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- Gathered feedback on proposed data model (data elements, labeling sections) and draft guidance documentation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 thought 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
 - <u>http://www2.epa.gov/pesticide-registration/pesticide-smartlabel-pilot</u>
- Comments welcome
 - <u>Smartlabel@epa.gov</u>
- Project leads
 - Label: Nicole Zinn, <u>zinn.nicole@epa.gov</u>
 - Use Index: Claire Paisley-Jones, <u>paisley-jones.claire@epa.gov</u>
 - MRL: Julie Chao, <u>chao.julie@epa.gov</u>