US EPA ARCHIVE DOCUMENT

Documenting Label Workflows

PPDC Sub-Committee on WDL

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Three major electronic labeling initiatives

1. ALSTAR
2. Web-Based Distribution of Labels
3. Structured Product Labeling

Groups discussing electronic labeling

- EPA Internal Workgroup on Web-Distributed Labels
- PPDC Sub-Committee on Web-Distributed Labels
- EPA Internal Workgroup on Structured Labels (E-Label)
- ALSTAR Project Team
- CLA Electronic Labeling Issues Management Team
- CLA Electronic Submission Work Group
- SFIREG-POM Committee
- Pesticide Stewardship Alliance
- Others?

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

Workflow: Definition

A logical sequence of operations, decisions, and activities. Includes statuses, status transitions, information dependencies, interdependent tasks, and prerequisites.

The basic components can be defined by three parameters:

Workflows Generally	**In This Workflow**
1. Input Description	1. Initiation
2. Transformation Rules	2. Physical or electronic format of the label and comments
3. Output Description	3. Result

Why so many workflows?

- Is the net effect of the workflow chart to overstate the complexity or are we just organizing a very complex system?
- The attempt, at least, was to simplify the system by only showing a separate workflow for each important change in accountability.
- One thing we know for sure. By presenting 50 state registration workflows as a single process, the chart understates the complexity of that portion of the chart.

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

Section 3 Registration Workflows

Workflow 1: egistrant Brainstorms R l
Initiation: Registrant business decision to opose new sed label anguage or revi sed
• Photo Label Language
• handwritten notes, emails, wordprocessing files
Comments: Mostly Registrant Regulatory Affairs Staff, but Mkt Mgr, Prod Dev Mgr, ng of Language, artwork, ng Regulatory Affairs Staff may be involved
• handwritten notes, emails, wordprocessing files, correspondence between Registrant & ats, by paper, PDF(Sent)
Result: Proposed Label ed to Master Label

Workflow 2: PA Change to E isting Registered
Initiation: EPA issues rder o hange label ent
• Photo Label Language
• Communications between EPA and Registrant, PA eb site
Comments: Methods of communication include letter from Registration Div, PR-Notices, Reregistration Eligibility ocuments.
Result: Registrant is ified to necessary label ed. change

Workflow 3: egistrant Develops Pr posed Master Labe
Initiation: Registrant re ved to change label text or indi spensibility decides to change label
• Photo Label Language
• handwritten notes, emails, wordprocessing files, correspondence between EPA & Registrant, by paper, PDF(Sent)
• Proposed Master Label
• wordprocessing files, by paper, PDF(Sent)
Comments: Editable electronic fo ality maintained in egistrant Regulatory ons/Records of Proposed Master Label d spond but is submitted or not submitted
Result: Proposed Master Label pared and submitted to EPA. com

Workflow 4: EPA Front-En
Initiation: EPA receives Proposed Master Label ication from egistrant
• Proposed Master Label
• paper, PDF(Sent)
Comments: OPP's Front nd Group (in ITRMD) is the processor. Proposed Master Label is entered into ms for the adding in the label itself. EPA ca ate electronic ed. For of receipt submitted by egistrant, rejected Master Label and to appropriate ir ganization Divisions, e EPA ma

No EPA has the ability to electronically ve Proposed Master Label ed labels do not come in s, ia ts. e

Workflow 5: Front-En RD
Initiation: RD rom End Group receives Proposed Master Label
• Proposed Master Label
• paper, PDF(Sent)
Comments: RD rom End group is the processor. Proposed Master Label is entered into ms for the adding in the Processes in ndividual Chemical Branch/Microbial and Pollution Prevention visions may be involved.
Result: Proposed Master Label is reviewed, PRIA decisions made, and Proposed Master Label is forwarded to the appropriate RD roduct Manager.

Workflow 6: Product Manager Reviews Pro osed Master Label
Initiation: RD M ger Proposed Master Label ication
• Proposed Master Label
• paper, PDF(Sent)
• Stamped Accepted Master Label
• paper, PDF(scanned)
Comments: If necessary, PM may ask PA ance groups, or overall Site Impact Statement to Su Re ew may use ANALYZE Chat electronic review and Explore function. rev
Result: Proposed Master Label is tamped Accepted, Stamped Accepted With Comments, or not ed. Th ge ted label is sent to RD Project Manager (ITRMD) and Branch Chief, and dec on of to ri) paper and

Workflow 7: A ut-Processing
Initiation: ITRMD ves copies tamped Accepted Master Label correspondence with Registrant of S. and
• Stamped Accepted Master Label
• paper, PDF(scanned)
Comments: Historically, adult documents are scanned but new ons are paper only
Result: Stamped Accepted Master Label is scanned and ? posted to PPLS product jacket (i.e., ? ment file) put in ? jacket

Workflow 8: Registrant Post-Decision Letter Activities
Initiation: Registrant receives decision letter.
• Proposed Master Label
• paper, PDF(Sent)
Comments: If necessary, PM may ask PA ance groups, or overall Site Impact Statement to Su Re ew may use ANALYZE Chat electronic review and Explore function. rev
Result: Proposed Master Label is tamped Accepted, Stamped Accepted With Comments, or not ed. Th ge ted label is sent to RD Project Manager (ITRMD) and Branch Chief, and dec on of to ri) paper and

Container Label Workflows

Workflow 11: etermin Need for Con Container Components
Initiation: Business decision to produce product, production quantity determined, production scheduled. Label Change Request
• Printed Container Components
• Paper, plastic, Label etc
Comments: Procurement Mgr consults with Commercial Label ound and Reg Label ound to de whether Container Components Label ed. Mgr may ask ANALYZE Chat ANALYZE function. rev
Result: If rocurement Mgr issues workorder to typeset/revise/approve Printed Container Label components and/or pri C C

Workflow 12: Create Typese Container Label Components
Initiation: Workorder for Typeset ontainer Label ponents)
• Typeset Container Label components
• desktop publishing files, DF(text)
Comments: Reg Label ated provides the valid label text and proof/Adds PDF Container Label ed. Typesetter may ask ANALYZE Chat ANALYZE function. rev for packaging configuration Color ns, layout, trademarks, copyrights, Label ot codes, and bar codes. The Typesetter, after an external ve ndor, maintains an archive of ll sections files.
Result: Electronic files reated to Container Label ed. n 1) Printing tates the State Label).

Workflow 13: eate Printing Plates for Container Label Components
Initiation: Workorder for Printing Plates, availability of ypeset Container Label components
• Typeset Container Label
• desktop publishing files, DF(text)
• Printing Plates
• plastic
Comments: The Printing tate Maker, ally, a formal ves the desktop publishing file received from Label ontainer Label components and/or pri C C
Result: Printing plates are manufactured

Workflow 14: eate Printed Container Label Components
Initiation: Workorder for Printed Container Label components, availability of Printing Plates
• Printing Plates
• plastic
• Printed Container Components Label
• paper, plastic, etc
Comments: The Printer, normally a formal ives printing plates.
Result: Printed Container components are delivered to manufacturing site. amples are sent to Label Quality Control for examination and to egistrant/Label Users for approval.

Workflow of Product Ready for Sale
Initiation: Workorder or instruct Ready-For-Sale
• Printed Container Components Label
• Paper, plastic, etc
• Fully assembled Container Label
• Paper, plastic, to.
Comments: Application of rinted Container Label Components may occur offsite ing, or on filling. The Fully Assembled Container Label may be ed to Label Users.
Result: Printed Container Label components are applied to product and/or product is packaged. Product is now ready for sale. Finished Container Label package to

Supplemental ws Dist Workflo

Workflow 9: Supplemental Di tributor Form
Initiation: Registrant and Supplemental istributor business agreement
Comments: Container Label Workflows may be used for Supplemental Registrant approves Supplemental istributor submitted s. Printed Labeling of Supplemental Label Distributors is OT submitted to
Result: Supplemental istributor s igned and sent to EPA (Notification) or ? form) e.

Workflow 10: EPA Receives Supplemental Distributor Form
Initiation: EPA receives supplemental istributor notification
Comments: ITRMD/? front-end group is the processor.
Result: Notification is ntained into ase tracking system and E EPA c

Supplemental Disclosure Labels Only

Channels of Trade

Physical Location 1: rant (or Surrogate) Warehouse t
• Fully assembled Container Label
• paper, plastic, etc
Comments:

Physical Location 2: Public (Contract) Warehouse
• Fully assembled Container Label
• paper, plastic, etc
Comments: Maybe only 10 Public Warehouses for ag products

Physical Location 3 Distributor Warehouse
• Fully assembled Container Label
• paper, plastic, etc.
Comments: Maybe around 5000 Retail tors for products. Maybe 200 D

Physical Location 4: Retail (Point-Of-Sale) ation Loc
• Fully assembled Container Label
• paper, plastic, etc
Comments: Maybe around 5000 Retail tors for products. Maybe 200 D

FPL & State Registration Workflows

Workflow 16: Assembly f ate Registration/Licensing Lab el
Initiation: PDF files of ew typeset Container Label Components
• State Registration/Licensing Label
• PDF(text)
Comments: The State Registration/Licensing Label is ingle PDF file including certain Container Label components. Cartons, for example, are not included in this process.
Result: State Registration/Licensing Label

Workflow 17: Registrant s Final Printed Labels to EPA ubmit
Initiation: Either rinted Label ponents or the State Registration/Licensing Label ed by Reg Label. pared
• State Registration/Licensing Label
• paper, PDF(Sent)
• Final rinted Labels
• paper, plastic, etc
Comments: Final rinted ing includes only ten Container Label Components. Cartons, Labels, are not included. Submit y a typical package size. to
Result: Final rinted abel sent to EPA1 c e EPA r

Workflow 18: EPA ceives Final Printed Labels Re
Initiation: Receipt of Final rinted Labels
• Final rinted Labels
• Paper, plastic
Comments: Registrant checks Final Printed Labels for adherence to Container Label Components. Registrant Label t.
Result: Notification is ntained into ase tracking system and E EPA c

Workflow 19: Submission of State Registration/ Licensing Label and Application
Initiation: State egistration/Licensing Label is ilable.
• State Registration/ Licensing Label
• paper, PDF(Sent)
Comments: Prod Mkt Mgr identifies states in which product will sold. The timing of each submission is t mined on a state-by-state basis?
Result: Application for registration/ license to sell in ate states is appropriate.

Workflow 20: tates Process Application fo State License
Initiation: States receive state registration/license-to-sell ication
• State Registration/ Licensing Label
• paper, PDF(Sent)
Comments: Processes vary by states, product naming conventions, distributor requirements, ments, application forms, etc. Most Accepted Registrations are valid for a time period (usually 5 ars – normally 3 months to 5 years). Registrations must be renewed before expiration.
Result: Certificate or license-to-sell ed. Sometimes a decision letter ve is To registrant, product is ilable. or ance ? label

Workflow 21: Registrant ystem Allows ent of Product Shipm
Initiation: Shipment to registration/licensing decision or valent
Comments: Generally, the ship ments shipping ity of such ? ne ucts ? ucts Finish ? ? ucts Label ers ? ? ucts Label ers ? ? ucts Label ers

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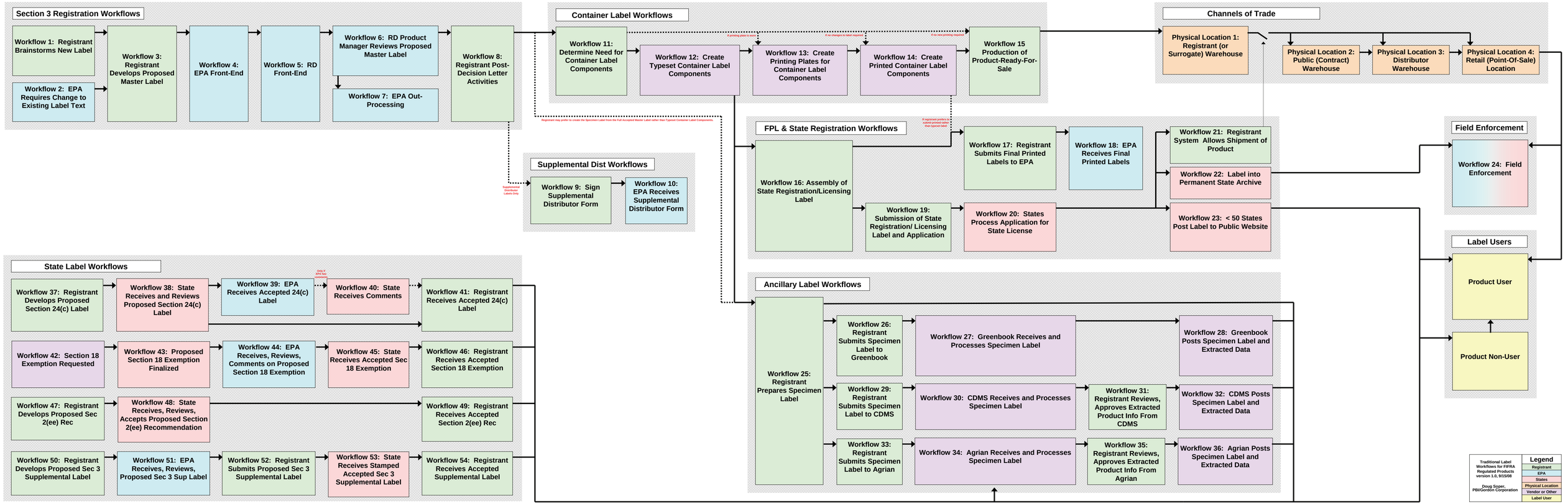

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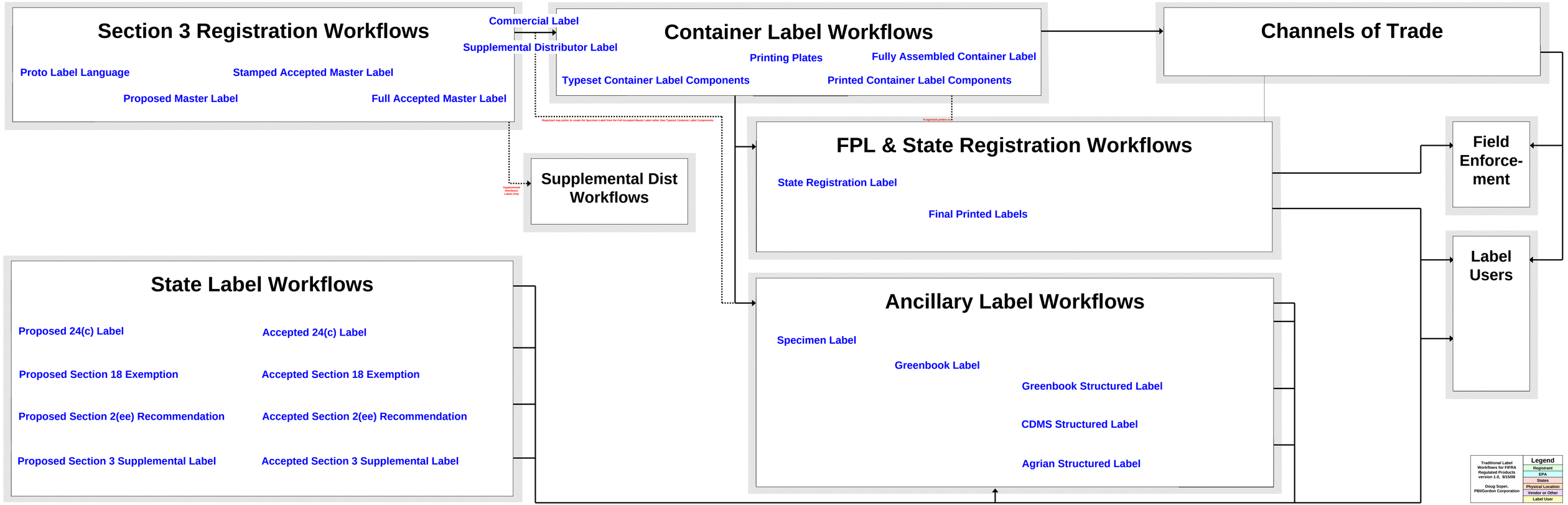

Five Observations

1. Large Scale Process and Not Uniform
2. Many Label Types
3. The Seamless Label
4. State-By-State Adoption
5. The Structured Label is the Lynchpin of WDL

1. Large Scale Process and Not Uniform

- The whole process is big enough that no one understands the details of all workflows.
- Workflows vary between registrants and vary between states.
- Many opportunities for improvement exist but changes will be complex and **will force more uniformity on registrants and states.**

2. Many 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

3. The Seamless Label

- The concept that the **same label content** flows through a series of approval processes. Today the label is not seamless.
- The Commercial Label may be a subset of the Stamped Accepted Master Label.
- The Master Label may include placeholder text for information that may change frequently and does not require EPA review. So the Commercial Label may include information that is not on the Master Label.
- A Seamless Label would **change the EPA review process and require additional resources.** Registrants would resist changes which reduce their existing flexibility to control labels in commerce.

4. State-By-State Adoption

- **Critical Issue:** Will each state make its own decision to adopt Web-Distributed Labels?
- Without simultaneous, nationwide implementation, Web-Distribution would increase registrants' SKUs, i.e., there would be a full-label and reduced-label version of each product/size combination in scope.
- It would increase costs and would be a new inventory control burden.
- **Registrants won't favor state-by-state adoption.**

5. 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.

Summary

Documenting existing **label worksflows** is an effective method to visualize the scope of the changes that would be necessary for Web-Distributed Labels.

Analysis of the workflows can help ensure that we don't leave something important "on the cutting room floor."

Documenting Label Workflows

Thank You

Backup Slides

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Traditional Label Types And Their Interaction With The Three Electronic Label Initiatives (v1.0)

Label Type	Electronic Form	Information Content	Comments	ALSTAR	Structured Label	Web Distribution
Proto Label Language	1. Handwritten notes 2. Emails 3. Wordprocessing files 4. Correspondence between EPA and Registrant 5. EPA web site	Fragments of text coming from almost anywhere, especially other labels, product development, marketing, EPA.	Used to produce a label for a new registration or an amendment /notification to an existing registration.	ALSTAR requires no changes to the existing Proto Label Language.	Structured Labels would require no change to the existing Proto Label Language.	Web Distribution requires no changes to the existing Proto Label Language.
Proposed Master Label	1. Wordprocessing file 2. Paper 3. PDF (text)	The Section 3 label language proposed by the registrant and submitted to EPA for acceptance. It contains all of the label text which must be accepted by EPA. (For amendments and notifications, sometimes it contains only those portions of the label which the Registrant proposes to change.) Very frequently, it includes text which the registrant opts not to print on a Commercial Label. For example: 1. use sites 2. rate ranges 3. container specific text (Storage and Disposal, Directions for Use) 4. application types 5. pests 6. alternate Warranty Statements 7. advertising claims 8. user specific text (commercial vs consumer) 9. alternate format (tabular vs narrative vs graphic instructions). Very frequently, it does not contain all information which may be printed on a Commercial Label. For example: 1. telephone number and product name placeholders instead of actual number or name 2. spreader setting placeholder chart 3. placeholder referral statements (see back panel for . . .) 4. fertilizer analysis details 5. graphics for attractive presentation 6. Spanish translation 7. company logo 8. alternate brand names 9. EPA Est No. Very frequently, it includes text which must not print on a Commercial Label. For example: document control numbers, summary of changes, comments for the benefit of the EPA reviewer.	Sometimes it is developed by a registrant but not submitted or not submitted immediately. EPA may use it for electronic document compare.	ALSTAR requires no changes to the existing Proposed Master Label.	Structured Labels would require major changes to the existing Proposed Master Label. _____ 1. Necessary for EPA/state/registrant group to develop the FIFRA label structure 2. Necessary for EPA/state/registrant group to develop a tool to build structured label or find an existing tool. 3. Necessary for EPA to develop internal systems to store, retrieve, and work with structured labels (includes document compare functionality). 4. Necessary for registrants to create structured labels from existing unstructured labels. 5. Necessary for EPA to validate that new structured label is comparable to existing unstructured label. _____ **Potential conflict with existing responsibilities** Necessary for EPA/state/registrant group to evaluate the idea of a central structured label respository where EPA could directly modify and accept a label. It would change the current understanding of the respective responsibilities of the EPA and registrant (who owns and edits the Proposed Master Label?). _____ **Potential conflict with existing responsibilities & special dependency between Structured Labels and Web Distribution** If the Structured Proposed Master Label included the same information submitted and accepted today, a registrant would need to append the label before it could be released for web distribution to end-users. If the Structured Proposed Master Label included **all** information used on **all** Commercial Labels, it would change the current understanding of what EPA reviews and increase EPA workload. It would also reduce a registrant's flexibility to quickly modify a Commercial Label to correct typos, add or remove approved text, or change the label layout.	As envisioned by EPA, web distribution depends on the implementation of structured labels. Therefore web distribution would require the same major changes to the existing Proposed Master Label. _____ Decisions made for Structured Labels must align with the requirements of web distribution.

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Traditional Label Types And Their Interaction With The Three Electronic Label Initiatives (v1.0)

Label Type	Electronic Form	Information Content	Comments	ALSTAR	Structured Label	Web Distribution
Stamped Accepted Master Label	1. Paper 2. PDF (image-only)	Same content as the Proposed Master Label except it reflects the regulatory status change and it very frequently includes changes required by EPA. Changes required by EPA are listed on a cover letter. Therefore the Stamped Accepted Master Label includes both the cover letter and the original Proposed Master Label (now stamped). The EPA comments may be unambiguous about changes, e.g., "page 3, paragraph 4, add sentence '.Do not use on grasses grown for seed.'" Sometimes EPA comments are less specific, e.g., "add sentence to label 'Do not use on grasses grown for seed.'" And occasionally EPA comments are less specific, e.g., "Tables 1, 2, and 3 have similar content but different layouts. Choose the best format and layout all three tables the same."	The stamping process is physically performed on a paper copy. It is posted to PPLS.	ALSTAR requires no changes to the Stamped Accepted Master Label. It is treated as a document supporting state registration. Registrant chooses to upload (image-only PDF) or not.	Structured Labels would require major changes to the existing Stamped Accepted Master Label. 1. Physical stamping and scanning would almost certainly cease. 2. Necessary to develop a mechanism to capture EPA comments and send them to the registrant. 3. Necessary to insure that new Structured Accepted Master Label includes adequate means to establish document authenticity for organizations which may use it in their own processes.	Web Distribution probably does not require changes to the existing Stamped Accepted Master Label beyond those required by Structured Labels.
Full Accepted Master Label	1. Wordprocessing file	Same content as the Stamped Accepted Master Label but with the changes described on the EPA cover letter now included in the label itself.	Also the place where a registrant would combine accepted label text from simultaneous regulatory actions or submission of label subsets. If it is "too different" from the most recent Stamped Accepted Master Label, the registrant (or EPA) may decide it is necessary to resubmit the Full Accepted Master Label for EPA to review and to be stamped accepted in its new form.	ALSTAR requires no changes to the Full Accepted Master Label.	Structured Labels would require major changes to the existing Full Accepted Master Label. **Potential conflict with existing responsibilities** Today the registrant does not normally send the Full Accepted Master Label back to EPA. To do so would change the current understanding of what EPA receives (and reviews?) and would increase EPA workload. But structured labels don't make much sense unless EPA has the Full Accepted Master Label to compare against future Proposed Master Labels.	Web Distribution probably does not require changes to the existing Full Accepted Master Label beyond those required by Structured Labels.
Commercial Label	1. Paper 2. Wordprocessing file 3. PDF (text)	The label text which the registrant intends to put on the Fully Assembled Container Label. It may be a subset of the Full Accepted Master Label. It may contain additional text not present on the Full Accepted Master Label. It normally does not include graphics (for attractive presentation) used on the Typeset Container Label Components.	Some registrants do not formally maintain such a document.	ALSTAR requires no changes to the Commercial Label. Some registrants upload the Commercial Label to ALSTAR instead of the State Registration Label. If so, ALSTAR requires it to be a text PDF file.	Structured Labels would require no changes to the Commercial Label. Pouring the Structured Label into subsetted and/or multiple Commercial Label Stylesheets would require additional structure in the Structured Label. This "commercial structure" is different from label structure. Is this dual structure practical? **Potential conflict with existing responsibilities** See comments under Proposed Master Label.	Web Distribution starts with the content in the Commercial Label. Therefore Web Distributiion probably requires major changes to the existing Commercial Label. **Special dependency between Structured Labels and Web Distribution** Will Web Distribution start from: - A Structured Label containing some but not all of the text on a Commercial Label and then appended with the rest of the information? - A Structured Label containing all text on a Commercail Label?
Supplemental Distributor Label	1. Paper 2. Desktop publishing file 3. PDF (text)	Same as Commercial Label but branded under a different company name than the registrant.	Essentially a kind of Commercial Label. Normally exists only when the Typeset Container Label Components are needed. Requires submission of Supplemental Distributor Form to EPA but Final Printed Labels are not submitted.	See Commercial Label.	See Commercial Label.	See Commercial Label.
Typeset Container Label Components	1. Desktop publishing files 2. PDF (text)	The content is mostly the same as the Commercial Label except 1. text is limited to single package size and 2. reflects several commercial content elements: packaging configuration, label graphics, layout, trademarks, copyrights, product codes, and bar codes.	Prepared by a Typesetter, often a vendor hired by the registrant. Each label component of each package size is prepared as a separate file.	ALSTAR requires that the Typeset Container Label Components be available as text PDF files. This is not a major change for most registrants.	See Commercial Label.	Web Distribution would require major changes to the existing Typeset Container Label Components. It would reduce the amount ot text necessary to typeset.
Printing Plates	1. Plastic	Same as Typeset Container Label Components.	Prepared by a Printing Plate Maker, virtually always a vendor hired by the registrant. Relatively expensive to produce (especially color) so changes to labels at this stage are avoided.	ALSTAR requires no changes to the Printing Plates.	Structured Labels would require no changes to Printing Plates. A structured label implemented at this level would likely look different than today.	Web Distribution would require major changes to the existing Printing Plates. It would reduce the amount ot text necessary to plate.

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Traditional Label Types And Their Interaction With The Three Electronic Label Initiatives (v1.0)

Label Type	Electronic Form	Information Content	Comments	ALSTAR	Structured Label	Web Distribution
Printed Container Label Components	1. Paper 2. Plastic, etc.	Same as Typeset Container Label Components and Printing Plates.	Each label component is still a separate physical item.	ALSTAR requires no changes to the Printed Container Label Components.	Structured Labels would require no changes to Printed Container Label Components. A structured label implemented at this level would likely look different than today.	Web Distribution would require major changes to the existing Printed Container Label Components. It would reduce the amount ot text necessary to print.
Fully Assembled Container Label	1. Paper 2. Plastic, etc.	Same as Printed Container Label Components except now the components are applied to or otherwise included with the filled bottle, bag, etc.	Actual assembly may occur prior to, during, or after filling. The Fully Assembled Container Label includes the carton.	ALSTAR requires no changes to the Fully Assembled Container Label.	Structured Labels would require no changes to the Fully Assembled Container Label. A structured label implemented at this level would likely look different than today.	Web Distribution would require major changes to the existing Fully Assembled Container Label. It would reduce the amount ot text present.
State Registration Label	1. PDF (text)	Same as Typeset Container Label Components except 1. includes only a single package size 2. cartons are not included 3. single PDF file rather than separate file for each component.	After acceptance many states post on a public web site. Some states require paper rather than electronic files.	ALSTAR requires that the State Registration Label be available as single text PDF file. This is not a major change for most registrants.	Structured Labels would require no changes to the State Registration Label. A structured label implemented at this level would likely look different than today.	Web Distribution would require major changes to the existing State Registration Label. Since the Fully Assembled Container Label would no longer contain the complete label, the definition of the State Registration Label would change.
Final Printed Labels	1. Paper 2. Plastic, etc.	Normally the same as the State Registration Label.	Registrants submit different things as Final Printed Labels: 1. the Full Accepted Master Label 2. the Printed Container Label Components (only one container size) 3. the State Registration Label 4. the Commercial Label.	ALSTAR requires no changes to the Final Printed Label.	Structured Labels require no changes to the Final Printed Label. A structured label implemented at this level would likely look different than today.	Since Web Distribution redefines the label as it is distributed, the Final Printed Label would change. Q: Given a central database of web distributed labels, would submissiion of a Final Printed Label still be necessary? A: Probably
Specimen Label	1. Desktop publishing file 2. Wordprocessing file 3. Paper 4. PDF (text)	Normally the same as Commercial Label except sometimes including extra information like a list of 24(c)s and/or advertising. Some registrants use the State Registration Label.	Aside from the Fully Assembled Container Label, it is the primary written means to communicate product information to potential product users.	ALSTAR requires no changes to the Specimen Label.	Structured Labels require no changes to the Specimen Label. A structured label implemented at this level would likely look different than today.	Web Distribution would require no changes to the Specimen Label. Q: Given a central database of web distributed labels, would registrants still produce Specimen Labels? A: Reduce but not eliminate.
Greenbook Label	1. XML 2. Book	Same as Specimen Label. Re-entered as XML and re-flowed into Greenbook Stylesheet for printed book.	Registrant also provides information like MSDSs.	ALSTAR requires no changes to the Greenbook Label. ALSTAR would be a potential source of full label.	Structured Labels would require no changes to the Greenbook Label. If similar enough, Structured Labels might flow into Greenbook Label.	Web Distribution would require no changes to the Greenbook Label. Q: Given a central database of web distributed labels, would the Greenbook still have a role. A: Probably
Greenbook Structured "Label"	1. XML	Certain information extracted from Greenbook Label: e.g., crops, pests, precautionary statements. Also state registration status.		ALSTAR requires no changes to the Greenbook Structured "Label." ALSTAR would be a potential source of label and state registration data.	Structured Labels would require no changes to the Greenbook Structured "Label." If similar enough, Structured Labels might flow into Greenbook Structured "Label."	Web Distribution would require no changes to the Greenbook Structured "Label."
CDMS Structured "Label" **(proposed & accepted)**	1. Structured data	Most of the information in the Specimen Label is extracted into database. For use in writing and validating pesticide application recommendations.	Proprietary database. Registrant approves records before release. Largest group of users is in California. Registrant also provides other information like MSDSs and state registration status.	ALSTAR requires no changes to the CDMS Structured "Label." ALSTAR would be a potential source of label and state registration data.	Structured Labels would require no changes to the CDMS Structured "Label." If similar enough, Structured Labels might flow into CDMS Structured "Label."	Web Distribution would require no changes to the CDMS Structured "Label."
Agrian Structured "Label" **(proposed & accepted)**	1. Structured data	Most of the information in the Specimen Label is extracted into database. For use in writing and validating pesticide application recommendations.	Proprietary database. Registrant approves records before release. Largest group of users is in California. Registrant also provides other information like MSDSs and state registration status.	ALSTAR requires no changes to the CDMS Structured "Label." ALSTAR would be a potential source of label and state registration data.	Structured Labels would require no changes to the Agrian Structured "Label." If similar enough, Structured Labels might flow into Agrian Structured "Label."	Web Distribution would require no changes to the Agrian Structured "Label."
Section 24(c) Label **(proposed & accepted)**	1. Paper 2. Wordprocessing file 3. PDF (text)	Full text of 24(c) label.	The route to regulatory acceptance is different than for the Proposed Master Label and not captured in this document.	ALSTAR requires that the Section 24(c) Label be available as a text PDF file. This is not a major change for most registrants.	Presumably the scope of Structured Labels would include Section 24(c) Labels. Structured Labels would require changes to the Section 24(c) Label. Similar issues as Section 3 labels but also new ones since acceptance takes place at state and federal level.	Presumably the scope of Web Distribution would include Section 24(c) Labels. Web Distribution probably does not require changes to the existing Section 24(c) Label beyond those required by Structured Labels and Proposed Master Label.

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US EPA ARCHIVE DOCUMENT

Traditional Label Types And Their Interaction With The Three Electronic Label Initiatives (v1.0)

Label Type	Electronic Form	Information Content	Comments	ALSTAR	Structured Label	Web Distribution
Section 18 Exemption **(proposed & accepted)**	1. Paper 2. Wordprocessing file 3. PDF (text)	Full text of Section 18 Exemption.	The route to regulatory acceptance is different than for the Proposed Master Label and not captured in this document.	ALSTAR requires that the Section 18 Exemption be available as a text PDF file. This is not a major change.	Presumably the scope of Structured Labels would include Section 18 Exemptions. Structured Labels would require changes to the Section 18 Exemption. Similar issues as Section 3 labels but also new ones since Section 18 Exemptions are proposed by state and accepted by EPA.	Presumably the scope of Web Distribution would include Section 18 Exemptions. Web Distribution probably does not require changes to the existing Section 18 Exemption beyond those required by Structured Labels and Proposed Master Label.
Section 2(ee) Recommendation **(proposed & accepted)**	1. Paper 2. Wordprocessing file 3. PDF (text)	Full text of 2(ee) Recommendation	The route to regulatory acceptance is different than for the Proposed Master Label and not captured in this document.	ALSTAR requires that the Section 2(ee) Recommendation be available as a text PDF file. This is not a major change for most registrants.	Presumably the scope of Structured Labels would include Section 2(ee) Recommendations. Structured Labels would require changes to the Section 2(ee) Recommendation. Similar issues as Section 3 labels but also new ones since acceptance takes placel at the state.	Presumably the scope of Web Distribution would include Section 2(ee) Recommendations. Web Distribution probably does not require changes to the existing Section 2(ee) Recommendations beyond those required by Structured Labels and Proposed Master Label.
Section 3 Supplemental Label **(proposed & accepted)**	1. Paper 2. Wordprocessing file 3. PDF (text)	Full text of Section 3 Supplemental Label.	A special case of the Proposed Master Label.	ALSTAR requires that the Section 3 Supplemental Label be available as a text PDF file. This is not a major change for most registrants.	Presumably the scope of Structured Labels would include Section 3 Supplemental Labels. Structured Labels would require changes to the Section 3 Supplemental Label. Similar issues as Section 3 labels.	Presumably the scope of Web Distribution would include Section 3 Supplemental Labels. Web Distribution probably does not require changes to the existing Section 2(ee) Recommendations beyond those required by Structured Labels.

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