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# Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

## Minutes of the April 28, 2010 Meeting

### Workgroup Members Attending:

Donna Bishel, Biosafe Systems on behalf of Biopesticides Industry Alliance  
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)  
James Kunstman, PBI/Gordon on behalf of Chemical Producers and Distributors Association (CPDA)  
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  
Julie Schlekau, Valent on behalf of Responsible Industry for a Sound Environment (RISE)  
RISE  
Has Shah, American Chemistry Council  
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. Introduction and Announcements
- II. Updating the Pesticide Registration Manual “Blue Book”
- III. Panel - Public Process
  - Process Improvements
  - Pesticide Program Contest
  - E-Label Review
- IV. Labeling – Labeling Committee and Label Accountability Workgroup Update
- V. Antimicrobial Efficacy Protocol Approval Process
- VI. Issues with Conventional Identical/Substantially Similar Product Applications
- VII. Updates on [Pesticide Product Label System \(PPLS\)](#) and Web Chemical Searches

## VIII. Public Comment

### IX. Summary and Next Workgroup Meeting

## Minutes

The powerpoint presentations 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.

### Updating the Pesticide Registration Manual "Blue Book"

The Pesticide Registration Manual was published on the Pesticides Web site on March 16, 2010 as reported by Elizabeth Leovey, a member of the Office of Pesticide Programs' Blue Book Committee. It is an update of the previous document titled, "General Information on Applying for Registration of Pesticides in the United States" issued in August 1992. The 1992 document had a blue cover and became commonly known as the "Blue Book". In 2006, a draft was available that incorporated the PRIA and FQPA amendments to FIFRA and was then reviewed by a focus group of potential users as described in previous meetings [<http://www.epa.gov/oppfead1/cb/ppdc/pria/june06/june06-minutes.pdf>]. The focus group commented that it was one of the most helpful EPA documents available for pesticide registrants and provided the basics on registration. Their comments led to further revisions, however publication was delayed due to the passage of PRIA 2 which required additional revisions.

In publishing the Blue Book, it will be available electronically and in hardcopy. In formatting the Blue Book web page, each chapter became a separate Web page to allow the Agency to easily update it by chapter. An e-mail box is provided for comments on improvements that are answered by the Blue Book Committee composed of experts from each of the registering division and EPA's Office of General Counsel.

Prior to publication of a hardcopy, stakeholder organizations have been requested to provide comments. Suggestions were requested on the "Decision Tree", portions that could be expanded, corrections, additional application examples and incorrect or inoperable links or references. All comments and suggestions should be sent to the e-mail box, [bluebook@epa.gov](mailto:bluebook@epa.gov) to allow the Committee to maintain and keep track of all of the comments. In the interim, a PDF copy of each chapter will be posted.

The workgroup suggested that a questions and answer section be developed similar to the one maintained by the Labeling Committee, each chapter should be dated with the date of revision, and a response should be provided to each comment indicating what happened to the comment. Ms. Leovey responded that the Blue Book Committee anticipates developing a Q&A section,

each chapter will be dated as to its last revision and there will be a response to each individual comment.

### Public Process

Diane Isbell, Registration Division provided an overview of OPP's public participation process implemented as of October 1, 2009 to allow the public an opportunity to comment on proposed registration decisions and risk assessments. The types of actions that will undergo the public participation process are new active ingredients, first food uses, first outdoor uses, first residential uses and actions with significant public interest. A Notice of Receipt (NOR) is published in the Federal Register for all new active ingredients and new uses. A public docket will be opened when a NOR is published for an action that will undergo the public process and will be available on <http://www.epa.gov/pesticides/regulating/registration-status.html>. The public then can request email notification within the chemical-specific docket when new information is added to the public docket. .

Prior to making a risk assessment public, the Agency will contact the applicant concerning Confidential Business Information claims not made through the 86-5 process. Such claims will need to be substantiated. A Pesticides Update [\[http://www.epa.gov/oppfead1/cb/csb\\_page/form/form.html\]](http://www.epa.gov/oppfead1/cb/csb_page/form/form.html) will be issued when the proposed decision, risk assessments and proposed product labels are available for comment. Final decisions are announced in the Federal Register with a Notice of Issuance. In response to a question, Ms. Isbell reported that Notices of Issuance are currently being batched. Information on this public process is available on <http://www.epa.gov/pesticides/regulating/registration-public-involvement.html> with the process described on <http://www.epa.gov/pesticides/regulating/public-participation-process.html>.

In response to questions, Ms. Isbell explained that a Notice of Receipt is always published for new active ingredients and new uses, however, only some of the new uses will go through the public process. Publication of a Federal Register Notice requesting public comments on a risk assessment would add to the amount of time required to process an action and consequently, the Agency decided to announce the request for public comment using a Pesticides Update and the Agency's website to enable the public process to be incorporated into PRIA timeframes. In response to a comment, Lois Rossi, Director, Registration Division, reported that the registrant will know in advance that an action will undergo the public process.

Robert Forrest, Biopesticides and Pollution Prevention Division (BPPD), described the status of the 17 PRIA actions undergoing the public process (12 BPPD and 2 RD new active ingredients and 3 Plant Incorporated Pesticides of significant interest). Five biopesticide actions received a time-limited registration while the public process was being conducted. Some of the factors that will be considered in determining whether an action will undergo a concurrent public process are risks, results of a public interest finding and no adverse comments anticipated. PRIA due dates were extended for each of these because of data deficiencies. Of the remaining actions, two were completed without an extension of the PRIA due date. Due dates were extended for five actions for data deficiencies while for another five, due dates were extended for both data deficiencies and the public process. As of the meeting, all 53 comments received were associated with PIP actions.

In response to questions on the criteria for a concurrent public comment period and time-limited registration and the States reaction to the time-limited registration, Mr. Forrest responded that to date, this approach was only used for BPPD actions and because of low risk. Thus far, the Agency has not received any comments from the States on this approach.

Concerning the workgroup members' questions on the criteria for "significant interest", Lois Rossi responded that at this time, the Agency has not developed specific criteria and will make these determinations when the Agency understands the pesticide's risks. With time and experience, criteria will be described. In responding to a question on why the label was included in the material available for public comment since it will provide notice to a registrant's competitor of the impending registration, Ms. Rossi mentioned that what is being proposed for registration has already been described in the Notice of Receipt.

### **Process Improvements - Pesticide Program Contest**

As background information to a process improvements suggestion contest, Marty Monell described a previous OPP contest to suggest an alternative name for related actions besides "parent/child". The winning suggestion was primary/secondary (<http://www.epa.gov/pesticides/fees/related-apps.html>). Michael Hardy, Special Assistant, OPP, reported that OPP's employees were solicited for suggestions on improvements and efficiencies in the registration process and were reminded that science and risk management decisions would not be compromised. Twenty-four submissions ranging from the regulatory process to science review and risk assessment to information technology will be considered by a panel of Division Directors meeting on April 30. Recommendations will be forwarded to Marty Monell for a final decision anticipated in May.

### **Process Improvements - E-Label Review**

Lois Rossi, Director, Registration Division, updated participants on electronic label review. Using comparison software, proposed labels are compared to the approved label electronically and differences are identified that reviewers then comment upon. The comments are forwarded electronically to the applicant and the applicant and the reviewer can then resolve the comments via e-mail. The electronic label may be submitted on a CD ROM along with the paper application or on a CD ROM in an XML format. Participants were reminded that the e-label specifications needed to be closely followed ([http://www.epa.gov/pesticides/regulating/registering/submissions/critical\\_specs.htm](http://www.epa.gov/pesticides/regulating/registering/submissions/critical_specs.htm)). Common errors observed by RD with submitted electronic labels were incorrect file names and unreadable CDs. Almost 7,000 labels are currently in the e-label database and Ms. Rossi thanked all of the applicants who had been sending them in over the years.

In response to a workgroup member's question on RD's effort to pilot other comparison software, Ms. Rossi reported that RD reviewers did not like the proposed software and preferred the one they were currently using. She asked participants for their suggestions on alternative document comparison software. Workgroup members suggested that RD look into systems currently used by some of the State programs. Some participants do not see any advantage of

submitting labels electronically. Ms. Rossi noted that based on RD's experience, the Agency saved a significant amount of time reviewing a label electronically.

A workgroup member suggested that the final printed label be submitted so that RD could conduct future comparisons. Other workgroup members observed that the master label was not necessarily the label submitted for State registrations and for marketing purposes. In addition, NPRIS did not always have the latest version of a label.

A member inquired as to the address where electronic labels should be sent. They should be sent to OPP's document processing desk [<http://www.epa.gov/pesticides/bluebook/chapter21.html>].

### **Labeling – Labeling Committee and Label Accountability Workgroup Update**

Jim Roelofs, Chair, Labeling Committee updated the Workgroup on the status of the recommendations developed by the Label Accountability Workgroup (LAW) and on the activities of the Labeling Committee. The LAW recommendations of 2008 are all currently being implemented to improve pesticide labeling. These activities include completing the Label Review Manual update, developing label review training, improving the State Label Information Tracking System (SLITS) and developing divisional quality assurance procedures in the pesticide registering divisions. After completing a training session for OPP employees last year, a web-based training program was developed for new pesticide label reviewers to assure that reviewed labels are consistent with Agency policies and regulations, enforceable, clear and accurate. The three hour web based training is designed to supplement the Label Review Manual and is currently undergoing internal review and clearance. It is expected to become publicly available on the pesticides Web site on or about June 1.

All of the chapters of the Label Review Manual have been updated and are publically available (<http://www.epa.gov/oppfead1/labeling/lrm/>). They will be updated as needed and a blog is being considered to solicit comments on improvements. A State FIFRA Issues Research and Evaluation Group (SFIREG) committee already intends to provide comments. A Workgroup member suggested that the LRM contain a link to the Agency's guidance on submitting electronic labels and the Agency will implement this suggestion.

A number of improvements have been suggested to SLITS to enable the Agency to determine the timeliness and accuracy of its responses to questions posed by the States and EPA Regional offices. An improved, more user-friendly system is expected in the near future. In response to a question, Mr. Roelofs noted that a reason for the enhancement was to assure that a State's question on a product was addressed by the appropriate individual. Currently, reports are difficult to generate from the system which then makes it difficult to monitor answers and to identify issues. Ms. Rossi reported that RD managers are meeting weekly to discuss their Product Managers' answers to assure consistency and accuracy.

The pesticide registering divisions continue to implement their label quality assurance programs as described in previous meetings (<http://www.epa.gov/pesticides/ppdc/pria/april09/april09-minutes.pdf>). The Label Committee continues to post answers to questions forwarded by the public to its e-mail box ([http://www.epa.gov/pesticides/regulating/labels/label\\_review\\_faq.htm](http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm)).

Approximately 350 questions have been received. The Committee had no new issue papers for comment on its web site.

The Pesticide Operations and Management working committee of SFIREG has three issue papers concerning 1) expiration dates on supplemental labels, 2) use of the phrase “for professional use only” on labels, and 3) requiring a physical distinction between advisory versus mandatory language on labels. These issue papers will be discussed with OPP management. In response to a request for copies of the SFIREG issue papers, Mr. Roelofs responded that they will be made available and are attached to these minutes.

### **Antimicrobial Efficacy Protocol Approval Process**

The differences between a Tier 1 and a Tier 2 efficacy protocol review were described by Dennis Edwards, Branch Chief, AD. A Tier 1 protocol review has a PRIA timeframe of 3 months (A531), is for minor changes to an existing approved efficacy protocol and is reviewed within AD. Tier 2 protocols have a one year PRIA timeframe, are new protocols or major changes to existing protocols and are reviewed by an external panel. A draft label must accompany either application and a Tier 2 submission must also contain performance measures. Pre-submission meetings are encouraged and the Agency will indicate during these meetings whether the submission will be a Tier 1 or 2. If during the Agency’s review of a Tier 1, the Agency determines that the protocol should undergo external review, the applicant will be notified. Examples of a Tier 1 are varying the test conditions while a Tier 2 protocol may contain field test components, a different application method or surface or involve a novel protocol. Protocols need to be approved prior to the test being conducted. Once approved, the Agency publishes the approved protocol on its web site (<http://www.epa.gov/oppad001/regpolicy.htm>).

Regarding Tier 2 protocol reviews, the PRIA timeframe reflects the time needed to form an external panel and to obtain their review. An external panelist may be an OPP employee outside of AD, from another government agency, from academia or from a user group. Once a review is obtained, it undergoes a secondary review within AD and then forwarded to the submitter to address the issues to enable the protocol to be approved. In response to questions, Mr. Edwards stated that the protocol when published is a generic document without any information to identify a company or active ingredient.

### **Issues with Conventional Identical/Substantially Similar Product Applications**

Lois Rossi, RD, reported that RD currently has five improvement priorities. Two of which are e-label review and actions involving substantially similar new products. FIFRA Section 3(c)(7)(a) defines substantially similar as “...the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects,” and “...approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment.” OPP’s interprets this provision as the proposed product must have the same active ingredient(s), in substantially the same proportion, and chemical composition (solid, liquid, granular), and substantially similar approved inert ingredients as a registered product. In addition, substantially similar means the proposed product’s label bears the same use patterns, signal words and precautionary statements as the

referenced product. These actions fall in the PRIA fee categories R300 and R301. Unless the product is a 100% repack or identical to a currently registered product, both Group A and B product chemistry data must be submitted with the application and all six acute tox studies must be addressed.

In an analysis of the reasons for due date extensions among the identical/substantially similar actions completed in 2009, product chemistry issues occurred more often than other reasons and included citing incorrect registration numbers to refer to the substantially similar product, citing a cancelled product, citing a product with a different active ingredient, not submitting product chemistry data because the proposed product is “nearly identical”, math errors, the label and nominal concentration did not exactly match, and certified limits were outside the Agency standard. Currently, Confidential Statements of Formula (CSFs) are being screened for unapproved inerts and this program has been successful. The Pesticides Program is considering expanding the 21 day content screen to include verifying whether all of the required data has been submitted. RD also encourages registrants to use the e-CSF and requested feedback on the tool available since spring 2009. The Agency is also exploring whether registrants could supply PC codes on CSFs. Other reasons for due date extensions besides product chemistry included the data matrix, CSF, and label.

Workgroup members commented that the e-CSF was cumbersome to use and some companies had their own software which were more user-friendly. The Agency inquired whether these companies would be willing to make their software available or work with OPP in improving its e-CSF.

A workgroup member asked about a proposed product chemistry study report template drafted by an Antimicrobial registrant. The Agency will look into it as an appendix for the “Blue Book”. Another workgroup member observed that there were differences between consumer and agricultural products and consequently, there needed for guidance for both. Pesticides mixed with fertilizers were also a problem for some registrants under PRIA as it was difficult for the registering divisions to categorize them in the existing fee structure. A separate fee category was suggested and may be a topic for PRIA 3.

### Updates on [Pesticide Product Label System \(PPLS\)](#) and Web Chemical Searches

Nikos Singelis, Chief, Internet and Training Branch, Information Technology and Resources Management Division (ITRMD), OPP observed that EPA’s web site contains numerous chemical lists and documents in different locations. Consequently, the public has a difficult time finding specific chemical information without referencing various bookmarks. The web team demonstrated the multiple steps needed to be able to find a tolerance document. To help the public in their search for information, the web team is creating a centralized location to display the information available on a chemical that is easy to search and sort. The chemical portal page would contain plain English explanations and will present users with basic and advanced search options to find chemical information. The first phase of this project will be to address active ingredients with subsequent phases addressing inert ingredients and then integration of product and label databases. Workgroup members were very interested in the improvements. The Agency is requesting feedback on the proposed approach and to work with the Agency during its development. Participants were encouraged to volunteer to review prototypes and to forward



their ideas on the chemical search page to Mr. Singelis and Andrew Yuen (yuen.andrew@epa.gov).

Mr. Singelis also described the Agency's efforts to improve the Pesticide Product Label System. Currently, labels can only be retrieved by company and product number. Furthermore, the labels are stored as TIF files that can not be searched. The Agency plans on improving the web application so that labels can be retrieved not only by registration number but also by common product names. Labels will be converted to a PDF format. In the future, the labeling system will be integrated with systems supporting electronic submission and contain a review module for OPP staff to conduct label comparisons. Workgroup members suggested that the stamped label be available on the web, cautioned the Agency that marketing and final printed labels could be different from the approved label, and recommended that the Agency look at what is currently available from NPRIS and other labeling sites. Mr. Singelis responded that the Agency is reviewing other labeling sites to identify features that would be useful.

### **Public Comment**

William McCormack, Clorox suggested that the recently released "Determining if a Cleaning Product is a Pesticide under FIFRA" (<http://www.epa.gov/pesticides/factsheets/pest-habitat-claims.html>) be discussed. Ms. Monell responded that the Agency will place it on the agenda for the next meeting of the Process Improvement Workgroup.

### **Summary and Next Workgroup Meeting**

Ms. Monell suggested that if participants had additional questions, they could contact the presenters. In planning the next meeting of the workgroup expected in October 2010, Elizabeth Leovey will contact workgroup members on the date and topics.

## SFIREG Issue Paper: **Differentiation of Label Language**

**Priority:** High

**Issue:** State Lead Agencies (SLAs), as well as the EPA, spend a great deal of time, effort, and resources responding to pesticide product label interpretation questions. Many of these questions have to do with the enforceability of label statements. A confounding and consistent factor in these interpretive questions is that labels often comingle guidance, advisory language, recommendations and mandatory or imperative statements in the same paragraph and often times, the same sentence. This makes interpretation and implementation of label directions challenging and ineffective for both applicators and regulators.

**Background:** SLAs have received confusing or inconsistent information from the EPA upon label interpretation requests, depending on who answers the question. A label language interpretation or enforceability question submitted to an OPP product manager via SLITS may elicit one opinion or position. The same question submitted to OECA for a formal enforcement case review may elicit a completely different opinion or position. Many SLAs would not be able to compel a user to do anything that falls under a “Recommendation” or “Advisory” heading. States are called upon daily by applicators to provide label guidance. Additionally, successful enforcement response by SLAs is made problematic if uncertainties about label language are introduced by responsible parties.

**Recommendations:** Whereas the EPA is considering moving towards web based labeling (e-labeling) initiatives, SFIREG requests that the agency differentiate mandatory vs. advisory pesticide label language by either:

- 1) requiring that labels be printed with two easily discerned, understood, different, and distinctive formats. Different “formats” means, for example, different font styles, font sizes, or bolded or italicized print. One distinctive and consistently required format would be inclusive of all enforceable language. Another distinctive, different, and consistently required print format would include guidance, advisory statements and Best Management Practices (BMP’s); or,
- 2) requiring that all mandatory and advisory language be completely separated from one another on pesticide product labels. One section of a label would contain all mandatory, enforceable language. Another separate, and located elsewhere section of the product label would contain all advisory, guidance and Best Management Practice (BMP) language.

Either labeling approach would enable a pesticide user to easily find and discern exactly what is required of him or her, as well as assist a user in meeting goals or protections that the EPA and product registrants believe valuable. SFIREG requests that the EPA immediately begin internal processes necessary to accomplish this label language differentiation, or separation, as described above. SFIREG recommends that the EPA prepare mock example labels- incorporating one or the other of these two options- and that SFIREG be requested to promptly review and comment on the example labels. This measured approach would be of great value in determining a preferred option and which option would then be required to be used on pesticide product labels by the EPA. The result will ultimately aid e-labeling initiatives, and in the short term, this gross

label language differentiation or separation will immediately aid pesticide product users and SLAs by making pesticide product labels much more easily understood.

## SFIREG Issue Paper: “For Use By” Label Statements

**Priority:** High

**Issue:** State regulators are frustrated with the continued use of unenforceable “for use by” statements on pesticide labeling.

**Background :** “For use only by” statements are often used by registrants in an attempt to limit the sales or use of pesticides to certain segments of the pesticide user community. Examples include such statements as, “for commercial use only”, “for professional use only”, “for use by professional applicators”, and “for sale to or use by professional personnel only”. State regulators are also noting a recent increase in label statements referencing “homeowners”, such as “not for sale to or use by homeowners” and “not intended for sale to or use by homeowners”. These sorts of label statements are sometimes meant to mitigate risk by restricting use of certain products to commercial applicators without classifying a product as a Restricted Use Pesticide (RUP). However, “for use only by” statements are also used as marketing tools by registrants to imply that a product has “commercial” or “professional” strength, thereby increasing sales to citizens who view the products as having superior efficacy. It is SFIREG’s position that “for use only by” pesticide labeling statements are vague and unenforceable. These statements imply that certain products are RUPs, causing confusion in the regulated community. More important, “for use only by” statements lower the regard that pesticide dealers and users have for products that truly are RUPs, hampering efforts to restrict pesticide sales and use to qualified applicators when there is a real-world need to do so in order to mitigate risk.

On October 24, 2006, EPA released a discussion paper and a synopsis of comments received from state regulators and other stakeholders in response to an issue paper on “for use only by” statements. In their synopsis, EPA stated that “for use only by” statements are acceptable and enforceable if the statements limit use to clearly identifiable applicators. However, EPA stated that it was inappropriate to use language that limits use of non-RUP products to certified applicators. EPA further stated that the terms “institutional use” and “residential use” are defined in 40 CFR 152.3 and can be used to clearly identify allowed use sites. SFIREG agrees that certain label statements can be developed to clearly restrict use of non-RUPs to certain pesticide applicators. For example, many termiticide products now carry the following statement: “For use by individuals/firms licensed or registered by the State to apply termiticide products. States may have more restrictive requirements regarding qualifications of persons using this product. Consult the structural pest control regulatory agency of your State prior to use of this product.” In addition, EPA worked with states and other stakeholders to develop standard language for mosquito control products that reads: “For use only by federal, state, tribal or local government officials responsible for public health or vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision.” Unlike other “for use by” statements, these two examples are acceptable to states because they are written using enforceable language, and the statements were developed in consultation with state regulators.

**Recommendations:**

- A. Adopt a policy prohibiting use of all “for use by” statements besides those statements developed to date for the termiticide and mosquito control products.
- B. Replace all “for use by statements” to include enforceable terms defined in FIFRA and the corresponding regulations.
- C. Reclassify all products with “for use by” statements referencing “commercial” or “professional” uses as Restricted Use.

SFIREG requests that EPA immediately discontinue accepting any other “for use only by” label statements besides those statements approved for the termiticide and mosquito control products unless the targeted user group: a) is clearly defined in statute or regulation, b) can be identified by a license or other government issued credential, or c) can demonstrate employment by an entity identified by the label.

## SFIREG Issue Paper: **Expiration Dates - Supplemental Labeling**

**Priority:** For EPA review, consideration and recommendation.

**Issues:** There are 100s of supplemental pesticide labels in the market that it is unknown to their validity/legality. New labels come in and supersede old labels and yet there is nothing to indicate the old labels are no longer valid and there is no mechanism to get them cleared out of the marketplace.

**Background:** In Chapter 3 of EPA's Label Review Manual (Dec 2006) "**Supplemental Labeling**" is a term used by the Agency to describe labeling which includes newly approved uses, use directions, or other instructions which have been added since the last accepted Master label. These are partial labels distributed with the product by the registrant or distributors. There are hundreds of supplemental labels registered by State Pesticide Regulatory Programs in the United States. According to the Washington State University's Label Database, there are over 850 supplemental labels registered by the state and nearly a third of these were issued five or more years ago. About 10% of the total number involves Restricted Use Pesticides (RUPs).

- EPA generally asks that supplemental labeling should be incorporated into the EPA Master Section 3 label within 18 months or the next printing of the registrant's label. However, there does not seem to be a specific requirement on the lifespan of a final printed supplemental label in the marketplace.
- Outdated supplemental labels are being retained as "active" state registrations and/or posted on the Internet. Applicators may be referencing outdated information contained in old treatment manuals, which are "Supplemental Labeling". Maintaining old supplemental labels can delay record retention schedules for state agencies. Maintaining unnecessary records can increase workload and archive costs.
- It is difficult for regulators to know which label version is valid when there are multiple revisions to a supplemental label. A label with errors or other issues can remain in circulation beyond an acceptable time period.

POM has previously reviewed supplemental label issues related to web based label distribution. The pros and cons of requiring an "expiration date" was discussed at the April 2001 POM meeting. At the April 2003 POM meeting, Jack Neylan, EPA/OECA, asked AAPCO/SFIREG to get EPA to think about what to do with supplemental labels. At the April 2005 POM meeting, Jack Neylan said there need to be dates on each supplemental label, so that previous supplemental labels are rendered obsolete. Several states (e.g. HI, ID, OR, WA) have been using expiration dates on 24(c) labels. Some registrants may add an expiration date to section 3 supplemental labels. There is a need for flexibility in the lifespan (1-5 years) of the supplemental label depending upon the need and use.

**Recommendation:** Add an expiration date statement on all federal supplemental labels with a lifespan between 1-5 years: "**This label is valid until December 31, 20XX, or until otherwise amended, withdrawn, canceled, or suspended.**"