Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup

October 1, 2009

Introductions and Announcements

Marty Monell
Deputy Director
Office of Pesticide Programs
October 1, 2009

Statutory Provision

- “To the maximum extent practicable consistent with the degrees of risk presented by pesticides and the type of review appropriate to evaluate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Act of 2003 for pesticide registration actions for covered pesticide registration applications (including reduced risk applications).”

Registration Review Improvement Priorities

Marty Monell
Deputy Director
Office of Pesticide Programs
October 1, 2009

Label Accountability Initiatives

Update for PPDC – PRIA Process Improvement Workgroup

Jim Roelofs
Chair
Labeling Committee
Oct. 1, 2009

Background

- Label Accountability Workgroup (LAW) analyzed the impact of labeling problems, and developed recommendations in 2008.
- Enforcement is a central issue for Regions and States, but is NOT the only problem.
- The Recommendations are all being implemented

Summary of the LAW Recommendations

- Finish updating Label Review Manual
- Develop Training for Label Reviewers
- Improve SLITS as a feedback and management tool
- Develop Divisional Quality Assurance procedures

In this report:

- Training event for OPP staff – Principles of Quality Labeling
- Plan for web-based training tool
- Up-dating the Label Review Manual
- Enhancements to the SLITS system
- Divisional Quality Assurance plans
- Some issues from recent SFIREG meeting

Training event on label quality

- March 19 for 127 OPP staff
  - Second session in May for 30 more people
- Introduced by Debbie Edwards – committed to label quality improvement
- Then an overview of enforcement
- Then each of the 4 core principles, with examples

Enforcement portion

- Started with this because
  - Enforcement raised the label quality issues
  - OPP staff least familiar with this part of the pesticide regulatory system
- About 30 minutes – overview of roles for OPP, Regions/States/Tribes, Laboratory analysts, case developers

Core Principles: What a Label Should Be

- Consistent with Agency Policies and Regulations
  - Guidance is not “just guidance” – variations need to be justified by registrant and accepted by EPA.
- Enforceable/Advisory Intentions Clear
  - Critical to Regional and State partners as well as users.

What a Label Should Be (cont)

- Clear -- fully understandable to the user, in terms of language and organization.

- Accurate –
  - reflects EPA's science reviews.
  - does not have errors in instructions for use.

Web-based training tool for label reviewers

- Goal – compact introductory basic training
  - What should a reviewer know on Day 1?
  - Not replace LRM.

- The core principles; importance of label to various stakeholders; the tools available to reviewers; how to resolve issues.

Training tool continued

- Probably 3 hour – 10 to 12 modules
  - Including a guide to using the LRM
- Contract funded; work began in August
- Scheduled to see draft storyboards shortly
- Scheduled for completion – end of January
- We intend to share product with industry

Updating the Label Review Manual

- Nearly done – only chapter 13 needs some updating to reflect container-containment rule
  - Not updating chapter 19 on CLI
- Now entirely a web document – accessible, links to supporting policy docs.
- Intent is to keep it “alive” – open to improvement
- We will solicit comments soon

Enhancements to SLITS

- State Label Issues Tracking System
  - Designed to ensure that a state (or Region) can direct a product specific question to right product manager
  - Get a timely answer
  - The answer is posted, so it is shared, others don't have to repeat it

SLITS continued

- Workgroup compiled its wish list of functional improvements;
- Have met with contractors, but schedule uncertain;
- Most desired improvements
  - Improved searchability
  - Way to track if follow-up actions when they are promised.

Label Committee

- Continues to operate public “label consistency” Q and A website.
  - Over 300 received;
  - Revised the subject matter categories
- Published chemigation paper on website
  - 17 comments;
  - Looking for state involvement

Label Issues raised by SFIREG

- Pesticide Operations and Management working committee – Sept. 21-22
- Update guidance on 24(c)s
- Interested in reviewing LRM
- Supplemental Labels – want expiration date
- Want EPA to stop allowing “for professional use only” and its variants

Antimicrobial Division Label Audits

Dennis Edwards
Branch Chief
Antimicrobial Division
October 1, 2009

AD Label Quality Improvement Program Goal

- To increase the overall quality of pesticide labels in order to ensure that Agency policies are fully reflected in labeling, that labels for similar products are consistent and that all applicable requirements are met.

Process Components

- At least 5% of labels under review as part of an FQPA or PRIA action will be selected for review each month.
- Selection of labels to be reviewed will be random
- A record of the issues and questions raised will be maintained as a tool for reviewers and PMs to aid in future label reviews and to identify areas where additional policy development or training is required

Process Components

- At least 10% of labels under review as part of an FQPA or PRIA action will be selected for review each month for each branch that process these actions.
- The review will be conducted by the Branch Chief.

Concerns Identified

- Many labels need to be upgraded in a number of areas
- Precautionary language often inconsistent with 40 CFR 156.90 and label review manual
- Use sites need further definition. Often terms of art are used which need to be better clarified.

Concerns Identified

- Some use sites are overly broad and/or very vague. Difficult to determine what the intended use actually is.

- Some products labeled as disinfectant/cleaner/deodorizer with only disinfectant directions.

Concerns Identified

- Much discussion around marketing claims
- Mold remediation/restoration directions often inadequate
- Mandatory vs advisory language

Next Steps

- We are addressing rebuttals in Thursday meetings
- Will post supplementary guidance and clarification for labeling and claims

Biopesticides and Pollution Prevention Division Label Audits

Robert Forrest
Biopesticides and Pollution Prevention Division
forrest.robert@epa.gov

Registration Division's Label Accountability Team (LAT)

Diane Isbell
Registration Division
isbell.diane@epa.gov
703-308-8154

Mission of RD's LAT

- Correct specific label problems.
- Improve label clarity, potentially reducing applicator misuse.
- Improve enforceability.
- Improve label consistency.
- Decrease review times.

LAT Membership

- Members include a mix of experience levels in order to share knowledge.
- Members rotate every 2 months (terms are staggered to ensure consistency).
- Each product branch has one representative each term.

Type of Labels to be Reviewed

The LAT provides two types of reviews:

- Retrospective – compares new label with most recently approved label to insure past errors have been corrected.
- Prospective – compares new label with current requirements, any errors in the request must be corrected before label is approved.

Review Process

- Weekly review of random new fast-tracks (herbicide, fungicide, insecticide, etc.).
- Thorough review of entire label -- not just fast-track changes.
- Concentrates on clarity, enforceability, inconsistency, and claims.

Label Issues

Mandatory Vs Advisory Text

- “should” for mandatory text
- “must” for advisory text
- mandatory and advisory text in the same sentence or paragraph
- “recommended” for mandatory text (label rates)
- “required” for advisory text

Label Issues (continued)

Directions for Use

- Omission of application rates
- Lack of specificity in crop sites/pests
- No use of tables to present rates
- Need for logical organization

  (intertwining mixing and application directions)

  (putting “Use Restrictions” at the end of text)

Label Issues (continued)

Other Issues

- Lack of up-to-date “Storage and Disposal” Text (PR Notice 2007-4)
- Many false or misleading marketing claims
  - “Earth friendly,” “family friendly,” “safe,” “kills all.”
- Unqualified disclaimers in warranties

Assessment Of Potential Toxicity Of Impurities In New Technical Grade Active Ingredients with HED

Deborah McCall
Branch Chief
Registration Division
October 1, 2009

Process Steps

- If impurity or impurities of unknown toxicity are found in the proposed TGAI/MUP (nominal & upper certified limits) which are not present in the cited TGAI/MUP
- TRB prepares a Table of Impurities (next slide)
- Action sent to HED by PM
- HED will evaluate the parent and impurities in question using a Structure Activity Relationship analyses (DEREK software)

Table of Impurities

DP Bar Code:---------- Reviewer:---------- Basic CSF Date:---------- or Alternate CSF Date:----------	Proposed Product File Symbol No. --------			Cited Product Reg. No.------		
Ingredients	NC (%)	UCL (%)	LCL (%)	NC (%)	UCL (%)	LCL (%)
Chemical Name of an active ingredient CAS No. ---------- Structure:						
Chemical name of a new impurity of unknown toxicity:--------- CAS No.-------- Structure:---------						

NC = Nominal concentration (% w/w); UCL = Upper certified limits (% w/w); LCL = Lower certified limit (% w/w).

Process Steps

- HED prepares a one to two page summary of the results of the SAR analysis, along with the DEREK output to PM team usually within 90 days
- TRB re-evaluates new product for substantially similarity determination within 30-45 days

Basic Requirements for a Product Chemistry Submission

Karen P. Hicks
Antimicrobials Division
October 1, 2009

Purpose of Product Chemistry Data

- To determine whether the product contains any ingredient in an amount which may cause unreasonable adverse effects on the environment.
- Some of the information provided is needed by the Agency to respond to emergency requests for identification of unlabeled pesticides involved in accidents or spills.
- Physical and chemical characteristics data are used directly in hazard assessment.
- Also, certain data in this series are needed as basic or supportive evidence in initiating or evaluating studies required by other disciplines.

Requirements for a Product Chemistry Submission

Studies that adhere to the 830 Guideline Series must be submitted for all pesticide products

Group A – Product Identity, Composition, and Analysis Test Guidelines

Group B – Physical / Chemical Properties Test Guidelines

Requirements for a Product Chemistry Submission cont…

The Guideline Series 830 has replaced the previously used Guideline Series 60, 61, 62 and 63.

All studies must be submitted or addressed.

Requirements for a Product Chemistry Submission cont…

All studies must be submitted under GLP or state how if differs. See CFR 160.135.

The pesticide product classification category must be listed.

The same product name must be used throughout.

Requirements for a Product Chemistry Submission cont…

Include the most recent CSF (completely filled out).

The total in column 17 should equal 100.

The nominal concentration should be based on the purity in the product.

Requirements for a Product Chemistry Submission cont…

All inerts should be cleared for use in pesticide products

Signatures must be included on the CSF, lab tests and certification statements.

Certified limits must be based on the nominal concentration of the active ingredient.

Requirements for a Product Chemistry Submission cont…

Certified limits must be according to the equation listed in 40 CFR 158.350.

Lower certified limits – not zero or nominal

Impurities greater than 0.1% and of toxicological concern must be determined for all samples.

Requirements for a Product Chemistry Submission cont…

Alternate CSFs should have an appropriate designation for identification (especially if there are multiple alternates).

The product must meet the requirements stated in PR Notice 91-2 (nominal on label must exactly match that of the CSF).

Inert Ingredients Update

CSF Inert Ingredient Screening, Fragrance Component Review, and Inert Ingredient Tolerance Reassessment

Kerry Leifer
Inert Ingredient Assessment Branch
Registration Division
October 1,2009

CSF Inert Ingredient Screening

- Applications for product registration and product registration amendments submitted to the Registration Division (RD) are checked for completeness
- For PRIA actions this is part of initial 21-day review
- Completeness check includes a screen of the Confidential Statement of Formula (CSF) form submitted with application

CSF Inert Ingredient Screening (con't)

- Began as pilot in RD in May 2007
- To date some 3000 products have been subject to the CSF Inert Ingredient Screening process

CSF Inert Ingredient Screening (con't)

Elements of CSF Inert Ingredient Screen

- Determination of acceptability for proposed use for all inert ingredients listed on CSF
- Verification that for trade name inert ingredients/inert mixtures full compositional information is on file with Agency
- Verification of correctness of chemical names/CAS Reg. Nos.
- Deficiencies are noted and applicant is informed of results of screen

CSF Inert Screening Results: Year 1 vs. FY '09

	Year 1 of Screen	FY 2009
Deficiency/error rate (before corrections)	37%	15%
% of deficient submissions corrected	28%	54%
Net deficiency rate (after corrections)	26%	**7%**

CSF Inert Ingredient Screening (con't)

Conclusions

- Screening process has improved quality of CSF submissions
- Significantly lower error rate results in more efficient review process
- Resource savings to the Agency and to Industry

Fragrance Component Review

- Part of a program designed to allow for self-certification of fragrances used in antimicrobial pesticide products
- Industry provided the Agency a list of approximately 1500 substances that are used as components in fragrances
- Under the conditions of the self-certification program, the fragrance components would not comprise more than 0.1% of pesticide formulation

Fragrance Component Review (con't)

- IIAB/RD has evaluated the list to determine if the fragrance components would be expected to be safe for use
- The evaluation has consisted of a review of publicly available data and other peer-reviewed safety assessments of these chemicals by organizations such as JEFCA and FDA
- Exposure modeling used to estimate potential exposures
- Screening level risk assessments performed by using available hazard data and exposure estimates

Fragrance Component Review (con't)

- Screening level risk assessments performed by using available hazard data and exposure estimates
- Upon completion of process, Agency will post list of acceptable fragrance components
- Criteria and process for additions to list will be also established

Inert Ingredient Tolerance Reassessment

- In August 2006, as part of the overall tolerance reassessment process, the Agency identified 132 inert ingredient tolerance exemptions for which insufficient data were available to make the requisite safety finding
- The 132 tolerance exemptions were revoked due to insufficient data with the effective date of the revocation given as August 2008 (subsequently extended until August 2009) to allow interested parties time to provide or generate data to maintain the tolerance exemption

Inert Ingredient Tolerance Reassessment (con't)

- An industry consortium of pesticide registrants and inert ingredient manufacturers was formed to support certain of the to-be-revoked tolerance exemptions.
- 70 of the 132 tolerance exemptions were supported by the submission of data (in many cases including new test data developed expressly to support the tolerance exemption) by this consortia, the Joint Inerts Task Force (JITF).

Inert Ingredient Tolerance Reassessment (con't)

- Clustering concepts were used to identify chemicals and tolerance exemptions which could be grouped together for data development/risk assessment purposes
- The 70 tolerance exemptions were grouped into 18 clusters each with separate data development and risk assessment efforts
- The 18 clusters represent a total of over 300 individual inert ingredients

Inert Ingredient Tolerance Reassessment (con't)

- EPA was able to make the safety findings for 16 of the 18 clusters and published final rules in the Federal Register for each cluster to establish new tolerance exemptions for these groupings which comprise some
- The risk assessment documents supporting these actions are part of the publicly-available rulemaking docket
- Recent new data made available to the Agency on two clusters has resulted in the extension of the effective date of the revocation for those clusters to allow the Agency sufficient time to complete its assessment

e-Dossier Builder
e-CSF ver. 2

Requirements and Development Effort

Robert Schultz
Information Technology and Resources Management Division

Background

- e-Submission
  - Receipt capability July 2008
  - Expansion of PMRA's e-Index
    - Additional meta data required
    - Some inconsistencies
- e-CSF Builder
  - Stand-alone application
  - Download from web
  - Version 1 available spring 2009

e-Submission Issues

- PMRA e-Index Builder insufficient
- Manual editing of XML
- e-Submission limited to
  - Sect 3
  - EUP
  - Tolerance petitions
  - Distributor products

e-CSF Builder Issues

- Minimal validation
- No inert ingredient clearance verification
- Limited help
- Assorted field issues
- Based on internal workgroup
- Limited user input during development

Upcoming

- e-Dossier Builder
  - Version 1
  - “Domestic” applications
- e-CSF Builder
  - Version 2
  - Inert ingredients
  - Electronic signature?
- Starting - fall 2009

Engagement

- Independent efforts
- ID stakeholders
  - Registrants
  - Agents
  - Other?
- Requirements gathering
- Design and Development
- Testing

Involvement

- Contact
  - e-Dossier Builder
    - Bob Schultz
    - Schultz.robert@epa.gov
  - e-CSF Builder v. 2
    - Peter Chen
    - Chen.peter@epa.gov

OPP Science Policy Council

Jennifer McLain
Vicki Dellarco
Co-Chairs