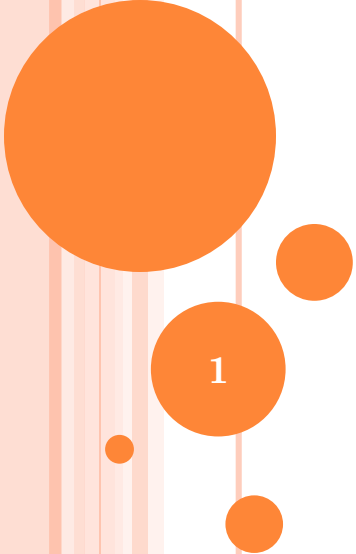


US EPA ARCHIVE DOCUMENT

SESSION 7 – UPDATES: SMARTLABEL



Philip Villanueva
Office of Pesticide Programs
May 2015

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SMARTLABEL IS...

- Master pesticide label in a structured format
- Address label pain points
- Part of OPP Vision to have instantaneous access to quality information
- Inclusive of all EPA-registered products
- Building on previous work (e.g., FDA structured labeling)



LABEL PAIN POINTS

- Manual/time-intensive label review
- Manual extraction of label information; manual entry into EPA databases
- Unclear label information; uncontrolled vocabularies
- Inconsistent EPA reviews/interpretations
- Limited ability to query across products
- Diminishing resources

Unstructured Information

2777 S. Crystal Drive,
Arlington, VA 22202

RESTRICTED USE PESTICIDE
ACUTE TOXICITY AND GROUND WATER CONTAMINATION
(This label shall not be used only by Certified Applicators or persons under their direct supervision or Certified Applicators, and only for uses listed on the Certified Applicator's certificate.)

EPA Registered Pesticide

For Control of Certain Insects, Mites, and Nematodes

ACTIVE INGREDIENT: Atrazine (2-methyl-2-propylthio) propanedimide (2-methyl-2-propylthio) 15%
INERT INGREDIENTS 85%

EPA Reg. No. 284-330 EPA Est. No. 284-GA-01

KEEP OUT OF REACH OF CHILDREN
ANGER POISON
PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL AND TRANSPORTATION Emergencies ONLY: Call 24 Hours A Day 1-800-334-3377
For PRODUCT USE Information: Call 1-800-999-9001 (1-800-992-2937)

FIRST AID

IF SWALLOWED:

- Immediately call a poison control center or doctor for treatment advice.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Have person sip a glass of water if able to swallow.
- Do not give anything by mouth to an unconscious person.

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

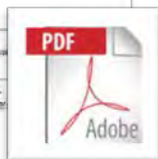
IF ON SKIN OR CLOTHING:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

IF INHALED:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial breath if possible.
- Call a poison control center or doctor for further treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-3377.
Keep the product container or label with you when calling a poison control center or doctor or hospital.



Structured Information

Street Address:	2777 S. Crystal Drive
City:	Arlington
State:	VA
Zip Code:	22202



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Unstructured

- Master label
- Available in PPLS
- May be text searchable

“Meets EPA requirements for killing norovirus.”

“Kills norovirus.”

Structured

- Master label information
- Available in EPA database
- 100% searchable

A conceptual drawing of a structured data entry form. It consists of two columns of dropdown menus. The left column has a top dropdown labeled 'Kills' and four identical dropdowns labeled 'Select Effect' below it. The right column has a top dropdown labeled 'Norovirus' and three identical dropdowns labeled 'Select Organism' below it. The 'Norovirus' dropdown is open, showing a list of options: 'Norovirus' (highlighted), 'HIV', and 'C. diff.'.

Note: image above is a conceptual drawing for informational purposes only.

PILOT OVERVIEW

- Gather feedback on proposed data model (data elements, labeling sections) and draft guidance documentation
- December 2014 to ~ September 2015
- Meetings in December, February, April & May
- Participants:
 - Bayer CropScience, Syngenta, Dow, SePRO, Reckitt Benckiser, EcoLab, Marrone Bio, Clorox, United Industries Corporation

FEEDBACK

Feedback	EPA Response
Data entry is labor-intensive and not user-friendly	The pilot's purpose is to evaluate the data model concept
Certain data fields are not applicable to antimicrobials	Data fields may or may not apply to individual products
Certain data fields are new or different	SmartLabel does not change 40 CFR 156.10
Overly complicated model	Working to simplify
Burden to regulated community and benefits are not apparent	Expected benefits are presented on slide 9

SMARTLABEL BENEFITS

Pain points	SmartLabel Solution
Manual/time-intensive label review	Electronic comparison of labels and claims
Manual extraction of label information	Automated label extraction and entry into EPA databases
Unclear label information	Improved label quality
Inconsistent EPA reviews/interpretations	More consistent EPA reviews
Limited ability to query across products	Advanced querying ability
Unlevel playing field	Level playing field
Diminishing resources	Reduced review time

SMARTLABEL BENEFITS

Benefit	Registrants	EPA	States	Public
Electronic comparison of labels and claims		✓	✓	
Automated label extraction and entry into EPA databases	✓	✓	✓	✓
Improved label quality	✓	✓	✓	✓
More consistent EPA reviews	✓	✓	✓	✓
Advanced querying ability	✓	✓	✓	✓
Level playing field	✓	✓	✓	
Reduced EPA review time	✓	✓		✓

NEXT STEPS

- Incorporate feedback received during phase 1 pilot
- Phased approach:
 - **Label** sections, data elements, draft vocabularies, guidance, and XForm - June 2015
 - **Use table** data elements, draft vocabularies, guidance, and XForm - September 2015
- Continue collaborating with states, industry, and FDA

CONTACTS AND RESOURCES

- Pilot web page
 - <http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot>
- Project leads
 - Patricia Parrot: parrot.patricia@epa.gov
 - Marietta Echeverria: echeverria.marietta@epa.gov
 - Philip Villanueva: villanueva.philip@epa.gov