Pesticide Program Dialogue Committee
PRIA Process Improvement Workgroup

Draft Summary of October 1, 2009 Meeting

Topics

Registration Review Improvement Priorities

The Office of Pesticide Programs held a meeting with representatives of 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 and reported during the next Workgroup meeting.

Label Accountability Initiatives

A web-based training tool is being developed to introduce new OPP employees to the requirements, policies and process of reviewing and approving pesticide labels. The goal is to assure accuracy and consistency. 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.

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).

Label Audits

The Antimicrobial Division, Biopesticide and Pollution Prevention Division, and Registration Division in conducting internal audits of pending and approved labels observed that many labels were inconsistent with guidance and regulation. Use of mandatory versus advisory language was an issue as well as clarity in the directions for use. Label also contained marketing claims that were false and misleading.

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.

Process for Reviewing Impurities in Conventional Technical Products

If impurities of unknown toxicity are identified in conventional technical grade active ingredients, the Registration Division requests that the Health Evaluation Division

determine whether they may be of toxicological concern. HED uses structure activity analysis along with DEREK to make such determinations.

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.

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 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.

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.

The manner in which data to support 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 a number of other ingredients.

e-Dossier Builder and e-CSF version 2

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.

OPP Science Policy Council

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" website (http://www.epa.gov/pesticides/science/testing-assessment.html) and a voluntary pilot program to evaluate use of a non-animal testing approach for the eye irritation study (http://www.epa.gov/oppad001/).

The powerpoint presentations and handout are available on http://www.epa.gov/pesticides/ppdc/pria/index.html.