Agenda items include highlights of the Office of Children’s Health Protection (OCHP) activities and a presentation on the National Children’s Study. Other potential agenda items include a presentation on lead in drinking water and EPA activities concerning children’s health in schools.


Joanne K. Rodman,
Designated Federal Official.

Children’s Health Protection Advisory Committee

Hotel Washington, 515 15th Street, NW., Washington, DC 20004–1099
May 25–27, 2004

Tuesday, May 25, 2004
Work Group Meetings
Wednesday, May 26, 2004
Plenary Session
9:00—Welcome, Introductions, Review Meeting Agenda
9:15—Highlights of Recent OCHP Activities
9:45—Presentation: National Children’s Study
10:45—Break
11:00—Science Workgroup Report
12:00—Lunch (on your own)
1:30—Science Workgroup Report [continued]
2:30—Regulatory Work Group Report
3:15—Break
3:45—Presentation: Lead in Drinking Water
4:45—Public Comment
5:00—Adjourn

Thursday, May 26, 2004
9:00—Discussion of Day One
9:15—Presentation: Schools
10:30—Break
10:45—Discuss and Agree on Recommendation Letters and Other Action Items
12:15—Wrap Up/Next Steps
12:30—Adjourn Plenary

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of particular interest to stakeholders including environmental, human health, public health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the use of pesticides on food. Other Federal, state, and Tribal government agencies also may be interested. Since other entities also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0411. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 2121 Jefferson Davis Hwv., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the “Federal Register” listings at http://www.epa.gov/fedreg.ntr/.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select “search,” then key in the appropriate docket ID number.

II. What Action is EPA Taking?

A. Background

EPA is making available to the public the full and modified versions of the public participation process that will be used for pesticide tolerance reassessment and reregistration. This public participation process was developed in partnership with USDA. EPA has considered the comments received from the public on the proposed public participation process that was published in the Federal Register on March 15, 2000 (65 FR 14199) (FRL–6496–2). EPA’s response to public comments is available in the docket under docket ID number OPP–2003–0411.

This public participation process is based on EPA and USDA’s experiences with the pilot public participation process used for the organophosphate pesticides, comments received from the Tolerance Reassessment Advisory Committee and the public during the public comment period, and our experience with the interim process
used in developing decisions for a number of non-organophosphate pesticides during the past few years. EPA remains strongly committed to public participation, and as a result of the experience gained from the pilot, has learned how to effectively tailor our public participation process to meet the needs of our stakeholders in the most efficient and timely manner possible. The public participation process encompasses full and modified versions that enable EPA to tailor the level of review to the level of risk, use, complexity, and public concern associated with each pesticide.

Highlights of the public participation process include increased communication with stakeholders prior to initiating the process, meetings and conference calls with stakeholders and our regulatory partners throughout the process, public meetings as appropriate on the risk assessments and risk reduction proposals, and scheduled public comment periods on risk assessments and risk reduction proposals. In addition, the public participation process emphasizes increased communication among those Federal government agencies concerned with pesticides and pest management - EPA and primarily USDA, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services, which has the lead in working with EPA to address public health pesticide issues, and the Department of the Interior, Department of Commerce, and Department of Defense, as appropriate.

EPA is applying the full public participation process or one of the modified versions described below to all pesticides beginning tolerance reassessment and reregistration eligibility decision making. The decision to extend an updated version of the organophosphate pilot process to all pesticides still to be reviewed for reregistration and tolerance reassessment was supported by public comment. Implementation of the public participation process is proceeding according to schedules established annually and published in the Agency’s Federal Register notices on Pesticide Reregistration Performance Measures and Goals, posted on EPA’s Web site at http://www.epa.gov/pesticides/reregistration/status.htm. Schedules for upcoming reregistration eligibility and tolerance reassessment decisions also are posted on the Agency’s Web site at http://www.epa.gov/pesticides/reregistration/candidates.htm.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. In working to achieve this goal, the Agency recognizes the need to identify and address, as appropriate, disproportionately high pesticide exposure and potential adverse human health and environmental effects on minority or low-income populations. This public participation process provides an opportunity to obtain additional information that will enable the Agency to consider environmental justice in its pesticide reregistration and tolerance reassessment decision-making.

EPA will continue to issue risk management decisions for certain uses of pesticides at any time before or during the public participation process if such action is warranted by high risk concerns identified in the risk assessments. While EPA may exercise this authority at any time during this process, the Agency will work to ensure that USDA and appropriate other Federal agencies, EPA’s state and Tribal regulatory partners, and stakeholders, including proponents of public health pesticide uses, will be involved in the process.

1. Modifications to the public participation process. EPA is applying the principles of public participation to all pesticides undergoing tolerance reassessment and reregistration. In conducting these programs, the Agency reserves the right to tailor its public participation process to be commensurate with the level of risk, extent of use, overall complexity of the issues, and amount of public concern associated with each individual pesticide.

EPA’s experience during the past several years has been that the full, 6-phase public participation process is not necessary for many pesticides under review. In most cases, the Agency can use a 4-phase process, or shorter, to obtain public input as needed while making timely decisions and meeting our statutory deadlines and program goals. Today, many initial pesticide risk assessments are highly refined, or pesticide risk screening studies are available in the public literature to adequately characterize risks. The Agency often can reach conclusions about risk and the need for risk mitigation early in the process. In such cases, EPA accelerates the process to avoid unnecessary delays in completing decisions. Tailoring the public participation process in this manner is good public policy – it enables EPA and others to target resources most effectively, and avoids process for its own sake, while still providing transparency and opportunities for consultation and public participation. Such a flexible, tailored process is essential to meeting the Agency’s tolerance reassessment and reregistration deadlines and goals.

During the past several years, alterations to the public participation process have typically included a tailoring of the stakeholder communication opportunities. For example, the public participation process has often been modified for pesticides with a small number of users by substituting a stakeholder meeting(s) for a technical briefing upon release of the risk assessments for public comment in Phase 3. (Stakeholder meetings are opportunities for stakeholder groups to meet with EPA, USDA, and other appropriate Federal government agencies to discuss specific uses of the pesticide that are of significant concern to them, whereas technical briefings provide a general overview of the pesticide’s risk assessments.) In another example, pesticides with highly refined risk assessments, limited use, low risk concerns, few complex issues, and/or low public interest may need only one public comment period, at most, as long as appropriate consultation opportunities are utilized.

EPA will inform the public of any modifications to the public participation process that will be used for a specific pesticide.

a. 4-Phase process. A modified, 4-phase public participation process often is appropriate for pesticides with highly refined risk assessments and other factors. A pesticide with highly refined risk assessments that requires some risk mitigation - and that has limited use, a small number of users, few complex issues, few interested stakeholders, and/or other factors - may need only one public comment period, as long as ample opportunity for public consultation is afforded. The 4-phase process provides a framework for public input and consultation among government agencies and stakeholders during EPA’s review of such pesticides.

b. Low risk process. EPA has found that we can expeditiously reach decisions for certain pesticides, that pose few or no risk concerns and require little or no risk mitigation. These pesticides often show low levels of (non-target) toxicity and/or pass through screening models and show very low levels of risk. Agency toxicology reviews for these pesticides may be supplemented with studies available in the public literature. These pesticides may have low use, and they do not raise
complex issues or public concerns. Once EPA assesses uses and risks for such pesticides and finds that little or no risk mitigation is needed, the Agency may go straight to a decision and prepare a document summarizing its findings. This decision document and the risk assessments and other related documents will be issued simultaneously for public review and comment.

c. Pesticides needing only tolerance reassessment decisions. EPA anticipates that a modified version of the public participation process, that is, a 4–phase or low risk single phase process as described above, generally will be appropriate for pesticides that require tolerance reassessment but do not also require reregistration eligibility decisions at this time.

Many pesticides are subject to both tolerance reassessment and reregistration; however, some pesticides require only tolerance reassessment decisions at present. Tolerances were established for these pesticides before the Food Quality Protection Act (FQPA) was enacted on August 3, 1996; now the Agency must apply the new, stricter standards brought about by that law to the existing tolerances. While their tolerances must be reassessed to ensure compliance with current standards, these pesticides do not need to undergo reregistration because:

a. EPA completed Reregistration Eligibility Decisions for the pesticides earlier, before FQPA was enacted.

b. The pesticides were initially registered after November 1, 1984, and are not subject to reregistration.

c. The pesticides are not registered for use in the United States but tolerances are established that allow crops treated with them to be imported from other countries.

Tolerance reassessment decisions, involving only the assessment and management of a pesticide’s aggregate risks through food, drinking water, residential, and any other non-occupational exposures, generally are narrower in scope and have fewer issues than decisions including both tolerance reassessment and reregistration eligibility. In cases where EPA’s assessment indicates that low or no aggregate risks are posed and little or no risk mitigation is needed, a modified process provides transparency and opportunities for consultation and public input, while enabling EPA to complete a tolerance reassessment decision expeditiously. A modified process also facilitates the Agency’s continuing completion of tolerance reassessment within statutory deadlines.

2. Pesticide registration – process for tolerance reassessment through registration and revocation. Through the Agency’s routine pesticide registration process, EPA also may complete tolerance reassessment decisions and provide opportunities for public participation through notice and comment rulemaking. No additional public participation is needed or envisioned for these decisions.

a. Registration. EPA completes certain tolerance reassessment decisions during the pesticide registration process, in evaluating proposed new food uses for registered pesticides. To determine whether a proposed new food use meets the current safety standard, EPA first must reassess all the existing tolerances established for the pesticide. These tolerance reassessment decisions are made through the notice and comment rulemaking process used to establish the new food use tolerance.

b. Revocation. EPA completes other tolerance reassessment decisions by revoking tolerances for pesticide uses that have been voluntarily canceled by their registrants. In handling these tolerance revocation requests, the Agency also uses a notice and comment rulemaking process to inform and involve the public.

B. The Public Participation Process

The number of days indicated for each phase of the process represents EPA’s goal for each phase; however, the circumstances of a particular evaluation may require the Agency to adjust the length of these phases.

EPA will inform the public well in advance about pesticides that are scheduled for the public participation process. Registrants will be asked to identify any ongoing studies and analyses that are relevant to the risk assessments, and EPA will establish for each pesticide the due dates for the submission of data, information, and analyses. In this way, the public will be able to prepare for the initiation of the public participation process for pesticides that they may be interested in. Registrants and the public may prepare data and information for consideration by the Agency.

1. The full public participation process. The full public participation process is described below.

a. Pre-phase 1—Stakeholder and government Agency engagement, and develop updated pesticide use and usage information. A significant focus of the process is to engage stakeholders as early as possible to ensure the accuracy of key information about pesticide use and use practices that affect risk assessment. The information on current labeled uses, actual pesticide use and usage, and other information on pesticide use practices serves as important building blocks for the dietary, residential, worker, and ecological exposure and risk assessments. Pre-Phase 1 ideally begins approximately 1 year prior to the formal initiation of the public participation process (i.e., release of the risk assessments to the registrants for error correction). Initially, EPA shares information describing EPA’s understanding of currently labeled pesticide uses and summary usage information with USDA and other appropriate Federal, state, and Tribal government agencies and with key stakeholders, including as appropriate the public health use community, and posts this information on the Internet for public viewing. EPA also reviews any already completed Agency assessments for the pesticide (for example, from pesticide program registration-related records and files) and identifies crops and other use sites for which updated use and usage information could be particularly valuable in developing the risk assessments for public review and comment. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to the pesticide, compared to the general population.

To initiate Pre-Phase 1 for a pesticide, EPA, USDA, and other Federal government agencies may work cooperatively to organize a meeting or meetings with interested stakeholders who possess unique and specific information on a pesticide’s use and usage, and encourage them to share their information with the agencies. One of the objectives of these meetings is to allow for the early refinement of key use-related inputs to the dietary, residential, worker, and ecological risk assessments. Ideally, this early input and sharing of key use-related information will result in more accurate and representative risk assessment documents earlier in the process. Within 60 days after the use/usage meeting(s), and following its verification and analysis, EPA provides an updated summary of its understanding of current use, usage, and use practices for crops and other use sites to be included in the pesticide’s risk assessments. Stakeholders’ submissions are compiled and made publicly available (preferably on the Internet) to encourage further discussion. This updating may
continue throughout the process as
additional use/usage information
becomes available to the Agency.

b. Phase 1—Risk assessment
registrant error-only review (30 Days).
EPA initiates the public participation
process by transmitting its human
health and ecological risk assessments
to technical registrant(s) of the pesticide
do a 30-day day error correction review.
The registrants are asked to identify and
correct any computational or other
errors that EPA has made in developing
its assessment of the pesticide
as appropriate at this time.

EPA, working with TRAC, determined
that it was appropriate to provide
registrants with this opportunity to
review the initial risk assessments, prior
to their public release, so that the
registrants could provide comments on
any errors in the documents, such as in
data transcription or calculations, that
might result in erroneous risk estimates.
Comments on the analysis and
interpretation of the data are not
expected in this phase of the process,
and any such comments received will
be considered during Phase 3, along
with comments received from other
stakeholders.

Soon after the risk assessments are
sent to registrants, EPA transmits the
risk assessments to USDA and other
appropriate Federal government
agencies to initiate their review and
comment. If the pesticide has public
health uses, then the risk assessments
would be sent to CDC and other relevant
agencies as appropriate at this time.

c. Phase 2—Agency considers
registrant error comments (Up to 30
Days). In Phase 2, EPA summarizes and
considers the errors that have been
identified by the registrant(s) and makes
changes in the risk assessments to
correct any errors, as appropriate. EPA
also considers risk assessment
comments received from the initial
review by USDA and other Federal
government agencies, and transmits an
overview that summarizes the
pesticide’s risk assessments to USDA
and other appropriate Federal agencies.
By the end of this phase, the risk
assessments are prepared for public
release. Discussions with other Federal
government agencies on comments and
issues will continue throughout the
public participation process, as needed.

d. Phase 3—Public participation
period: public comment on risk
assessments and risk characterization
(60 to 90 Days). Phase 3 provides the
public and pesticide registrants with an
opportunity to comment on the
pesticide’s risk assessments. The phase
begins when EPA publishes in the
Federal Register a Notice of Availability
of the risk assessments and related
documents (e.g., overview, summary,
registrant’s error comments, and EPA’s
response to comments, etc.) for a 60–to
90–day public review and comment
period. The length of the public
comment period will be set according to
the complexity of the risk issues
associated with the pesticide in order
to give stakeholders adequate time for
review and comment. The summary
documents will clearly characterize the
risks associated with each use of the
pesticide, and identify areas that the
risk assessment indicates may be of
concern (e.g., dietary risks). To help
address potential environmental justice
issues, EPA requests information on any
groups or segments of the population
who may have atypical, unusually high
exposure to the pesticide, compared to
the general population. All of the
documents will be made available in the
public docket and in the EDOCKET
on EPA’s Internet website.

In addition, an effort will be initiated
among Federal government agencies to
engage stakeholders in a dialogue on the
risk assessments and risk
categorization of the benefits of the
pesticide for particular uses, early in
Phase 4. When agricultural uses
(including turf, ornamental, and forestry
uses) are affected, EPA will consult with
USDA, and stakeholders as needed,
regarding the potential benefits and risk
reduction proposals. EPA will consult
with CDC on the benefits of public
health uses, with other agencies as
appropriate, and with other parties who
commented during Phase 3.

A Federal interagency senior
management briefing may be held to
discuss the revised risk assessments and
preliminary risk reduction options. EPA
also will keep its state and Tribal
regulatory partners informed, and may
hold a regulatory partners conference
call with interested states and Tribes to
discuss the risk assessments and initial
risk reduction options.

USDA, when appropriate, will
organize conference calls with
stakeholders to review and discuss the
revised risk assessments and
preliminary risk reduction options.
Minutes from all meetings and
conference calls that EPA participates in
will be included in the public docket.
EPA and USDA will work to summarize
and address the comments and ideas
received during the stakeholder
conference calls. In addition, an effort
will be made among Federal
government agencies to continue to
engage stakeholders in a dialogue on the
risk assessments and risk
categorization, and to discuss
pesticide benefits and transition. This
effort may continue through Phase 6 of
the public participation process.

Where EPA deems appropriate, a
comprehensive, general technical
briefing and/or smaller, more
specifically focused stakeholder
meeting(s) (as appropriate for pesticides
with limited use and usage, a small
number of stakeholders, or other factors)
may be held at the end of Phase 4 to
share with the public the revised risk
assessments and begin discussing the
range of possible risk reduction options.

f. Phase 4—Public participation
period: public comment on risk
reduction (60 days). EPA publishes a
Federal Register Notice of Availability
announcing the release to the public of
the revised risk assessments and the
Agency’s response to comments. This
Federal Register notice will also
announce the release of EPA’s
preliminary risk reduction options, EPA’s initial assessment of the impacts of risk reduction options, and/or EPA’s preliminary assessment of benefits in cases where the Agency has identified risks of concern, and a discussion of any potential transition issues identified by USDA, CDC, and other agencies as appropriate. The Federal Register notice will open a 60–day (or longer, if needed) comment period during which the public is encouraged to comment on the preliminary risk reduction options, the initial impacts and/or preliminary benefits assessment(s) described above, and any transition issues. The public also is encouraged to suggest risk management proposals.

The effort among Federal government agencies during Phase 5 to engage stakeholders in a dialogue on risk reduction and management, including EPA’s regulatory partners as appropriate, may continue through Phase 6. For pesticides that pose risks of concern from a public health use, EPA will work closely with CDC and interested stakeholders to identify and propose mitigation measures to reduce those risks while maintaining the benefits of the pesticide’s public health use to the greatest extent possible.

g. Phase 6—Develop final risk management (up to 60 Days). In Phase 6, EPA summarizes, reviews, and considers the comments, data, and risk management ideas and proposals received during the Phase 5 public comment period, and during stakeholder dialogue and the meetings that have occurred during Phases 3–5. EPA continues to elicit input from USDA and other Federal government agencies, as well as EPA’s regulatory partners and stakeholders. EPA develops the risk management documents, and a revised impacts assessment and/or benefits assessment, if needed. EPA releases to the public the risk management decisions for the pesticide, including the revised impacts and/or benefits assessment. USDA may prepare a transition strategy, if needed. The transition strategy is likely to include time frames in which EPA expects to make decisions regarding registration of new pesticides/uses.

2. The modified public participation process—a. The 4-Phase Process—Pre-Phase 1 - Stakeholder and government agency engagement, and develop updated pesticide use and usage information. Same as the full public participation process.

Phase 1 - Risk assessment registrant error-only review (30 Days). Same as the full public participation process.

Phase 2 - EPA considers registrant error comments on risk assessments, and develops preliminary risk reduction options (30 to 60 Days). Phase 2 is the same as in the full public participation process. However, in addition to preparing the risk assessments for public release, EPA also develops preliminary risk reduction options, making a significant effort to consult with stakeholders and other Federal and state government agencies. Meetings, conference calls, and other discussions with stakeholders and other agencies on issues and risk reduction options will continue through Phases 3 and 4, as needed.

Phase 3 - Public participation period: public comment on risk assessments and preliminary risk reduction options (60 to 90 Days). Phase 3 provides the public and pesticide registrants an opportunity to comment on EPA’s pesticide risk assessments, risk characterization, and preliminary risk reduction options, and to suggest risk management ideas and proposals. This phase begins when EPA publishes a Federal Register Notice of Availability announcing the release of the risk assessments and preliminary risk reduction options for 90 days of public comment. EPA releases the risk assessments and related documents through the public docket and EDocket on the Agency’s website. During the comment period, to help address potential environmental justice issues, EPA requests information on any groups or segments of the population who may have atypical, unusually high exposure to the pesticide, compared to the general population. EPA continues significant efforts to consult with other government agencies and stakeholders on the pesticide’s uses and possible risk management options.

Phase 4 - EPA Develops Final Risk Assessments And Risk Management (Up to 90 Days). EPA reviews and considers the comments and risk management ideas and proposals received during Phase 3, continues the ongoing dialogue with other government agencies and stakeholders as needed, and develops a risk management decision, which the Agency issues for public review and comment. If EPA finds that additional issues warranting further discussion were raised during Phase 3, the Agency may decide to lengthen the process and include a second comment period, as needed.

b. The low risk process. If EPA’s initial screening of a pesticide indicates that it has low use/usage, affects few if any stakeholders or members of the public, and/or poses low risk and requires little or no risk mitigation, the Agency may determine that neither the full 6–phase process nor the modified 4–phase process is needed. In such cases, the Agency would go straight to a regulatory determination and prepare a decision document for the pesticide, concluding the review process. This decision document, the risk assessments, and other related documents will be issued for public review and comment.

List of Subjects

Environmental protection. Pesticides and pests.


James Jones, Director, Office of Pesticide Programs.

[FR Doc. 04-10985 Filed 5–13–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7661–6]

Draft Physical Stream Assessment: A Review of Selected Protocols for Use in the Clean Water Act Section 404 Program

AGENCY: Environmental Protection Agency (EPA); National Oceanic and Atmospheric Administration (NOAA), Commerce; U.S. Army Corps of Engineers (USACE), Defense; U.S. Fish and Wildlife Service (USFWS), Interior; Natural Resources Conservation Service (NRCS), Agriculture; Department of Transportation.

ACTION: Notice of availability to review and comment.

SUMMARY: In accordance with the National Mitigation Action Plan signed in December of 2002 by the Environmental Protection Agency, Department of Commerce, Department of Defense, Department of the Interior, Department of Agriculture, and Department of Transportation, the Federal Interagency Mitigation Workgroup (FIMW) commissioned the preparation of a technical resource document to assist with stream mitigation entitlement: Physical Stream Assessment: A Review of Selected Protocols for use in the Clean Water Act (CWA) Section 404 Program (Stream Mitigation Compendium). The Stream Mitigation Compendium is intended as a reference that can be consulted by regulatory agencies, resource managers, and restoration ecologists in order to select, adapt, or devise stream assessment methods appropriate for impact assessment and mitigation of fluvial resources in the CWA Section 404 Program.