additional information. USDA and EPA will also prepare guidance to explain when residue data may be needed to permit the incorporation of typical use/usage data in risk assessments. Additionally, USDA is evaluating the most recent food consumption survey information which focuses more on foods consumed by infants and children.

EPA will publish in October 1998 an overview document that describes how we do acute and chronic dietary risk assessment and, more importantly, where in our existing guidance one can find methods for doing such risk assessments. Each of the other nine science policy issues will be included in this document. As they are individually refined through their separate notice and comment procedures described here, the overview document will be modified.

The following products are also expected to result: (1) EPA has completed the NPRD: field data have been established; data input is underway; prototype version of the database will

be available on the Internet; final version expected in October 1998; **(2)** EPA will complete Use/Usage matrices in September - December 1998; **(3)** updated USDA food consumption survey information will be available to the Agency in mid-1999; and **(4)** USDA and EPA will complete guidance for growers, states, and others collecting use information to explain the need for certain residue information.

(5) Drinking Water Exposures - Under the requirements of FQPA, in setting tolerances EPA must now aggregate exposures to a pesticide from all sources for which there is reliable information. Typically this includes exposure from food, drinking water, and residential exposures. However, the pesticide program in some cases does not have a database reflecting pesticide residues in drinking water. Available models for estimating potential drinking water exposure generally are believed to overestimate exposure. When aggregated with exposures from food and residential uses, in some cases estimated risks appear unacceptable even though actual risks may in fact be lower and acceptable.

Several efforts are underway to address the problem that current screening models may significantly overestimate residue levels in drinking water. EPA presented a proposed reservoir scenario as a replacement for the farm pond model and OPP's preliminary evaluation of watershed-scale models, including the American Crop Protection Association's regression approach at the July 1998 Scientific Advisory Panel (SAP) meeting. In addition, EPA has entered into a cooperative agreement with the International Life Sciences Institute (ILSI) to advance drinking water exposure assessment methodology. ILSI is organizing a workshop for

the fall and winter which will be held in two phases. It will include participation from scientists with expertise in fate, transport, and occurrence of pesticides in ground and surface water. The workshop will review methods for estimating drinking water exposure and for data and model development for probabilistic aggregate exposure assessments.

EPA is currently using interim HED Standard Operating Procedures which estimates the exposure to pesticides in drinking water. EPA will continue to update the interim HED guidance as important new information becomes available. Additionally, EPA will work with USDA, states, and EPA's Office of Water to discuss issues and obtain real data.

Three products will be completed as a result. First, the Agency will resolve the July 1998 SAP comments on the new water methods and update the November 1997 policy to include reservoir replacement for farm pond scenarios in November 1998. This revised policy will be made available for a 60-day comment period and will be completed in February 1999. Second, the current Standard Operating Procedure will be updated following receipt of SAP comments in March 1999 and will be published for a 60-day comment period. The final should be completed by June 1999. This document will be updated on an as needed basis. In addition, EPA plans to hold two workshops to discuss issues related to drinking water and residential exposure assessment, one in September 1998, and the second in January 1999.

(6) Assessing Residential Exposure - Similar to the drinking water issue, EPA must now include residential exposure in the aggregate risk assessments for pesticides. Generally speaking, residential exposure monitoring data have not been routinely required. Thus, EPA has

been relying on existing monitoring, survey, and modeling data, including information on activity patterns, particularly for children, to estimate residential exposure to pesticides.

Because specific residential exposure data are generally lacking and existing models and assumptions may significantly overestimate or underestimate exposure, several workgroups and task forces are working on various efforts to generate data and improved methods for conducting residential exposure assessments. Agency Standard Operating Procedures (SOPs) were completed and taken to the SAP for comment in November 1997. They are being revised based on the SAP comments and new information in the published literature and other sources.

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

The Agency plans to incorporate SAP comments for the SOPs by December 1998. This

will then be published with a 60-day Notice and Comment period. Public comments will be incorporated and a final document will be completed after 30 days. In addition, the Indoor Residential Joint Venture Task Force is expected to have a Phase 1 draft available March 1999; Phase 2 will be completed October 2000. Preliminary results from the Outdoor Residential Exposure Task Force are expected in August 1999. The Agency will review the chemical-specific data and information generated by the task force and use it in conjunction with or in place of the current SOPs, as judged to be appropriate.

(7) Aggregating Exposures from all Non-Occupational Sources - As noted in issues 5 and 6, under the requirements of FQPA, in setting tolerances EPA must now aggregate exposures from all sources for which there is reliable information. Methods for aggregating exposures to estimate these risks accurately are being developed.

The current method for aggregating exposures using simple addition does not account for the distribution of risks across the population, but provides only point estimates. Methods that more clearly demonstrate the range of risks across the population and population subgroups would better characterize risk for risk management decisions regarding pesticide use. These methods generally use Monte Carlo analyses.

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

EPA will be informed of the technical issues surrounding aggregation of distributions in an independent scientific assessment by ILSI. Their report will be completed in November 1998, along with other comments by the scientific community. The Agency will review these works and provide an Agency draft guidance document in March 1999. This guidance document will be published for a 60-day comment period, after which comments will be incorporated and a final document completed in 30 days. In addition, EPA is developing a Standard Operating Procedure paper for HED which will follow the same guideline.

(8) How to conduct a cumulative risk assessment for organophosphate or other pesticides with a common mechanism of toxicity - Under FQPA, EPA is required to consider available information on the effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity. EPA believes that the organophosphate pesticides, the first group examined, all operate via a common mechanism of cholinesterase inhibition.

In the Federal Register of August 6, 1998, EPA issued a notice announcing the availability of the proposed EPA pesticide policy guidance document entitled "Guidance for Identifying Pesticide Chemicals That Have a Common Mechanism of Toxicity, for Use in Assessing the Cumulative Toxic Effects of Pesticides." The guidance document describes the approach that EPA will use for identifying and categorizing pesticide chemicals that have common mechanisms of toxicity for purposes of assessing the cumulative toxic effects of such pesticides. There is a 60-day comment period for this document that will end in October 1998.

Since there is currently no accepted method for doing cumulative risk assessment, EPA is pursuing an open, peer-reviewed process to develop cumulative risk assessment methods and approaches. The Agency is also nearing completion of the revision of the Chemical Mixtures Risk Assessment Guidelines, which present methods for combining risks from multiple chemicals. In addition, ILSI is independently working to explore appropriate methods and to develop a framework for the hazard characterization and the exposure assessment components of a cumulative risk assessment. ILSI plans a workgroup meeting on this subject in September and a report in early 1999. The Agency will examine the ILSI work and other sources of information in preparation for release of an Agency draft guidance document by May 1999. Sixty days will be allowed for notice and comment, followed by 30 days to finalize the guidance.

(9) Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates - Most organophosphate (OP) and certain carbamate insecticides exert their principal toxic effects on insects, mammals, and other animals by the mechanism of cholinesterase inhibition. Measurement of cholinesterase levels in the blood or nervous system after exposure to OPs has become the most common endpoint used in risk assessments of this chemical class.

Since June 1997, ILSI has been addressing issues on experimental techniques measuring cholinesterase inhibition in peripheral tissues. A final report has been made available to EPA. The Agency believes that the concepts contained there represent the best available guidance for those submitting this type of data. EPA will publish a notice describing its views on these

approaches for a 30-day public comment period in October 1998.

Over the last several years, the Agency has engaged outside scientists and the regulatory community about which measures of cholinesterase inhibition should be used for setting reference doses in risk assessments. We have also discussed more generally how these data should be viewed along with the other types of data in risk assessments. We focused on two issues: (1) the role of blood measures, since blood cholinesterases are not part of the nervous system, so they are only an indirect measure of neurotoxicity; and (2) whether plasma cholinesterase should be treated differently from red blood cell cholinesterase.

In June 1997, the Agency made a major presentation to the SAP including a literature review, a series of case studies, a summary of activities related to methods of cholinesterase measurement, and a proposed policy to use a weight-of-evidence approach considering all of the data that might result in the use of cholinesterase measures in plasma, red blood cells, or brain for defining critical effects. In addition, EPA also asked the SAP about the feasibility of using measures of peripheral nervous system tissue to replace blood measures, which largely serve as indirect estimators of cholinesterase inhibition in the peripheral nervous system in animals. The briefing paper presented to the SAP entitled, "Office of Pesticide Programs Science Policy on the Use of Cholinesterase Inhibition for Risk Assessments of Organophosphate and Carbamate Pesticides," draft, April 30, 1997, and the corresponding SAP report will be published for a 30-day comment period in October 1998.

EPA's interim approach while assessing these policies:

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

How EPA will address comments:

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

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

On April 23, 1998, the NRDC and various other individuals and public interest organizations filed a petition requesting that EPA issue an interpretive rule/policy statement regarding EPA's implementation of the FQPA provision concerning an additional 10-fold safety factor to protect infants and children. The petition seeks three specific actions: (1) Issuance of a policy statement/interpretive rule providing that EPA "maintain the ten-fold safety factor unless the Administrator has determined that there are reliable data on pre- and post-natal toxicity and exposure for fetuses, infants, and children." The petition sets forth a minimum set of data that petitioners believe constitutes "reliable data" and requests that the statement/rule direct EPA to apply the additional ten-fold factor if any of these data are absent. (2) Convene a "blue ribbon panel" to assist EPA "in determining when there are 'reliable' data for pre- and post-natal toxicity to fetuses, infants, and children." This panel would be convened under the auspices of the Children's Health Protection Advisory Committee. (3) Issuance of a policy statement/interpretive rule providing that, pending completion of the panel's report, EPA will apply the ten-fold safety factor as required by FQPA.

On May 26, 1998, EPA received a Petition on Rulemaking Under the Food Quality Protection Act submitted by Kenneth Weinstein and Jeffrey R. Holmstead on behalf of several grower groups and trade associations. The petition requested EPA to use notice and comment rule-making to establish policies and procedures for implementing FQPA. The petitioners claim that rules are needed to establish policies and procedures for assessing aggregate exposures, common mechanism of toxicity, and cumulative effects, and for determining when the FQPA 10-

fold safety factor may be reduced or removed. The petitioners believe that EPA is using its current science policies as though they were binding requirements. The petitioners maintain that neither the advisory panel process nor the notice and comment rule- making on individual tolerances appropriately substitute for notice and comment rule-making on major procedural or policy issues.

As the Agency refines its approach to each of the nine science policy issues through the notice and comment process explained in the framework, the Agency will: (1) identify any comments EPA has already received on the various policies; (2) ask specific questions based on issues in those comments; and (3) provide a comment period through the Federal Register notice on each science policy issue as described in this notice, after which the Agency will respond to all comments, including those that were received through the TRAC process.

The following documents prepared for the TRAC are available in the docket and are available for comment: (1) a document entitled "Framework for Refining FQPA Science Policy," (2) a table entitled "Framework for Refining FQPA Science Policy" which summarizes the document of the same title, and (3) a timeline entitled "Schedule for Release of Guidance on Science Policy Issues." In addition, a compendium of the Agency's current operating guidelines are available in the docket; however, comment is not being requested at this time since they are being revised so opportunity for comment will be offered at a later date as noted above.

Closing:

This is EPA's approach to providing for notice and comment regarding the nine science

policy issues discussed above and on the timing of the process set out in the framework. Under this approach, for each science policy issue described above, a document which describes the Agency's approach for each issue will be published separately, as available, for public comment through the Federal Register. Any comments on this approach or on the timeframe can be sent to the docket.