SmartLabel Pilot Overview

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SmartLabel is...

- Master pesticide label as structured data
- Builds on previous work (e.g., FDA structured product labeling, SPL)
- Will provide up-to-date label information and allow querying across labels for critical use information to support risk assessment, risk mitigation and risk management decisions
- Inclusive of all EPA-registered products
Project Timeline

- December 2014 - Pilot Phase 1
- July 2015 – Pilot Phase 2
- February 2016 – EPA contract to develop builder
- September 2016 – Pilot Phase 3
- 2017 – Start accepting SmartLabel submissions as part of applications
Pilot Phase 1 Recap

- Gathered feedback on proposed data model (data elements, labeling sections) and draft guidance documentation

- Participants:
  - Bayer CropScience, Syngenta, Dow, SePRO, Reckitt Benckiser, EcoLab, Marrone Bio, Clorox, United Industries Corporation

- **Feedback: Overly complicated model**

- Resulted in revisions to the model and development of separate “Label” and “Use Index” modules
Pilot Phase 2 Recap

• Incorporated feedback received in Phase 1
• Completed draft vocabulary lists including definitions
• Pilot participants utilized User Guide and X-form to input labels (part of FDA’s SPL)
• Tested the “Label” module only
Feedback Pilot Phase 2

• Data model is simpler and more user friendly
• Appreciation for engaging stakeholders and iterative approach
• Data elements being collected will create efficiencies for states
• The x-form (xml builder) is cumbersome and may require IT security setting exceptions at your location
• IT challenges and need for “Use Index” resulted in new work on the builder
2016 Update

• Developed the XML schema, documentation, builder and query tool in order to test the data standard for “Label”, “Use Index” and “MRL” modules
• Builder is accessible in the Pesticide Submission Portal (PSP) test environment
• Completed internal testing and various sprint cycles of “Label” and “Use Index”
• Updated user guidance documentation
Pilot Phase 3

- Launch Phase 3 on September 21, 2016
  - In-person meeting with the 9 pilot participants to go through the builder and pilot timeline
- Registrant testing period through December 2016
- Registrants will test for ~ 3 weeks then submit feedback for us to take back to the contractors; 2nd round of testing
- During the pilot, the SmartLabel webpage will have a link so the public can also view the builder and provide feedback (October)
Contacts and Resources

• Pilot web page
  – http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot

• Comments welcome
  – Smartlabel@epa.gov

• Project leads
  – Label: Nicole Zinn, zinn.nicole@epa.gov
  – Use Index: Claire Paisley-Jones, paisley-jones.claire@epa.gov
  – MRL: Julie Chao, chao.julie@epa.gov