

SmartLabel Update

Pesticide Program Dialogue Committee Meeting

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What is SmartLabel?

- **Master pesticide label as structured data**
- **Part of OPP Vision for instantaneous access to quality information**
- **Beginning of a comprehensive IT plan**
 - **Paperless workplace**



Characteristics of the SmartLabel

Not *just* a Structured Label

- **Delineation of product Use Patterns, by the registrant**
Replaces EPA interpreted data entry
- **Standardized/Formal/Public OPP Vocabulary**
A common understanding of all terms for the first time
- **A process to improve label review and risk assessment workflow**
Increased label/review consistency, and faster review process
- **A scalable plan for OPP data management and access**
Linked to other OPP documents/information
Options for OPP, Federal/State partners, and Public access views



Benefits/Goals of Structured Electronic Content

Increased label quality/consistency

- Structured Label → consistent format
- Use Pattern Index → text as data
- Standard Vocabulary → no ambiguity
- Improved access to previous reviews → consistency with similar labels

Improved access to registration information

- Search across products → Increased ability to respond to public health inquiries
- Direct to PPLS upload → access to approved content in real-time

Save Resources

- Less paper
- Electronic validation



Terminology Development & Management

Develop vocabulary

- **Build** → Defined and developed by OPP staff
 - e.g. majority of lists
- **Borrow** → Sourced from external stakeholders
 - e.g. pest lists
- **Merge** → Lists merged and coded between FDA and EPA
 - e.g. ingredients list

Manage Vocabulary

- EPA Terminology Services: Synaptica
- Central repository to maintain terminology for EPA/OPP



Terminology Example

Traditional “use site” described by combination of two terms

- **Use Site** is the plant/building/animal/etc.
- **Use Site Location** qualifies where the site is found
 - Conceptually clarifies label information
- Simplifies sorting/filtering/aggregating

Example Label Site	Use Site	Location
Residential Lawns	Grass/Turf	Residential/Recreational/Schools/ Institutional/Retail (Outdoor)
Grass Around Oil Wells	Grass/Turf	Occupational/Manufacturing/Processing/Industrial Area (Outdoor)
Sod Farm	Grass/Turf	Agricultural (Outdoor)

1400 non-agricultural sites can be described with

- 140 sites
- 10 locations



Benefits of Structured Label

Increased consistency in reviews

- Compare to other labels and other versions
- Compare to supporting documentation
 - Use Index, MRL, CSF, etc
- Reduced need for interpretation

Reduced review time

- Easily identify only what has changed since prior submission
- Machine validation
 - Within label (currently active)
 - Across documents (in development)



Benefits of Use Index

Increased consistency in reviews

- Reduced need for interpretation
 - What does the registrant think the label allows
- Easy identification of data gaps
- Compare use pattern data to label during registration

Reduced review time

- Easily identify only what has changed since prior submission
- Machine validation
 - Within label (currently active)
 - Across documents (in development)



Pilot Participants

- Bayer CropScience
- Clorox
- Dow AgroSciences
- EcoLab
- Marrone Bio
- Reckitt Benckiser
- SePRO
- Syngenta
- United Industries Corporation



Pilot Feedback

Phase 1 *2014*

- Overly complicated model
- Benefit unclear to registrants

Phase 2 *2015*

- Simplified the data model
 - separated label and use index
- Updated User Guide Document

Phase 3 *2016*

- Production ready builder
- Improved guidance

Phase 4 *2018*

- Made builders more user friendly
- Cont. work with FDA to harmonize AI terms
- Updated Vocabularies

Phase 5 *2018*

- Soft launch: voluntary submissions from pilot registrants
- EPA test of internal storage and workflow



Soft Launch

Test of the entire system

- Builder
- Submission portal
- Database loader
- New database
- OPP electronic review tool
- Label approval and processing to PPLS



Next Steps

- **Production ready environment available for registrants**
 - **Integration of SmartLabel structured data into current workflows**
 - **Begin to build database of all registrations**
 - Develop requirements for submission of SmartLabels for all registrations
 - **Outreach, promotion, marketing/advertising**
 - Encourage voluntary adoption & provide assistance



Next Steps Cont.

- **Leverage SmartLabel work to further OPP IT modernization**
 - Establish governance to maintain vocabulary
 - Expand to include additional information in structured format
 - Develop new tools for access
- **Complete MRL work with FDA**
 - Structure/standardize tolerance data currently in CFR

SmartLabel Benefits Us All!



Benefit	Registrants	EPA	States	Public
Curated Vocabularies	✓	✓	✓	✓
Structured Labels/Use Index	✓	✓	✓	✓
Improved label quality & consistency	✓	✓	✓	✓
Fewer data gaps	✓	✓	✓	✓
Automated data extraction into EPA databases	✓	✓	✓	✓
Smart Database	✓	✓	✓	✓
Easy comparison of label, use patterns, and supporting information	✓	✓	✓	✓
More consistent EPA reviews	✓	✓	✓	✓
Reduced EPA review time	✓	✓		✓
Agency/Public Advanced Querying Ability	✓	✓	✓	✓
Electronic comparison of labels and claims (in field)	✓	✓	✓	✓
Efficient & accurate response to inquiries/emergencies	✓	✓	✓	✓
State access to master label data to review state label submissions	✓	✓	✓	✓



Contacts and Resources

- Pilot web page

<http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot>

- Comments are welcome

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