

Documenting Label Workflows

PPDC Sub-Committee on WDL

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Arlington, VA

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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 workflows 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

1. Input Description
2. Transformation Rules
3. Output Description

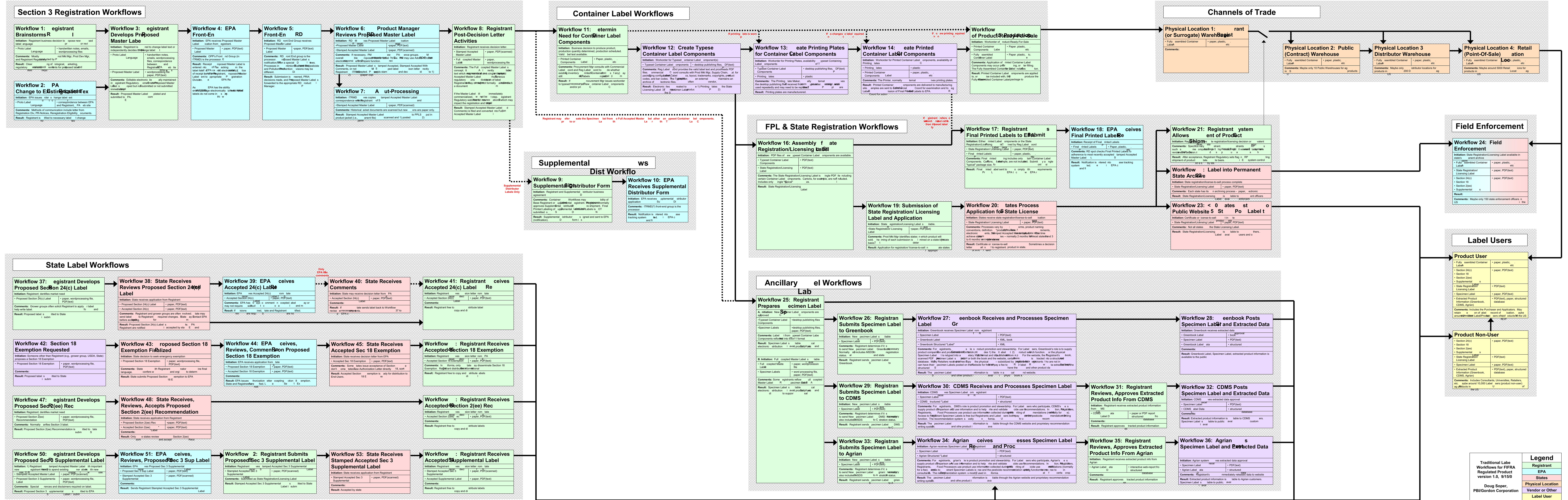
In This Workflow

1. Initiation
2. Physical or electronic format of the label and comments
3. Result

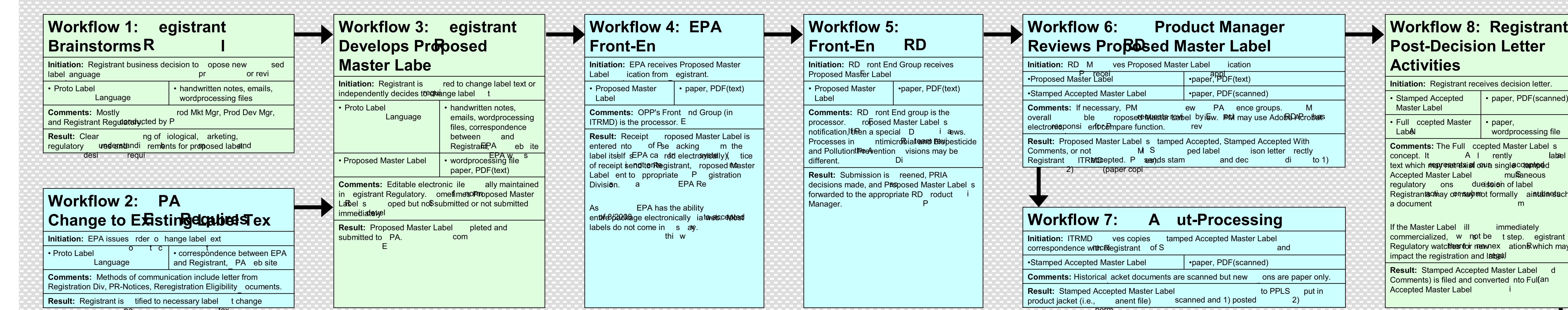
Why so many workflows?

- 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.

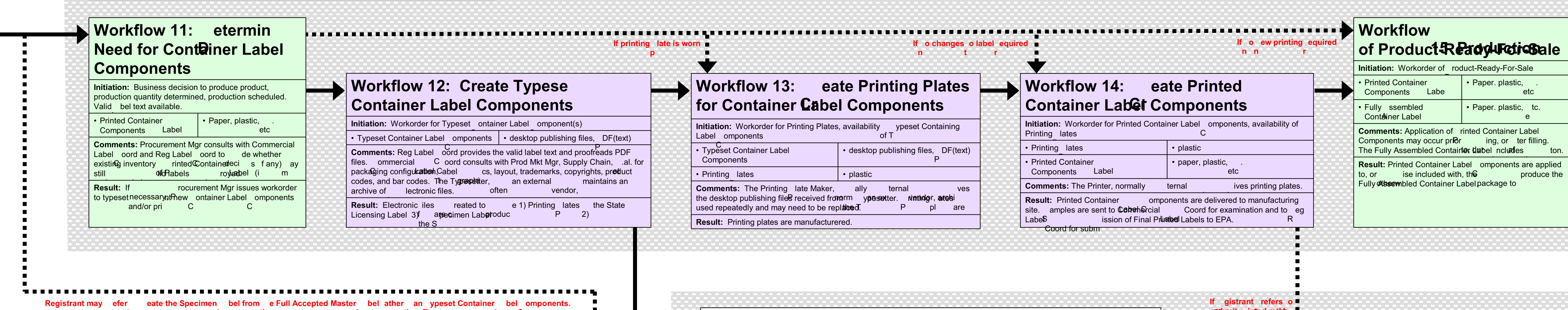
Traditional Label Workflows for FIFRA Regulated Products (v1.0)



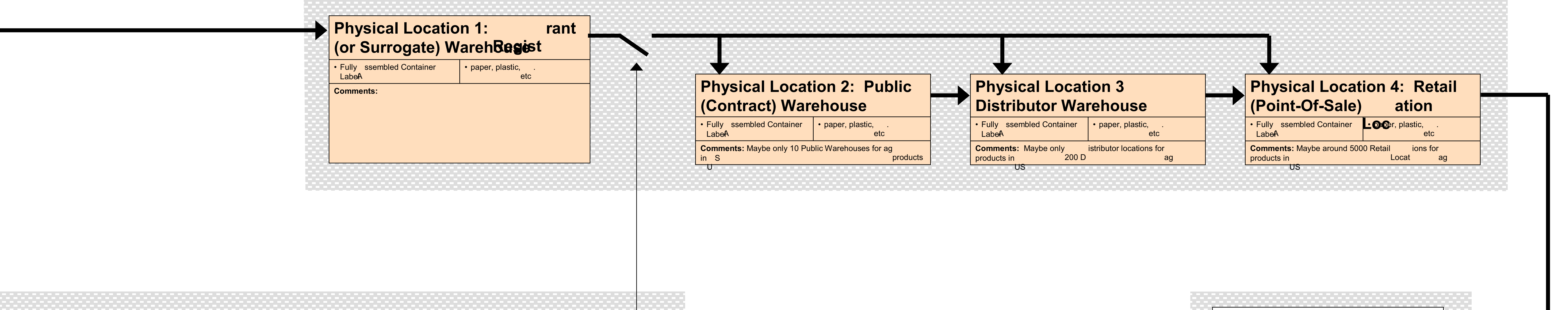
Section 3 Registration Workflows



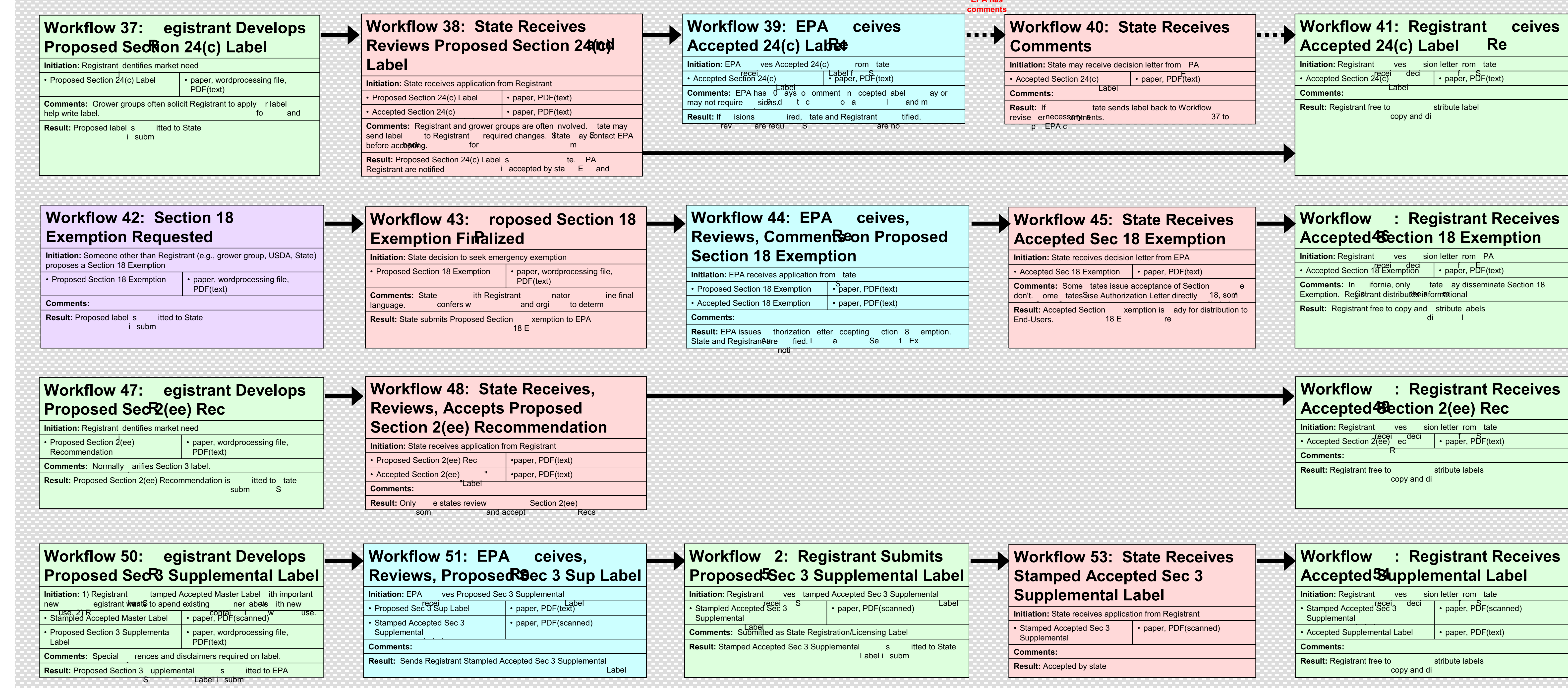
Container Label Workflows



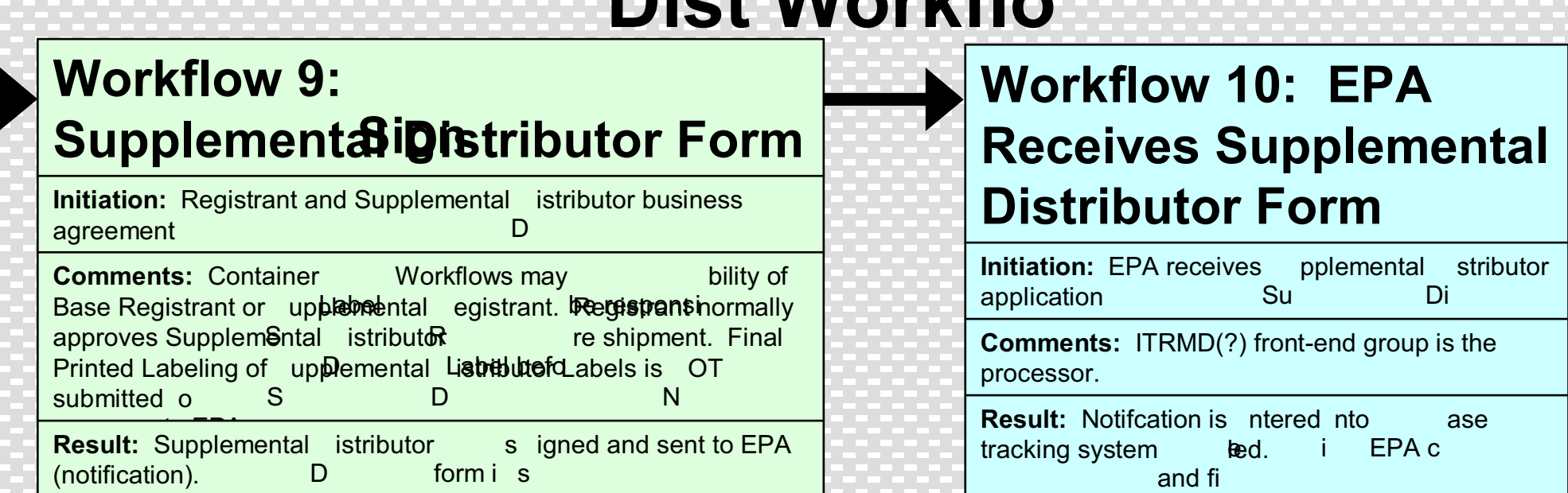
Channels of Trade



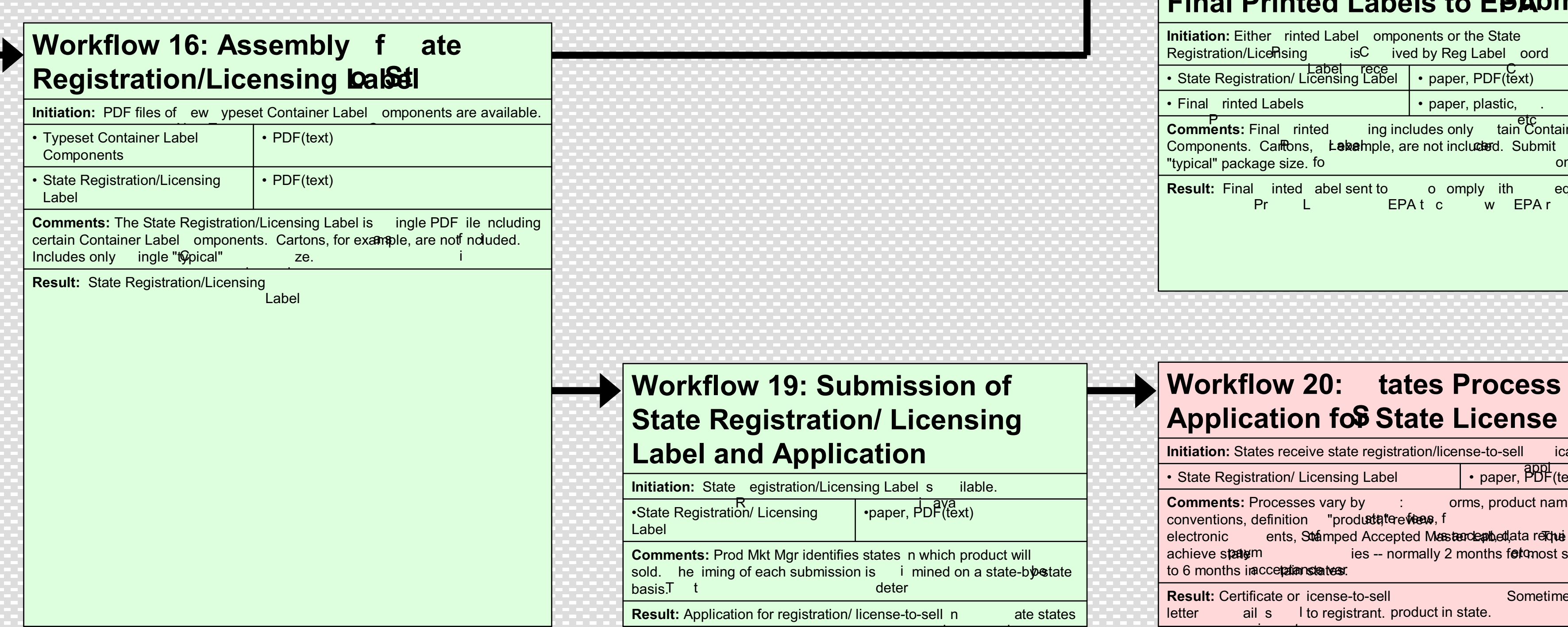
State Label Workflows



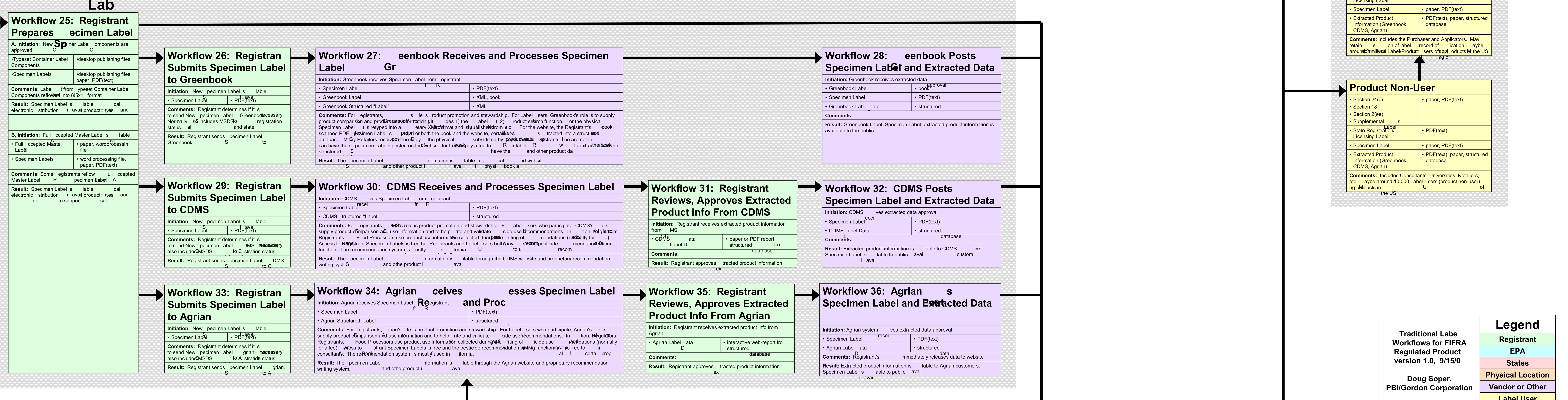
Supplemental Dist Workflows



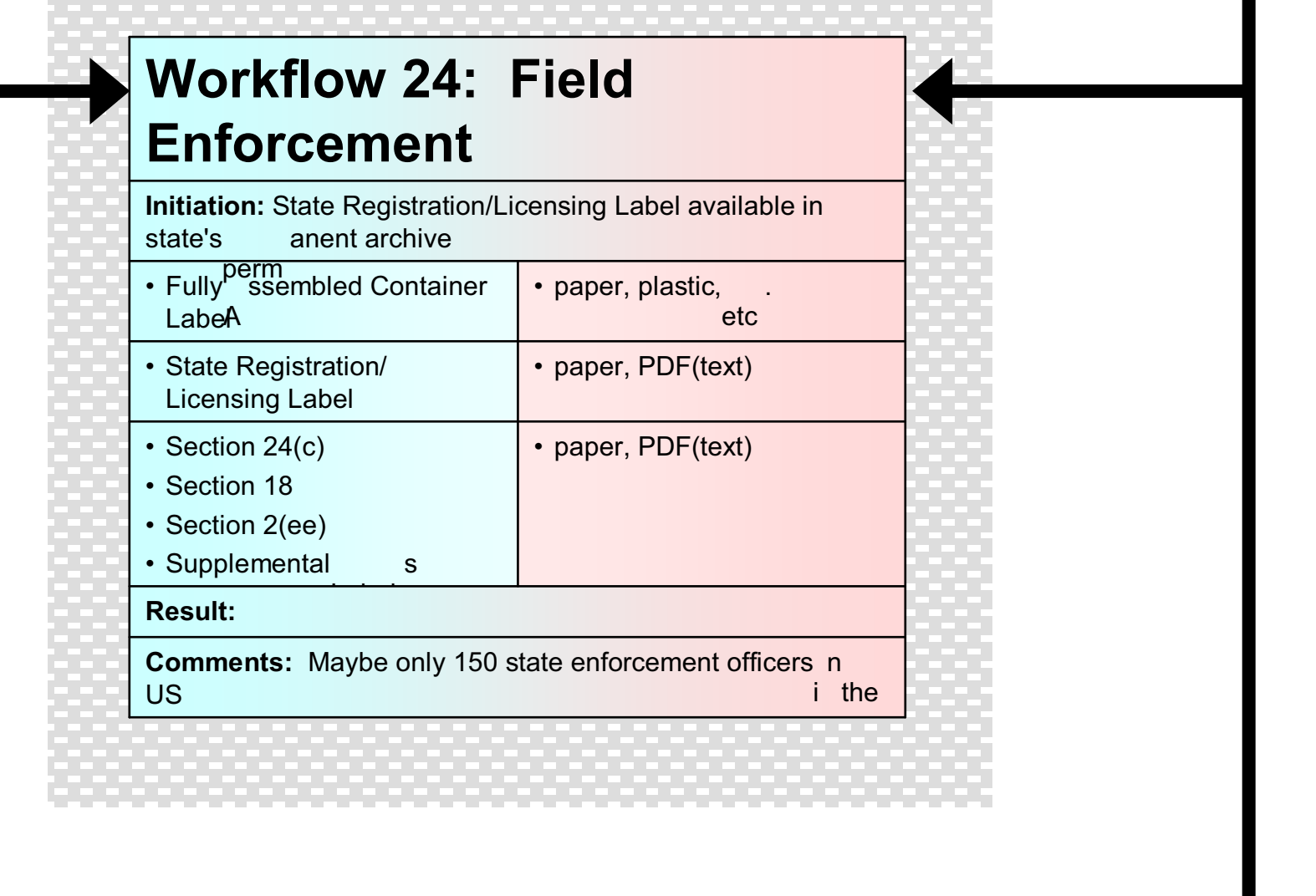
FPL & State Registration Workflows



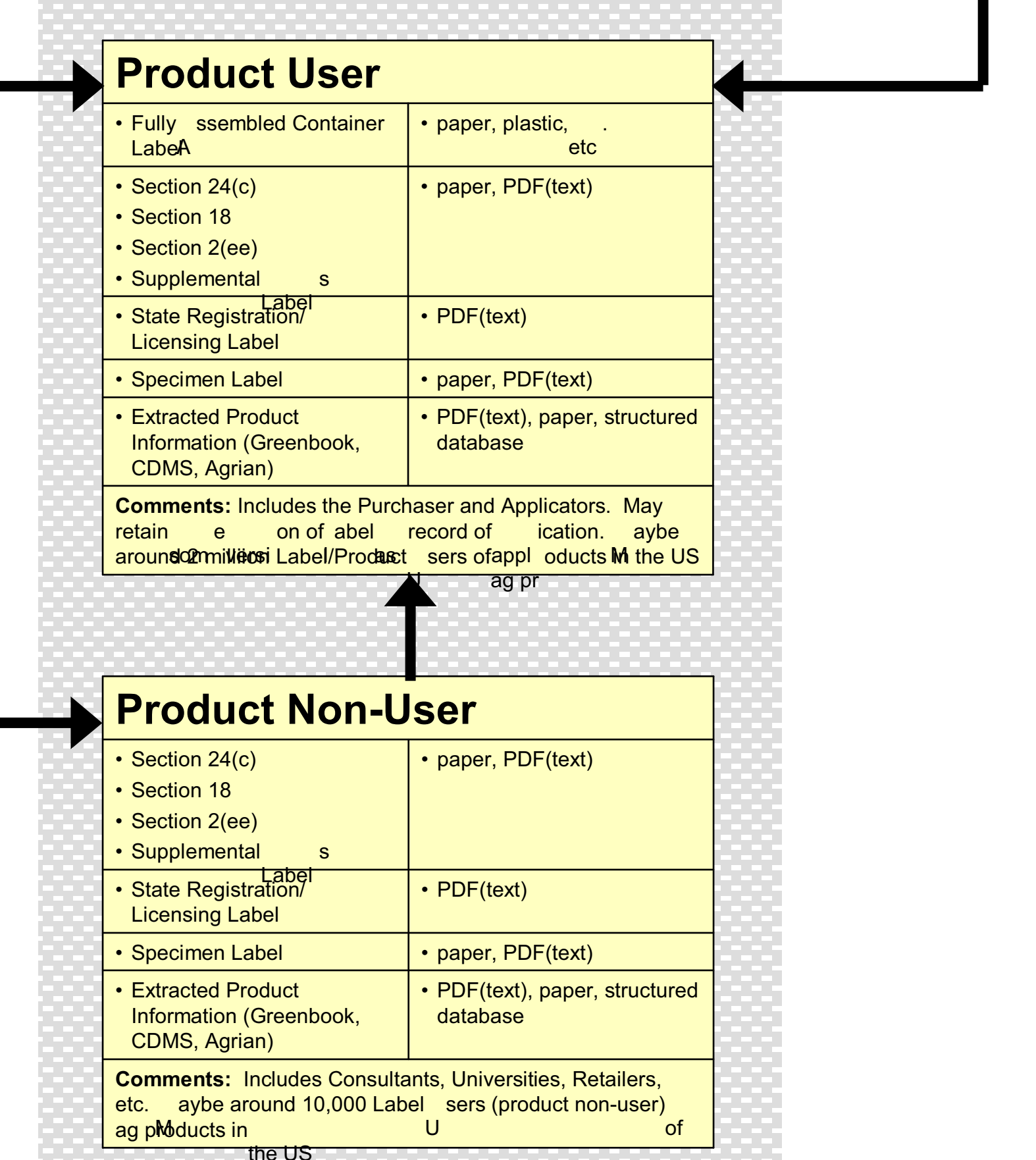
Ancillary Label Workflows



Field Enforcement

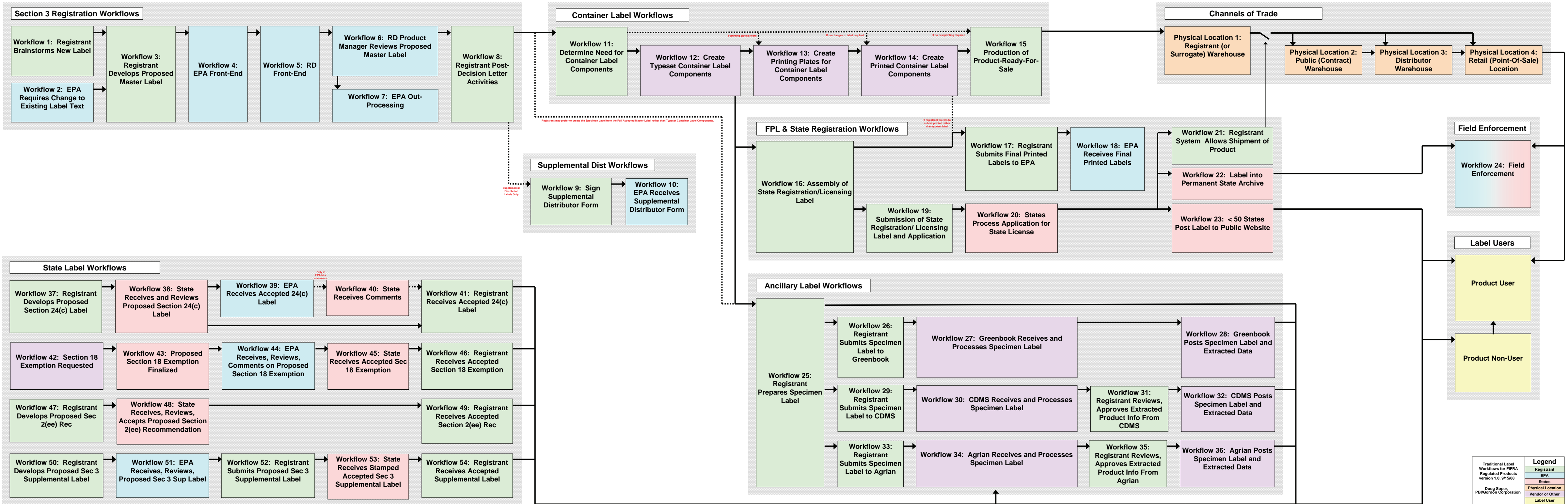


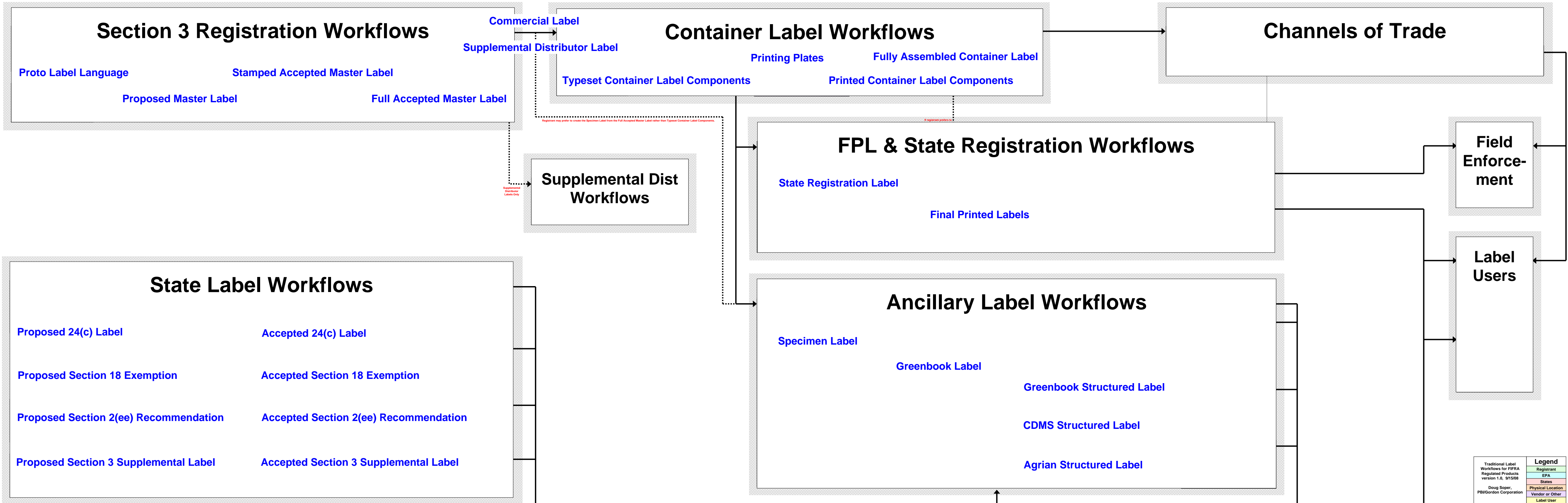
Label Users



Traditional Label Workflows for FIFRA Regulated Product version 1.0, 9/15/00	Legend
	Registrant
	EPA
	States
	Physical Location Vendor or Other
	Label User

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





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 workflows** 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

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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 1. Wordprocessing file 2. Paper 3. PDF (text) 	<p>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.)</p> <p>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).</p> <p>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.</p> <p>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.</p>	<p>Sometimes it is developed by a registrant but not submitted or not submitted immediately.</p> <p>EPA may use it for electronic document compare.</p>	ALSTAR requires no changes to the existing Proposed Master Label.	<p>Structured Labels would require major changes to the existing Proposed Master Label.</p> <ol style="list-style-type: none"> 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. <p>Potential conflict with existing responsibilities Necessary for EPA/state/registrant group to evaluate the idea of a central structured label repository 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?).</p> <p>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.</p> <p>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.</p>	<p>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.</p> <p>Decisions made for Structured Labels must align with the requirements of web distribution.</p>

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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 Distribution 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 Commercial 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 of 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 of text necessary to plate.

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 of 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 of 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 submission 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" <small>(proposed & accepted)</small>	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" <small>(proposed & accepted)</small>	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 <small>(proposed & accepted)</small>	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.

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 place 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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