EPA Office of Pesticide Programs Labeling Projects

Cindy Wire, OPP Field and External Affairs Division

Western Region Pesticides Meeting
Scottsdale, Arizona
May 18, 2016
Current OPP Labeling Efforts

- Labeling Consistency Committee
  - Submitting questions about labels
  - Label Review Manual
- SmartLabel
- Label Matching Project
- Web-Distributed Labeling
- Spanish Pesticide Labeling Pilot
Labeling Consistency Committee

- Formed in 2005
- Representatives from OPP, Office of General Counsel, and OECA
- More than 800 questions, about half of them posted
- Answers labeling questions submitted through website
- Questions are usually broad, general labeling questions
- Questions reviewed, discussed, and assigned
- Answers undergo review process
- Answers may be a direct reply and/or posted to our website
- Lorry Frigerio, Committee Chair

https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers
Labeling Consistency Committee – Q and A Website

Pesticide Labeling Questions & Answers

These answers are not intended to create significant new guidance or require any changes to previously accepted labeling. The Agency will contact registrants directly about how to correct problematic labels as appropriate. Changes to EPA accepted labeling will only be required in accordance with standard Agency procedures. These answers are primarily based on federal law, regulations and policies implemented by EPA. States, tribes, territories, and other federal agencies may have additional requirements relevant to their jurisdictions.

HINT: Use the browser search function (control+F) to locate keywords related to the issue you are researching.

If your question is not answered here, use the labeling consistency question form to submit a question. See guidance on how to obtain assistance with labeling issues.

On This Page:
1. Advertising claims
2. Antibacterial claims
3. Chemigation
4. Contract manufacture
5. Use after
6. Definitions of terms
7. Distributor product labeling
8. Exception to use in a manner not permitted (FIFRA Sec. 2ee)
9. Labeling stock
10. General labeling
   a. Use classification
   b. Product name
   c. Name and address of producer/registrant
   d. Product registration
   e. Establishment
   f. Use statement
   g. Ingredient statement

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Pesticide Labeling Questions & Answers – Form

Use this form to submit a question on labeling topics if you don't find the information you need on our labeling question and answer page.

Provide your contact information if you need a reply. We may add your question to the labeling Q&A page, if it is of general interest. (Note: Contact your Pesticide Product Registration Ombudsman for specific label issues about a single product).

Your Name

Your Email Address

Your Phone

Your Question or Comments (Required)

Submit

Contact Us to ask a question, provide feedback, or report a problem.
<table>
<thead>
<tr>
<th>Question and Answer Categories</th>
<th>Advertising Claims</th>
<th>Establishment</th>
<th>NAFTA Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemigation</td>
<td>Misuse Statement</td>
<td>Notifications</td>
<td></td>
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<td>Contract Manufacture</td>
<td>Ingredient Statement</td>
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<td>Use Sites</td>
<td>Precautionary</td>
<td>Packaging</td>
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<tr>
<td>Definitions of Terms</td>
<td>Environmental Hazards Statement</td>
<td>Pesticide Exemption (FIFRA 25b)</td>
<td></td>
</tr>
<tr>
<td>Distributor Product Labeling</td>
<td>Directions for Use</td>
<td>Pictures and Logos</td>
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<tr>
<td>Exception to Use in a Manner Not Permitted (FIFRA Sec 2ee)</td>
<td>Worker Protection Statement</td>
<td>Repacked Products</td>
<td></td>
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<tr>
<td>Existing Stocks</td>
<td>Storage and Disposal</td>
<td>Service Containers</td>
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<tr>
<td>General Labeling</td>
<td>Unattached or Attachment Issues</td>
<td></td>
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<tr>
<td>Use Classification</td>
<td>Labeling from Web Sites</td>
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<tr>
<td>Product Name</td>
<td>Miscellaneous</td>
<td></td>
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<tr>
<td>Name and Address of Producer/Registrant</td>
<td>Multiple Products Packaged Together</td>
<td>Subject to FIFRA</td>
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<td>Superlative Terms</td>
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<td>Import/Export</td>
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<td>Termiticides</td>
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<td>Supplemental Labeling (Not distributor products)</td>
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Q and As within a Category

E. Establishment

* Does the EPA Est. No. need to appear on the device itself or is it adequate for it to appear only on the container package? LC13-0648; 08/16/13

According to 40 CFR 152.500(b)(1), devices are subject to the standards for misbranding under FIFRA § 2(q)(1) and the labeling requirements set forth in 40 CFR Part 156. Section 2(q)(1)(D) provides that a product is misbranded if “its label does not bear the registration number assigned under [section 7] to each establishment in which it was produced.” 40 CFR 156.10(f) states that the EPA establishment number may appear in “any suitable location on the label or the immediate container.” If the establishment number on the immediate container cannot be clearly read through an outer wrapper or container, then the establishment number must appear on the outer wrapper or container as well.

* In the marketplace I’ve seen examples of products that have a complete EPA Establishment # coded on the container of a product in a format such as “EPA EST XXXX-XX-XX” when the product in the container is not a registered pesticide. In the examples that I’ve seen, there are no pesticidal claims on the product, only the inclusion of the establishment #. Would this be considered misbranding, or some other violation of FIFRA? LC11-0423; 05/02/11

An EPA Establishment Number coded on a container, in the absence of any pesticidal claims by the product labeling or advertising, would not make the product subject to FIFRA in most circumstances. If the presence of an establishment number is intended to imply the product has pesticidal effect or if consumers are misled by the establishment number to believe the product has a pesticidal effect, the product may be subject to FIFRA. Note that pesticide device packaging must bear the EPA establishment number for the place where the device was produced, so some unregistered products that bear establishment numbers may be devices. Further, labeling for all products are subject to the requirements of the Federal Trade Commission, which can take action against false or misleading claims.
Label Review Manual Chapters

Available at www2.epa.gov/pesticide-registration/label-review-manual
SmartLabel Pilot is one of EPA’s Efforts to Improve Pesticide Labeling

- Part of EPA’s approach to improve product labeling
  - A system that enables EPA to receive labeling submissions electronically to process them more efficiently and consistently
  - Internal agency procedures to improve clarity and enforceability of labeling content
  - A system for electronic dissemination of the most current approved version of product labeling to users.
SmartLabel Basics

- Master pesticide label as structured data
- Addresses label “pain points”
  - Manual extraction and entry of label information into multiple EPA databases
  - Inconsistent EPA reviews and interpretations
  - Limited ability to query across products
  - Unclear label information, uncontrolled vocabularies
- Inclusive of all EPA-registered products
- Builds on previous work
  - Partnered with FDA to learn from their success with Structured Product Labeling
  - Used the EPA Label Review Manual as a starting point for the structuring of the label
  - Leveraged current systems and registries to identify data fields and vocabularies
Project Goals – Change Label Structure

- **Label Standardization:** define label content sections which standardize where information appears on pesticide labels
- **Label Structuring:** propose label structure that can be applied to all products; allows for extraction/comparison of label content sections across labels and label versions
- **Label Data Elements:** identify discrete pieces of information which allow for the sorting, filtering and querying of labels
Phase 1 Pilot Goal and Results

- Gathered feedback on proposed data model (such as data elements, labeling sections, etc.) and draft guidance
- 9 Participants:
  - Bayer CropScience, Syngenta, Dow, SePRO, Reckitt Benckiser, EcoLab, Marrone Bio, Clorox, United Industries Corporation
- Several meetings and webinars from December 2014 to February 2015
- Overall feedback: needs more work
## Phase 1 Feedback

<table>
<thead>
<tr>
<th>Feedback</th>
<th>EPA Response</th>
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<tbody>
<tr>
<td>Data entry is labor-intensive and not user-friendly</td>
<td>The pilot’s purpose is to evaluate the data model concept</td>
</tr>
<tr>
<td>Certain data fields are not applicable to antimicrobials</td>
<td>Data fields may or may not apply to individual products</td>
</tr>
<tr>
<td>Certain data fields are new or different</td>
<td>SmartLabel does not change 40 CFR 156.10</td>
</tr>
<tr>
<td>Overly complicated model</td>
<td>Working to simplify</td>
</tr>
<tr>
<td>Burden to regulated community and benefits are not apparent</td>
<td>Discussion point</td>
</tr>
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</table>
Pilot Phase 2 Overview and Results

- Incorporated feedback received in Phase 1
  - Simplified the data model
  - Updated User Guide Document
- Completed Draft Vocabulary Lists with definitions
- Same pilot participants tested draft vocabularies, updated user guide and web-form to input labels
  - July 2015 – September 2015
- Phase II results:
  - Data model is simpler and more user friendly
  - Suggested changes to website and label data entry form
  - Some clarification needed in user guide
Next Steps and Contacts

- Currently working with a contractor build out the database
- Preparing for a 3rd pilot from July to September 2016
- There are still several steps in the process including possible rulemaking before this system will be ready for use
- Pilot web page:  
  [http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot](http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot)
- For more information:  [Smartlabel@epa.gov](mailto:Smartlabel@epa.gov)
- Project leads:
  Patricia Parrot:  [parrot.patricia@epa.gov](mailto:parrot.patricia@epa.gov)
  Marietta Echeverria:  [echeverria.marietta@epa.gov](mailto:echeverria.marietta@epa.gov)
  Philip Villanueva:  [villanueva.philip@epa.gov](mailto:villanueva.philip@epa.gov)
Label Matching Project

Vision: The Pesticide Label Matching App will be a mobile, electronic label comparison tool that can check market labels against state and federal label databases to assist enforcement personnel in identifying potentially violative products.

EPA is developing an app that can:

- Retrieve pesticide data from OPPIN with a picture or EPA Reg #
- Validate toxicity signal word
- Validate ingredients
- Work on iOS, Android devices + Mobile Web App.
This is an E-Enterprise Project

The mission of E-Enterprise is to protect the environment through modern business processes, technology, and partnerships.
To begin, Inspection Process Field Workshop held in Region 5 in March 2016
What Doesn’t Work

- Participants = EPA HQ and region 5, Indiana and development team
- 5 groups identified the following “pain points”:
  1. Investigators visit locations, but inspect products
  2. Current process results in many inefficiencies
  3. State and federal investigators conduct inspections differently
  4. Field investigators often struggle with their hardware
  5. Frequent calls to ask basic questions create bottlenecks
  6. Visual comparison of labels is difficult for a number of reasons
  7. Labels are stored in several different databases, if they’re stored at all
What Would Work

- A standard label format would make inspections significantly more efficient.
- Existing regulations could be used to create a national database of market labels.
- The app addresses some, but not all, of the pain points for inspectors.
- Improvements to help investigators do not all depend on the SmartLabel.
- Team needs to build organizational buy-in for the Label Matching application.
- Adding an inspector database to the Label Matching app would increase its usefulness.
Label Matching Project

After identifying the pain points during the investigation process, the group brainstormed additional features they’d like to see in the app including a National Inspector Database.

<table>
<thead>
<tr>
<th>Inspector Database Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIS locations of inspections</td>
</tr>
<tr>
<td>Spanish label information</td>
</tr>
<tr>
<td>Violation alerts</td>
</tr>
<tr>
<td>Input registration # via voice typing</td>
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<tr>
<td>Notification of label changes</td>
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<tr>
<td>Display investigator credentials electronically</td>
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<tr>
<td>Workflow logs for inspectors</td>
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<tr>
<td>Pull photos/other ID from UPC registration of common products</td>
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<tr>
<td>Creation of automatic notices of inspections</td>
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<tr>
<td>Provide offline access</td>
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<tr>
<td>Report generation</td>
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<tr>
<td>Prior state and federal inspection history</td>
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</tbody>
</table>
Potential Future Features for App:

Requires adding or integrating case management functionality:
- Integration with Smart Tools or expansion to cover entire inspection workflow
- Integration with case workflow
- Electronic capture of evidence/description in the field
- Case management tab or enhanced case management capability within the application

Requires a unified database of all state labels:
- Access to state label and registration data
- Access to market labels
- Latest market label for geography, prominently presented after EPA Registration number is entered

Requires rule-making/policy changes:
- Include all label/labeling and complete automated screening
- Inspection forms: create notice of inspection/stop sale/other notices
- Electronic notice of inspection form

Dependent on SmartLabels:
- Master Label language
Label Matching Tool App

Users may initiate a label screening by taking a picture of the label, or manually entering an EPA registration number.

Using the device camera, begin an automated label review by capturing the following pesticide label elements:

- Registration Number (Required)
- Use Sites
- Ingredients
- Pesticide Type
- Pests

Begin Label Review

Manual Entry of Registration Number

Enter the registration number found on the pesticides label to begin review.

Registration Number

Submit

Capture or upload an image from your camera.

Upload Photo

As of 3/23/2016, the system will only be able to submit one image at a time.

Click to switch to getUserMedia Method

Remove
Label Matching Tool App

The Label Matching Tool App allows users to input the product code and view information about the pesticide. The app is designed to help users match label information with specific products. The image shows an example of how the app works, displaying product information such as status, approval date, registrator, toxicity signal word, formulation, type, use sites, pests, and ingredients. Users can view the master label PDF for more detailed information.

Product data from NPRO | Master Labels from PPLS | Copyright © 2016 EPA

May 18, 2016 Western Region Pesticides Meeting
Label Matching Project Next Steps

- App scheduled for completion June 2016
- Beta test app with state & regional enforcement staff late June 2016
- Centralize pesticide data from PPLS, PPIS, SSTS, NPIRS, NPIC/NPRO
- Begin rulemaking process to improve label
- Determine feasibility of developing a national database of state labels
- Develop consistent communication between Label Matching & SmartLabel teams

Contacts:
Alan Boutureira, OCSPPP
Mardi Klevs, Region 5
David Scott, Indiana Office of State Chemist
Web Distributed Labeling

- Allows registrants to make legally-valid pesticide labels available online for users (PR notice published April 2014)

How it works: Registrant submits an application
- Product label includes a reference to web-distributed labeling and a website

Benefits include:
- Faster access to new pesticide uses
- Quicker implementation of public health and protective measures
- Improved compliance with label directions
- Lower cost for industry and EPA

Status: System in place, however no registrant applications have been received to date

For more information: contact Michelle Arling, OPP/FEAD
- Web link: [https://www.epa.gov/pesticide-labels/web-distributed-labeling-pesticides](https://www.epa.gov/pesticide-labels/web-distributed-labeling-pesticides)
Spanish Labeling Pilot Program

- Pilot developed in response to a 2009 petition
- Farmworker advocates stating that bilingual pesticide labeling is critical to the well-being of pesticide applicators, many who do not read or speak English
- Many agricultural and professional landscape product labels are only in English
- Pilot targets these products
Spanish Labeling Pilot Program

- The project provides registrants with a translation guide for human health precautionary language including:
  - Signal word
  - First aid
  - Hazards to human and domestic animals
  - Personal Protective Equipment

- And a translation of the misuse statement:
  “It is a violation of Federal law to use this product in a manner inconsistent with its labeling”
Participation & Next Steps

- Once EPA accepts translated label then product can be submitted to states
- Evaluation of pilot will be based on:
  - Effectiveness of translations
  - State registration and enforcement issues
  - Registrant issues
- The pilot is expected to run for two years, and then will evaluate feedback and necessary changes

Contacts:
- Jose Gayoso, OPP/PRD
- Christina Motilall, OPP/PRD
- Linda Arrington, OPP/PRD
Questions?

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