Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of the October 1, 2009 Meeting

Workgroup Members Attending:

Sue Crescenzi, Steptoe and Johnson on behalf of the American Chemistry Council (ACC) Biocides Panel
Dennis Edwards, Antimicrobial Division (AD), Office of Pesticide Programs (OPP)
Laurie Flanagan, DC Legislative and Regulatory Services on behalf of the International Sanitary Supply Association (ISSA)
Ted Head, Ecolab
Allen James, Responsible Industry for a Sound Environment (RISE)
Beth Law, Consumer Specialty Producers Association (CSPA)
Elizabeth Leovey, OPP
Ray McAllister, CropLife America (CLA)
William McCormack, Clorox on behalf of ACC Biocides Panel
Marty Monell, OPP
Steve Robbins, Information Technology and Resources Management Division (ITRMD), OPP
Amy Roberts, Technology Services Group on behalf of Biopesticides Industry Alliance
Julie Schlekau, Valent on behalf of RISE
Julie Spagnoli, FMC on behalf of the Pesticide Program Dialogue Committee (PPDC)
Greg Watson, Monsanto on behalf of CLA
Mike White, Chemical Producers and Distributors Association (CPDA)
Mae Wu, Natural Resources Defense Counsel (NRDC)

Agenda

I. Introductions and Announcements

II. Report on Registration Review Improvement Priorities

III. Panel – Labeling

- Labeling Committee
- Label Accountability Workgroup
- Results of Label Audits

IV. Panel – Product Chemistry

- Process for Reviewing Impurities – Conventional Applications
- Issues – Antimicrobial Applications

V. Inert Ingredients Update

VI. Requirements Development for e-Submission Builder and Next Version of e-CSF

VII. Science Policy Council

VIII. Public Comment

IX. PPDC Meeting and Next Meeting of the Workgroup

Minutes

The powerpoint presentations and handout were posted on the internet on http://www.epa.gov/pesticides/ppdc/pria/index.html.

Introductions and Announcements

Marty Monell began the meeting by reminding participants of the statutory provision in PRIA 2 on process improvements and of the Pesticide Program Dialogue Committee's (PPDC) recommendation that the Agency form a subcommittee under the PPDC to obtain stakeholder input on these improvements.

Report on Registration Review Improvement Priorities

Marty Monell reported that the Office of Pesticide Programs held a meeting with representatives from industry and public interest groups to identify process improvements in the registration review process. Ideas were suggested and these and others will be prioritized during future meetings. Progress will be reported during the next Workgroup meeting. In response to a question, Ms. Monell answered that to date, few comments had been received in response to a request for comments on the information and assessments the EPA had available on a pesticide undergoing registration review.

Labeling Committee and Label Accountability Workgroup

Jim Roelofs, Field and External Affairs Division, updated the workgroup on the activities of the Label Accountability Workgroup. The Workgroup was formed in response to labeling problems and enforcement issues identified by the States and EPA Regions. It recommended updating the Label Review Manuel, labeling training, improving the State Label Issues Tracking System (SLITS) and developing a quality assurance program. The Workgroup conducted a label training event for OPP employees in March, 2009 as an initial step in a training program. A web-based training tool is being developed to introduce new OPP employees to the requirements, policies and the process of reviewing and approving pesticide labels. The goal is to assure accuracy and consistency across the Office of Pesticide Programs. The training tool will eventually be available to the public. An update of the Label Review Manual (http://www.epa.gov/oppfead1/labeling/lrm/) is close to completion and once completed, comments will be requested from users on enhancements. Requirements for improving SLITS

were developed with the most desired improvements being improved searchability and the ability to track responses to questions and subsequent follow-up actions.

Questions from the public on labeling are addressed by the OPP Labeling Committee and over 200 answers have been posted on the Web (http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm). Seventeen comments were received in response to the Committee's options paper on chemigation (http://www.epa.gov/pesticides/regulating/labels/chemigation.pdf) and the Committee is currently seeking state involvement to further modify the paper. Options papers and other documents may be found on the Committee's project Web page (http://www.epa.gov/pesticides/regulating/labels/projects.htm). Label issues raised by the State FIFRA Issues Research and Evaluation Group (SFIREG) that may result in future projects include guidance on 24(c)s, expiration dates on supplemental labels, and restrictions on adding statements such as "for professional use only" on labels.

A workgroup member complemented OPP on updating the Label Review Manual and also on developing labeling training. A workgroup member requested better communication of when options papers from the Labeling Committee were available for comment. Another member inquired as to how EPA's Office of General Counsel viewed supplemental labels and whether Websites were an extension of labeling. Mr. Roelofs commented that information on a registrant's Websites on a product needs to conform to the label, supplemental labels must comply with labeling requirements and if Web material differed from the labeling, it needed to be justified. The Committee uses the epa-pesticides-updates (http://www.epa.gov/oppfead1/cb/csb_page/form/form.html) e-mail list to announce when an options paper is available for comment.

Results of Label Audits

As part of the Label Accountability effort, the Antimicrobial Division (AD), Biopesticide and Pollution Prevention Division (BPPD), and Registration Division (RD) have developed internal label quality assurance programs and are conducting internal audits of pending and approved labels to assure that labels are consistent with Agency policies and regulations and are enforceable, understandable to the user, and reflect science reviews. These programs and the results of the label audits were described by Dennis Edwards, Branch Chief, AD; Robert Forrest BPPD, and Diane Isbell, RD. The procedures were previously described in the April 20, 2009 [http://www.epa.gov/pesticides/ppdc/pria/april09/april09-minutes.pdf] meeting.

Based on their experience since the last meeting, the pesticide registering divisions have generally observed that many labels audited were inconsistent with guidance and regulation. Inhalation toxicity was typically not addressed or the directions for use were unclear. RD observed that labels were missing application rates or the rates were confusing and could have been more effectively provided in a table. Use sites needed to be better characterized or described, e.g. "non-porous construction material". Use of mandatory versus advisory language was an issue particularly in specifying use rates, for instance, "recommended rates" is advisory language. Differences between the stamped and final printed label were observed by BPPD. Labels also contained marketing claims that were false and misleading, i.e. "family friendly",

"safe", "kills all", etc. Storage and disposal statements had not been updated and there were unqualified disclaimers in warranty statement. If issues were identified, the registrant was requested to correct the label. The Antimicrobial Division plans on developing additional guidance and clarifications on labeling and claims.

Pesticide applicants and registrants are encouraged to submit their labels electronically (http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm) to speed up the review process.

A workgroup member expressed a concern that the Antimicrobial Division's reviewers did not have as much experience reviewing labels electronically as staff in other divisions. Workgroup members were assured by the Agency that employees in all three registering divisions have been trained in reviewing electronic labels and if registrants submitted them electronically, OPP will review them electronically. A workgroup member suggested that the guidance on submitting electronic labels recommend that the registrant submit an electronic copy of the existing label to allow reviews to conduct an electronic comparison. The Agency will consider the suggestion.

One workgroup member observed that warranty statements may be an issue if old labels are compared to current guidance on the Labeling Committee's Website.

In response to a workgroup member's question, Mr. Edwards responded that mold and mold remediation claims will be addressed in an anticipated Pesticide Registration Notice (PRN)

Process for Reviewing Impurities in Conventional Technical Products

Deborah McCall, Branch Chief, RD, described RD's process with Health Effects Division (HED) on toxicologically significant impurities in manufacturing products. If impurities of unknown toxicity are identified in conventional technical grade active ingredients, the Registration Division requests that HED determine whether the impurity(ies) may be of toxicological concern. HED uses structure activity analysis (i.e., DEREK or other models) to make these determinations and provides a one to two page summary of the results to RD. It takes HED approximately 90 days to conduct their analysis and then an additional 30-45 days for RD to re-evaluate the new product in light of the HED analysis to make a substantial similarity determination under FIFRA.

In response to a workgroup member's question, the Toxicology and Epidemiology Branch, HED conducts these reviews. Mary Manibusan is the Branch Chief.

Basic Requirements for Product Chemistry Submission – Antimicrobial Division

Product chemistry data deficiencies in antimicrobial actions have lead to PRIA due date extensions. A review of the product chemistry requirements was provided by Karen Hicks, AD. She emphasized that all Guideline 830 studies must be submitted or addressed and follow CFR 160.135. Whether the product is an end-use product, technical grade ingredient or manufacturing use product should be listed and the same product name should be used throughout the application. The Confidential Statement of Formula must be current, column 17

should add to 100%, all inert ingredients must be approved for the use and the nominal concentrations must match that on the label. Certified limits must be calculated per 40 CFR 158.350 and impurities greater than 0.1% must be identified.

Inert Ingredients Update

During initial content completeness screens, all conventional product Confidential Statements of Formula (CSF) are reviewed to determine whether the inert ingredients listed are approved for the uses on the label as reported by Kerry Leifer, Inert Ingredients Assessment Branch, RD. Agency employees verify the status of the inert ingredients listed including the components of mixtures and that chemical names and Chemical Abstract Service (CAS) numbers are accurate. As a result of these screens, quality improved. In the first year, 37% of CSFs were deficient and 26% remained deficient after correction attempts while in FY09, the deficiency rate was 15% which fell to 7% after corrections. In response to a question, if a CSF could not be corrected, the application was withdrawn or as a next step, the product manager resolved the issue or obtained additional data.

The Agency is currently reviewing data on fragrance components to be able to post a list of acceptable components on its Web site for a self-certification program and for CSF reviews. Approximately 1500 substances were listed. In the self-certification program, the fragrance components cannot comprise more that 0.1% of the formulation. After Agency review and risk assessment, it will post a list of acceptable fragrance components along with criteria and the process for adding additional ingredients to the list. There will be an opportunity for the public to comment on the process after internal and OGC review.

The status of the inert ingredients scheduled to be revoked was described. New tolerance exemptions were published for a majority of the ingredients involved and as a result of new data, the effective revocation date was extended for two clusters of chemicals. A concern was expressed that chemicals in these two chemical clusters will still be used without a safety finding. Mr. Leifer responded that based on the information available, a three month extension would not cause unreasonable adverse effects.

Workgroup members suggested that lists be publicly available that included food and non-food uses, specify the uses that have been approved for each chemical and provide chemical names and CAS numbers. Currently, the CSF screen is conducted on CSFs reviewed by RD and there was a suggestion that it should be expanded to antimicrobial and biopesticide applications. The Agency will be expanding this review to other applications.

Requirements Development for e-Submission Builder and Next Version of e-CSF

Robert Schultz, Information Technology and Resources Management Division updated the workgroup on these activities. Electronic submissions are being received by EPA as of July, 2008 and such submissions are encouraged. The stand-alone software application for applicants to use in developing their CSF was made available in spring 2009. OPP will be developing a tool for applicants to use to develop an electronic submission and a new version of its e-CSF tool. To assure that these tools can easily be used by applicants, OPP asked for volunteers

among the registrant community to participate in developing the requirements and then designing, developing and testing these tools. Interested registrants should contact Robert Schultz (schultz.robert@epa.gov) for the dossier builder and Peter Chen (chen.peter@epa.gov) for the e-CSF v. 2.

Workgroup members suggested volunteers and commented that electronic submission will result in efficiency gains, there were differences in the number of e-submissions received by the three registering divisions and that the Agency needs to work with smaller registrants. Currently, e-submissions received by OPP are from the major conventional pesticide registrants.

OPP Science Policy Council

Jennifer McLain, Field and External Affairs Division, reported that OPP's Science Policy Council was formed to enhance the consistent use of the best available science in pesticide regulatory decisions and to assist in identifying critical science issues for management's consideration. Accomplishments to date include the "Integrated Approach to Testing and Assessment in the Pesticide Program" Web site (http://www.epa.gov/pesticides/science/testing-assessment.html) and a voluntary pilot program to evaluate the use of a non-animal testing approach for the eye irritation study (http://www.epa.gov/oppad001/).

Public Comment

Ray McAllister commented that some of the questions and answers in SLITS should be made available to the public. The questions can be edited to remove any registrant identifier. The Labeling Training being conducted within OPP should also be made available to registrants. Expiration dates on supplemental labeling should make sense considering the process. Julie Schlekau commented that an 18 month period for a supplemental label was too short. Sue Crescenzi inquired as to what caused the States to require expiration dates and commented that expiration dates were a significant issue.

PPDC Meeting and Next Meeting of the Workgroup

Marty Monell mentioned that a short summary of this meeting will be distributed during the full meeting of the PPDC. Elizabeth Leovey will work with members to plan a date, time and topics for the next meeting.