DRAFT DOCUMENT

OFFICE OF PESTICIDE PROGRAMS (OPP)
LABELING COMMITTEE
STANDARD OPERATING PROCEDURE
January 2006

PURPOSE:

To address questions and comments from registrants, pesticide users, public interest groups, other stakeholders, and our state and tribal partners, on generic labeling policy issues.

BACKGROUND:

In 2005, the Pesticide Program Dialogue Committee, which provides recommendations for Pesticide Regulatory Improvement Act (PRIA) process improvement, recommended that an organizational structure for vetting and overseeing all cross-cutting label policy issues be created. The OPP Labeling Committee was created in April of 2005 for this purpose.

LABELING COMMITTEE RESPONSIBILITIES:

The task of the OPP Labeling Committee is to coordinate the development & communication of consistent OPP labeling policies and practices by:

1. creating a system that will collect broad, cross-cutting labeling policy issues;
2. recommending solutions and measures for implementing solutions for senior management consideration;
3. managing a public web site devoted to generic labeling policy issues; and
4. coordinating labeling issues across OPP.

LABELING ISSUES APPROPRIATE FOR COMMITTEE RESOLUTION

The following subsections describe the types of issues within the Labeling Committee's scope and those that are outside the scope:

1. Submissions within the scope of the Labeling Committee are generic or cross-cutting issues affecting a significant number of products, including the following:
    i. Labeling issues covering all product labels
    ii. Labeling issues covering a type of pesticide such as an antimicrobial, microbial, biochemical, fungicide, insecticide, herbicide, etc.
    iii. Labeling issues covering a broad use site such as aquatic uses, indoor uses, green house uses, etc.
    iv. Labeling issues covering a specific crop such as soybeans, cotton, carrots, etc.
    v. Labeling issues covering a class of pesticides such as sulfonylureas, organophosphates, pyrethroids, etc.

2. Submissions outside the scope of the Labeling Committee (to be referred to other points of contact):
    i. Labeling issues limited to a specific product that would not have broader implications
    ii. Labeling issues dealing with an enforcement case
    iii. Labeling issues dealing with a litigation case
    iv. Status questions dealing with pending FIFRA registration application actions
    v. Labeling issues dealing with unregistered pesticides, e.g. Section 18s, EUPs

I. PROCEDURES FOR PROCESSING SUBMISSIONS:

Partners and stakeholders are invited to submit cross-cutting labeling issues and questions to the OPP Labeling Committee. The OPP Labeling Committee established a webpage and an email address to receive cross-cutting labeling issues submitted by interested parties to OPP. The email address is **OPPlabelingconsistency@epa.gov**. Questions can also be sent through the web page at:
http://www.epa.gov/pesticides/regulating/labels/label_review.htm
Issues can be submitted by other means as well, for example, a SFIREG issue paper.

A. Committee Roles

1. The Labeling Committee will designate a Website Monitor responsible for retrieving mail from the mailbox.
2. Email notification of receipt will be sent automatically to email submitters when received.
3. All Labeling Committee members will have edit and read rights.
4. The Committee will appoint a Secretary to record its decisions.

B. Processing of Submissions

1. The Website Monitor, in consultation with the Committee, reviews submission and determines that submission is within scope of Labeling Committee, as discussed above.
2. If submission is NOT within the scope of the Committee, the submission is referred to the appropriate group (Risk Managers (RMs), The Office of General Counsel (OGC), Office of Enforcement Compliance and Assurance (OECA), Webmaster, etc.) The referral may be handled in either of the following ways:
    i. The appropriate group answers issues directly, and submitter is notified of the referral by the Committee.
    ii. Upon request of the Committee, the appropriate group answers issues and submits answer to Committee; Committee notifies submitter of the referral and answer.
3. All submissions determined to be within the Committee's scope will be added

to the list of issues to be dealt with and handled in accordance with section III below.

C. Response Time

1. Emails in the mailbox will be checked daily, excluding federal holidays, by the Website Monitor or in the absence of the Monitor, the Chair.
2. Secretary has a timeframe of 2 weeks to present to the Committee the issues received.

II. TRACKING OF SUBMISSIONS

A. Submissions not within the Committee's scope, and not of general interest as a cross-cutting labeling issue (as determined by the Committee) will be referred to appropriate group.

1. The submitter will be notified of referral.
2. The appropriate group to which the issue is referred to will address the issue directly.
3. The appropriate group will be responsible for tracking and handling the issue.

B. Submissions not within the Committee's scope, but found to be of general interest (as determined by the Committee), will be referred to appropriate group.

1. The group the issue is referred to will be requested to address the issue and return the answer to the Committee.
2. The Committee will notify the submitter of answer, and will post the question and answer on the Labeling webpage.
3. Referral and posting will be tracked.

C. Cross-cutting labeling issue submissions within the Committee's scope.

1. The Committee will notify submitter of acceptance of issue.
2. The question will be posted on the website in one of the following sections:
    i. questions currently being worked on;
    ii. questions in queue, to be worked on as resources permit; and
    iii. questions and answers.
3. The Committee will use OPP Updates to ensure wide dissemination of important labeling decisions or interpretations.

III. HANDLING OF CROSS-CUTTING LABELING ISSUES

A. Prioritization: The Labeling Committee will prioritize issues received taking into consideration available resources and the significance of the issue. Part of prioritization is determining if a response to the issue can be made within the scope of established policies or regulations, or whether it would require developing substantively new policy or guidance.

B. Mechanism: Committee meets after necessary research and involves all appropriate experts.

1. Committee conducts a meeting or series of meetings to discuss and resolve issue.
2. Committee may recommend the formation of a subgroup to research the issue and make recommendations. See Appendix A for subgroups formed and their operating procedures.
3. Committee may refer issues to an existing OPP group to research and make recommendations.

C. Issue Resolution and Oversight

1. Issue(s) that require substantive change or development of new policy is elevated to OPP senior managers for decision on whether to commit resources to pursuing the issue.

2. Labeling Committee reports to OPP senior management group on a quarterly basis regarding: (1) a summary of answers developed for posting to the web; (2) proposed changes to the Label Review Manual that do not require any notice and comment procedure (as determined by OGC); (3) current status of issues being worked on by the Committee or any of its subgroups; and (4) any requests for EPA action that would require substantive policy development and likely to require notice and comment or other forms of public input.

D. Communications: The Committee will use a number of mechanisms to ensure wide dissemination of important labeling decisions or interpretations to all stakeholders. These may include:

1. OPP Updates
2. The OPP Labeling Webpage
3. PR Notice, Press Advisory, mass e-mail message, etc.

E. Public Input:

1. **The Committee will seek public input on labeling issues at various times in the process of developing guidance or policy. For example the committee may:**
   i. Ask for the public for input on which labeling issues need to be addressed.
   ii. Frame an issue and ask for public input prior to drafting guidance or policy and/or
   iii. Ask for comments on draft guidance or policy.

2. The committee will seek pubic input on labeling issues from groups such as:
   i. State FIFRA Issues Research and Evaluation Group (SFIREG)
   ii. Tribal Pesticide Program Council
   iii. Pesticide Program Dialogue Committee (PPDC) Process Improvement Workgroup
   iv. Regulated industry
   v. Trade associations
   vi. Public interest groups

vii. Other groups and individuals as deemed necessary

APPENDIX A

OFFICE OF PESTICIDE PROGRAMS (OPP)
LABEL REVIEW MANUAL TEAM
STANDARD OPERATING PROCEDURE

PURPOSE:

1 Establish procedures for maintaining the Label Review Manual (LRM)
2 Identify roles of the LRM Team
3 Identify necessary regulation changes for the Labeling Committee (LC) to consider

BACKGROUND:

Working under the OPP Labeling Committee, the LRM Team was set up in June 2005, to work on maintaining the Label Review Manual. The following members of the LRM Team are: Janelle Christian (FEAD), David Stangel (OECA), Venus Eagle (SRRD), Breann Hanson (RD), and Karen Leavey (AD).

SCOPE

The LRM Team will work on labeling issues that are within the scope of work of the Labeling Committee. The team is a sub group of the LC.

LRM TEAM RESPONSIBILITIES:

1 Maintain the LRM: keep the LRM up-to-date capturing all new labeling policy
2 Gather LRM issues and items for consideration
3 Address all correspondence or e-mail regarding LRM issues, including those raised by stakeholders
4 Raise appropriate LRM issues to the LC for direction/discussion and prepare additional supporting documents as necessary
5 Provide appropriate regulatory expertise to LC as requested

PROCEDURES FOR MAINTAINING THE LRM:

1. Suggested or recommended changes to the LRM can come from a number of different sources. Primarily, changes will come from the Labeling Committee. As new or amended labeling policy is developed and approved, the LC will provide the LRM team with the necessary information on the policy for inclusion

into the LRM. Also, the LRM team works with their respective Divisions gathering expertise on labeling issues, and other changes that are identified for inclusion in the LRM.

2. The LRM Team in consultation with the LC will prioritize labeling issues for the LRM, taking in to consideration the resources necessary to address the issue, the time it will take to resolve the issue, the complexity of the issue, as well as the impact of the change.

3. The LRM Team will work each chapter relative to necessary changes as a team effort, working from a team copy of the LRM stored on the LAN share directory (Labeling Policy Directory). Changes will be made in Redline/Strikeout until the changes for a given chapter are accepted by the Labeling Committee, and OPP senior management has been briefed by the Labeling Committee. Once the changes to the chapter are accepted and recorded in the LC meeting notes, the Redline/Strikeout will be removed and that chapter will be given a new "Current as of…" date.

4. Forward revised LRM Chapter to OPP Web Team for posting to Website within one week.

5. Communicate LRM changes to the outside world using various means, including: posting changes on the OPP website including announcing it under "What's New"; announcing revised Chapter on the Labeling webpage; sending e-mail updates to "OPP ALL"; and sending updates via the EPA-Pesticides-Updates list, and State and Regional e-mail lists.