

US EPA ARCHIVE DOCUMENT

# *SESSION V - Update on IT Initiatives*

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# SmartLabels

- ▶ Electronic submission of label content
  - ▶ Receive, validate, & review of label content
  - ▶ Issue decision and make label content available
- ▶ Primarily focus on structured label content, rather than format
  - ▶ Structured content refers to information or content that has been broken down and classified using metadata
  - ▶ Label format reviewed for visual and graphical requirements (e.g., bee box)
- ▶ EPA partnering with FDA
  - ▶ Building on FDA's structure product labeling success
  - ▶ Drafting XML specification, vocabularies, and validation rules
- ▶ Targeting pilot late summer 2014
  - ▶ Actively seeking input from stakeholders and regulatory partners

# Electronic CSPA

- ▶ Confidential Statement of Product Specifications (CSPA) is a consolidated and harmonized version of EPA's CSF and Canada's Specification form
  - ▶ EPA and Canada's PMRA identified the need for a consolidated form during 2011 product chemistry workshop
  - ▶ Developed as an Action item under the U.S. - Canada Regulatory Cooperation Council (RCC)
  - ▶ Harmonizing will allow applicants to submit a similar form to both agencies
- ▶ Electronic tool will assist registrants in filling out CSPA, submit electronically to PMRA and EPA
  - ▶ EPA conducted an internal pilot using the CSPA paper form and CSFs of products
  - ▶ Planning to allow the current CSF form to be submitted on paper while conducting a voluntary pilot for the eCSPA
  - ▶ Preliminary work is underway to identify a common IT approach that is usable by both EPA and PMRA

# Endangered Species Assessment Knowledge Database

- ▶ Database with searchable life history and biological information for listed species
- ▶ Includes repository to store referenced publications
- ▶ Listed Terrestrial Animals
  - ▶ Species-specific body weights, diets, obligate relationships, habitat descriptions and elevation restrictions
- ▶ Listed Terrestrial Plants
  - ▶ Species attributes are currently being gathered for the 435 terrestrial plant species found within the lower 48 states
  - ▶ Initial data collection is 90% complete
- ▶ Interagency Data Sharing
  - ▶ EPA in discussions with USFWS to share ESA Knowledge Database to help populate their finer scale species location database
  - ▶ Pilot collaboration starts with roughly 50 species in Arizona

# Registration Submission Milestone Tracker

- ▶ Automated emails sent to registrants for seven key milestones
  - ▶ Integrated with internal workload tracking
  - ▶ Registrant must supply email address for each application to receive notifications
  - ▶ Phase 1 implemented January 1, 2014
  - ▶ EPA will work with stakeholder workgroup to identify desired Phase 2 implementation
- ▶ Bundling capability implemented
  - ▶ Single email per milestone for related decisions (e.g., new AI and multiple end use products)