QA Considerations for WDL Workflows

Pesticide Stewardship Conference

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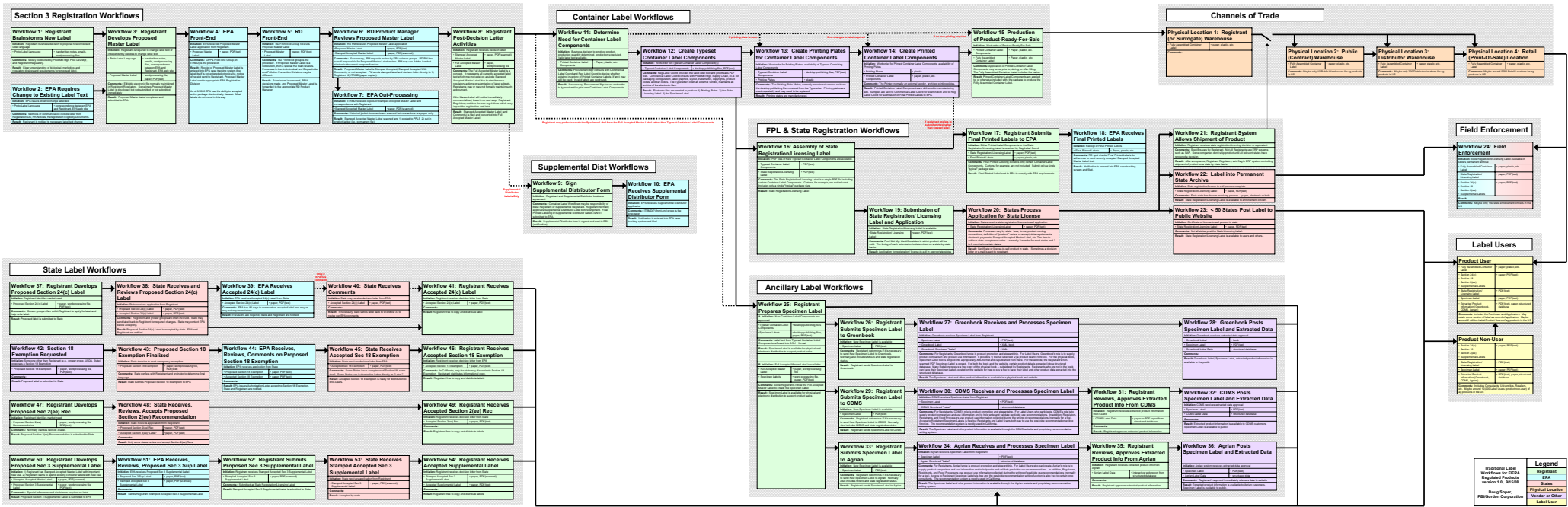
Doug Soper

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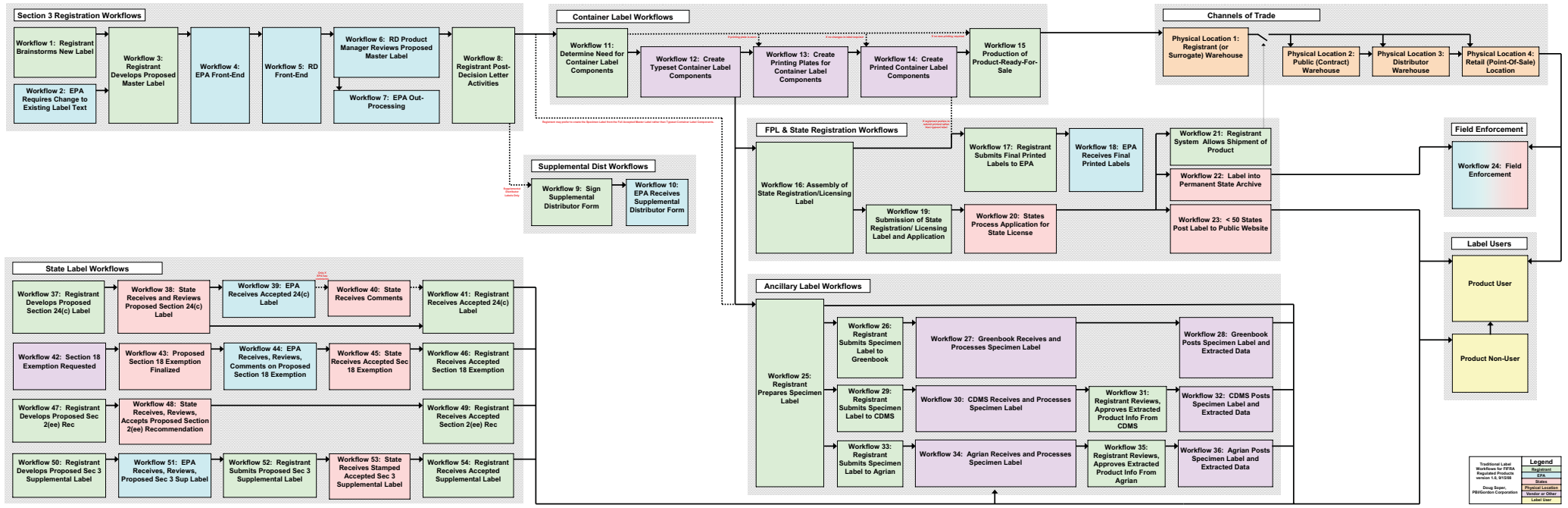
Three major electronic labeling initiatives

1. ALSTAR

2. Web-Based Distribution of Labels

3. Structured Product Labeling

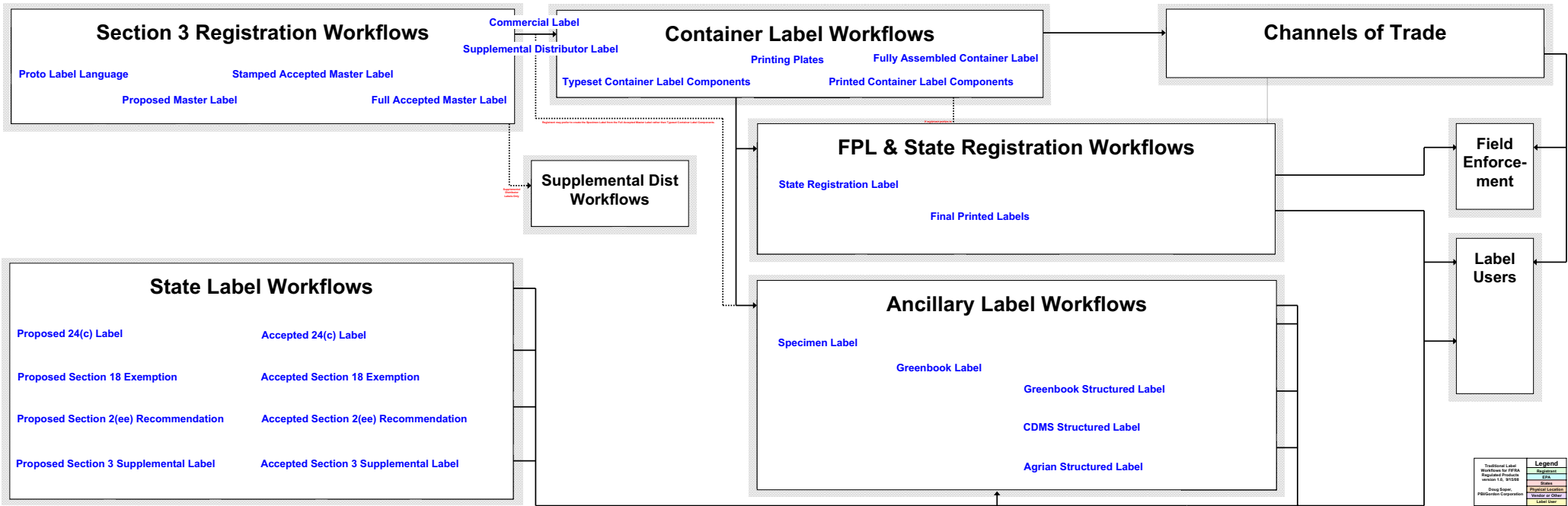# Traditional Label Workflows for FIFRA Regulated Products (v1.0)

Traditional Label Workflows for FIFRA Regulated Products (v1.0)

Section 3 Registration Workflows

- **Workflow 1:** Registrant Brainstorms New Label
- **Workflow 2:** EPA Requires Change to Existing Label Text
- **Workflow 3:** Registrant Develops Proposed Master Label
- **Workflow 4:** EPA Front-End
- **Workflow 5:** RD Front-End
- **Workflow 6:** RD Product Manager Reviews Proposed Master Label
- **Workflow 7:** EPA Out-Processing
- **Workflow 8:** Registrant Post-Decision Letter Activities

Container Label Workflows

- **Workflow 11:** Determine Need for Container Label Components
- **Workflow 12:** Create Typeset Container Label Components
- **Workflow 13:** Create Printing Plates for Container Label Components
- **Workflow 14:** Create Printed Container Label Components
- **Workflow 15** Production of Product-Ready-For-Sale

Channels of Trade

- **Physical Location 1:** Registrant (or Surrogate) Warehouse
- **Physical Location 2:** Public (Contract) Warehouse
- **Physical Location 3:** Distributor Warehouse
- **Physical Location 4:** Retail (Point-Of-Sale) Location

Supplemental Dist Workflows

- **Workflow 9:** Sign Supplemental Distributor Form
- **Workflow 10:** EPA Receives Supplemental Distributor Form

FPL & State Registration Workflows

- **Workflow 16:** Assembly of State Registration/Licensing Label
- **Workflow 17:** Registrant Submits Final Printed Labels to EPA
- **Workflow 18:** EPA Receives Final Printed Labels
- **Workflow 19:** Submission of State Registration/ Licensing Label and Application
- **Workflow 20:** States Process Application for State License
- **Workflow 21:** Registrant System Allows Shipment of Product
- **Workflow 22:** Label into Permanent State Archive
- **Workflow 23:** < 50 States Post Label to Public Website

Field Enforcement

- **Workflow 24:** Field Enforcement

Label Users

- Product User
- Product Non-User

State Label Workflows

- **Workflow 37:** Registrant Develops Proposed Section 24(c) Label
- **Workflow 38:** State Receives and Reviews Proposed Section 24(c) Label
- **Workflow 39:** EPA Receives Accepted 24(c) Label
- **Workflow 40:** State Receives Comments
- **Workflow 41:** Registrant Receives Accepted 24(c) Label

- **Workflow 42:** Section 18 Exemption Requested
- **Workflow 43:** Proposed Section 18 Exemption Finalized
- **Workflow 44:** EPA Receives, Reviews, Comments on Proposed Section 18 Exemption
- **Workflow 45:** State Receives Accepted Sec 18 Exemption
- **Workflow 46:** Registrant Receives Accepted Section 18 Exemption

- **Workflow 47:** Registrant Develops Proposed Sec 2(ee) Rec
- **Workflow 48:** State Receives, Reviews, Accepts Proposed Section 2(ee) Recommendation
- **Workflow 49:** Registrant Receives Accepted Section 2(ee) Rec

- **Workflow 50:** Registrant Develops Proposed Sec 3 Supplemental Label
- **Workflow 51:** EPA Receives, Reviews, Proposed Sec 3 Sup Label
- **Workflow 52:** Registrant Submits Proposed Sec 3 Supplemental Label
- **Workflow 53:** State Receives Stamped Accepted Sec 3 Supplemental Label
- **Workflow 54:** Registrant Receives Accepted Supplemental Label

Ancillary Label Workflows

- **Workflow 25:** Registrant Prepares Specimen Label
- **Workflow 26:** Registrant Submits Specimen Label to Greenbook
- **Workflow 27:** Greenbook Receives and Processes Specimen Label
- **Workflow 28:** Greenbook Posts Specimen Label and Extracted Data
- **Workflow 29:** Registrant Submits Specimen Label to CDMS
- **Workflow 30:** CDMS Receives and Processes Specimen Label
- **Workflow 31:** Registrant Reviews, Approves Extracted Product Info From CDMS
- **Workflow 32:** CDMS Posts Specimen Label and Extracted Data
- **Workflow 33:** Registrant Submits Specimen Label to Agrian
- **Workflow 34:** Agrian Receives and Processes Specimen Label
- **Workflow 35:** Registrant Reviews, Approves Extracted Product Info From Agrian
- **Workflow 36:** Agrian Posts Specimen Label and Extracted Data

Legend

Traditional Label Workflows for FIFRA Regulated Products
version 1.0, 9/15/08
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- Registrant
- EPA
- States
- Physical Location
- Vendor or Other
- Label User

Traditional Label Workflows for FIFRA Regulated Products (v1.0)

Section 3 Registration Workflows

Proto Label Language

Stamped Accepted Master Label

Proposed Master Label

Full Accepted Master Label

Commercial Label

Supplemental Distributor Label

Container Label Workflows

Printing Plates

Fully Assembled Container Label

Typeset Container Label Components

Printed Container Label Components

Channels of Trade

Supplemental Dist Workflows

FPL & State Registration Workflows

State Registration Label

Final Printed Labels

Field Enforce-ment

State Label Workflows

Proposed 24(c) Label

Accepted 24(c) Label

Proposed Section 18 Exemption

Accepted Section 18 Exemption

Proposed Section 2(ee) Recommendation

Accepted Section 2(ee) Recommendation

Proposed Section 3 Supplemental Label

Accepted Section 3 Supplemental Label

Ancillary Label Workflows

Specimen Label

Greenbook Label

Greenbook Structured Label

CDMS Structured Label

Agrian Structured Label

Label Users

Traditional Label Workflows for FIFRA Regulated Products version 1.0, 9/15/08	Legend
	Registrant
	EPA
	States
Doug Soper, PBI/Gordon Corporation	Physical Location
	Vendor or Other
	Label User

Label Workflows

Documenting existing label worksflows is an effective method to visualize the scope of the changes that would be necessary for any of the electronic label initiatives.

The workflow chart is a reminder that that organizations have real life workflows that will be affected:

- EPA
- State Agencies
- Field Enforcement
- Registrants
- Channels of Trade
- Label Users

- Other
  - Regulatory Consultants
  - Supplemental Distributors
  - Typesetters, Printing Plate Makers, Printers
  - Greenbook, CDMS, Agrian

Label Types

The workflow chart depicts the label as a set of 21 distinct representations which **vary in content, layout, and structure.**

- Proto Label Language
- Proposed Master Label
- Stamped Accepted Master Label
- Full Accepted Master Label
- Commercial Label
- Supplemental Distributor Label
- Typeset Container Label Components
- Printing Plates
- Printed Container Label Components
- Fully Assembled Container Label
- State Registration Label

- Final Printed Labels
- Specimen Label
- Greenbook Label
- Greenbook Structured "Label"
- CDMS Structured "Label"
- Agrian Structured "Label"
- Section 24(c) Label
- Section 18 Exemption
- Section 2(ee) Recommendation
- Section 3 Supplemental Label

WDL & Structured Labels

The Structured Label is the Lynchpin of WDL

- It is not a technical requirement that a WDL must be a Structured Label.

- It is not a technical requirement that a WDL must start its life as a structured Proposed Master Label.

- **HOWEVER . . .** workteams looking at the issues assume that a WDL **will be** structured at the Proposed Master Label stage before flowing through to Web Distribution

- Therefore EPA's Structured Label Project (E-Label) and the resulting process changes for EPA and registrants **loom large on the critical path** to WDL.

- **Also therefore, many of the workflow questions about WDL concern Structured Labels.**

Quality Assurance

1. High Level Issues   (Fit for Purpose)

2. Mid Level Issues   (How the Process Fits Together)

3. Low Level Issues   (Operational Details)

Mid Level Issues - Federal Registration Workflows

- Would EPA review Commercial Labels (and Supplemental Distributor Labels) for subsetting and text currently not reviewed?

- If so, would EPA review 1) the structured data or 2) a set of all possible assembled-on-the-fly labels which come from the structured data or 3) both? Would each new style sheet need to be reviewed?

- How would the migration of existing labels into structure be handled? Complete re-review? How long would it take?

- **Is the net effect an expansion of EPA responsibilities and the need for additional resources?**

Mid Level Issues - State Registration Workflows

- Would states still receive labels from registrants or review them directly in the central database? Would registrants or states maintain state registration status in the central database?

- Would states review 1) structured data or 2) a set of all possible assembled-on-the-fly labels which come from the structured data or 3) the typeset container label or 4) some/all of the above? Would each new style sheet need to be reviewed?

- If the label is assembled from a central database of EPA accepted labels, what sort of state label review is still necessary?

- Would 24(c)s, Section 18s, and 2(ee)s be structured? Requires special infrastructure at state level?

- **Would states continue to do things 50 different ways?**

Mid Level Issues - Registrant Workflows

- Today the registrant is able to subset, add non-reviewed text, and add presentation graphics **after** EPA review. Would these decisions be shifted **before** EPA review?

- Would label changes require revalidation of all possible assembled-on-the-fly labels?

- Less to typeset, plate, print, assemble? Still produced in QuarkXpress or InDesign? Via XML or current workflows?

- Need a new label code to link the Fully Assembled Container Label to Web Distributed Label? The code links to a: Registration number? Product name? Package size? Stamped Accepted Label/Notification? Date of production? Date of sale?

Mid Level Issues - Field Workflows

- Shifts responsibility for critical label workflows to Retailers/End-Users -- where previous label workflows were minimal?

- Even if the legal responsibility to obtain the label lies with the End-User, the Retailer will get drawn into it. Imagine, "If you can't sell me the product with all the necessary documentation to use it, then I'll buy it somewhere else."

- To work at the retail level, some kind of automation is necessary? Manually entered code likely to be too error prone, time-consuming? Labels connected to a (new?) bar code or directly integrated into Retailer systems?

High Level Issues

What is the core objective of WDL?

Increase real-world end-user compliance with the label by . . .

- Making long labels easier to read and comprehend
- Making it possible to update Directions for Use

- What is the value of the *mere presence* of the complete label on every container?
- Do we really believe we'll get better compliance by making the label *less easily* available?
- Is there an objective measure of readability? Lexile?
- How many "long labels" are there? Do these labels justify WDL and all it entails?
- Is there a model for what we're trying to do from another industry? Can we build on existing concepts (DITA, . . .)?

QA Considerations for WDL Workflows

Thank You

Backup Slides

Additional Mid Level Issues

- Will Structured Labels require new label authoring software to write a Proposed Master Label? New expertise required? Will the label writing process become more cumbersome?

- Will Structured Labels require a new process to communicate and incorporate EPA comments back into label? Resubmit corrected label for another review?

- Will Structured Labels kill the Stamped Accepted Master Label? What kind of document authentication is necessary outside EPA?

- With Structured Labels will the registrant still control the sole editable label file? Or will there be some kind of joint edit rights?

- There are potentially three kinds of Structured Label transformations? 1) registrant desired subsetting (exists today)? 2) end-user desired subsetting (print label only for specific crop, etc.)? 3) style sheet (presentation style rendition)?

Additional Mid Level Issues

- EPA would need new system to manage Structured Label in-processing, routing, review, and out-processing?

- What are core objectives of Structured Labels?
    - To create a more efficient label review process at EPA?
    - To create a new LUIS-like database of label information?

- How will label review efficiency be measured? If not achieved, what happens?

- Both WDL and Structured Labels probably will have different requirements for label structure.

- For the registrant, WDL implies a shift of internal responsibilities from Supply Chain to Regulatory?

Additional Mid Level Issues

- Phone access may be adequate for End-Users without Internet. But not practical for Retailers? Provision to stockpile labels for subsequent distribution?

- Greenbook, CDMS, Agrian must change their data models to conform to WDL? Registrant still proofs CDMS and Agrian?

- Structure comes in degrees. How structured will labels be? Three broad possibilities? Metadata only (minimal structure)? XML text markup for display? Index every piece of the label (fully structured)? Or some combination?

- Higher levels of structure imply separation between the text (content) and the rendering rules (layout, formatting). Effect on readability?

- What sort of system is required to parse the XML files and produce assembled-on-the-fly custom labels. Sophisticated? Subject to downtime? Expertise required?