PPDC LABEL REFORM WORKGROUP (LRWG)

UPDATE TO FULL PPDC

June 17, 2025

Lisa Dreilinger, Arxada

Sarah Hovinga, Bayer

Michelle Arling, OPP

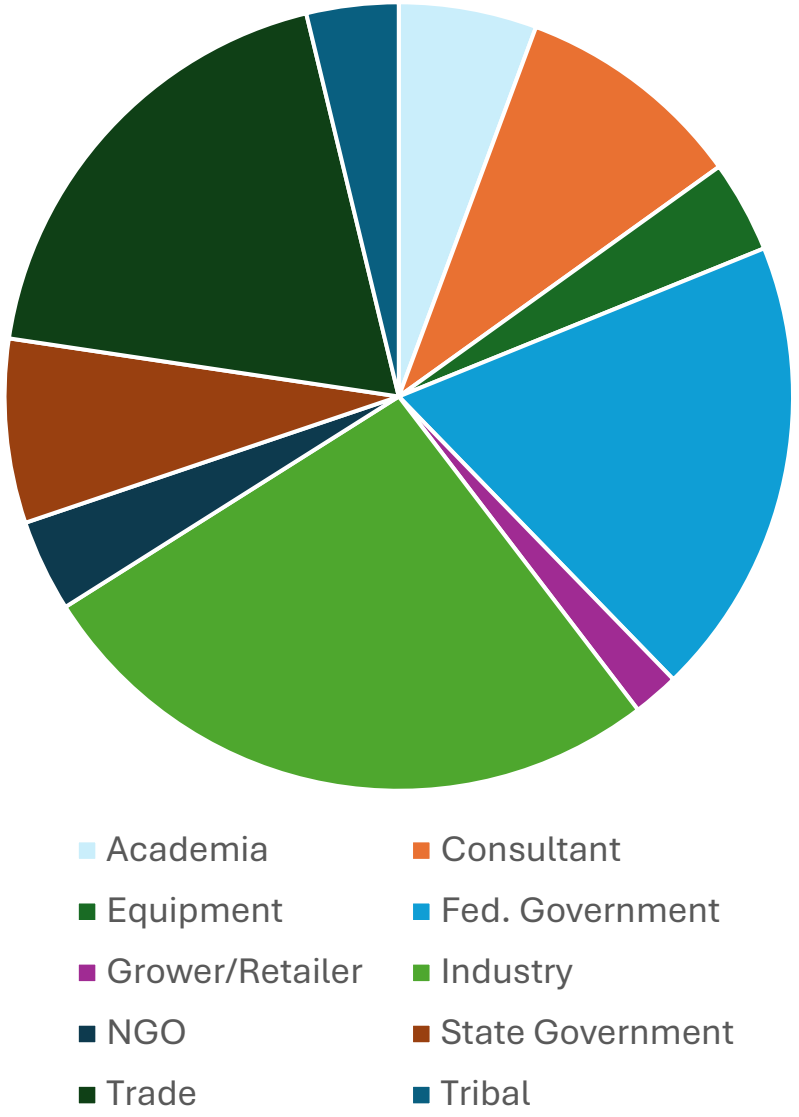
Agenda

- PPDC LRWG Information: Members
- PPDC LRWG Charge Questions
- Short-term Proposal Examples for Structured Labels
  - Antimicrobial
  - Conventional (Agricultural)
- Submission & Approval / Technology: What does the optimal electronic experience look like?
- Recommendations
- Next Steps

PPDC Label Reform Workgroup Members 2023-2025

- Lisa Dreilinger (Co-Chair) – Arxada
- Sarah Hovinga (Co-Chair) – Bayer Crop Science
- Michelle Arling (Co-Chair) – EPA

- Adam Barlow – John Deere
- Amanda Burwell – Stepan
- Amy Asmus – Asmus Farm Supply
- Anastasia Swearingen – Center for Biocide Chemistries (CBC)
- B Chennupati – Pebble Labs
- Bill Jordan – Environmental Protection Network
- Bob Mann – National Association of Landscape Professionals
- Bob Schultz – EPA
- Charles “Billy” Smith – EPA
- Christian Bongard – EPA
- Claire Paisley-Jones – USDA
- Dan Schoeff – EPA
- Daniel Skall – LANXESS Corp.
- Dennese (Flores) Grimm – Gowan Company, LLC
- Diana Stoyanova – Bayer
- Diane Boesenberg – Exponent
- Elizabeth Donovan – EPA
- Eric Gjevre – Coeur d'Alene Tribe
- Erik Janus – Vive Crop
- Garrett Goins – John Deere
- George Parker – Crop Jet/NAAA
- Gretchen Paluch – Iowa Department of Agriculture
- Hannah Alleman – American Chemistry Council
- Jackie Hardy – EPA
- Jasmine Courville – Tribal Pesticide Program Council
- Joseph G. Grzywacz – San Jose State University
- Julie Schlekau – Valent
- Karen Reardon – RISE (Responsible Industry for a Sound Environment)
- Kimberly Brown – University of Tennessee
- Kristian Paul – Syngenta
- Liza Fleeson Trossbach – Virginia Department of Agriculture and Consumer Services
- Ligia Duarte – HCPA
- Manojit Basu – Crop Life America
- Marcia Trostle – Nutrien
- Mayra Reiter – Farmworker Justice
- Monty Dixon – Syngenta
- Nina Heard – Independent Technology Consultant
- Paul Enwerekowe – CropLife Canada
- Ray McAllister – RSM Consulting LLC
- Rhonda Jones – Scientific & Regulatory Consultants (SRC)
- Russell Darling – California DPR
- Sarah Caffery – Office of Indiana State Chemist
- Shannon Whitlock – Corteva
- Stephen Schaible – EPA
- Steve Bennett – Household and Commercial Products Association (HCPA)
- Tasha Lott – Albaugh LLC
- Terry Kippley – CDPA
- Tony Herber – Scientific & Regulatory Consultants (SRC)
- Walter A. Alarcon MD MSc. – CDC NIOSH
- Wendy Sue Wheeler – Washington State University



PPDC LRWG Charge Questions

Overall workgroup goals

To develop recommendations that support:

- improvement to efficiency of the review and approval process
- quality and consistency of review and approval of labeling
- adoptability by industry and consumers

Charge questions 1 – Submission & Approval / Technology

- Short term: Are there tools that could be utilized for improving/maximizing efficiency during the label submission and review process? (e.g., PDF comparison tools, new software, e-CSF; structure/layout of labels; might distinguish between types of product labeling; recordkeeping/information within salesforce; optimization of salesforce usage)
- Long term: Ideally, what does the optimum electronic experience look like to maximize Agency resources and to maximize user adoption (submission, review, data tagging, and approval)?

Charge questions 2 – Content & Accessibility

- With DEIA (diversity, equity, inclusion, accessibilities) principles in mind, what are the requirements of accessibility for labeling? (e.g., scannable technology, blind, deaf, color blind, non-English speakers, illiterate, no access to internet)
- The EPA's Label Review Manual guides what's allowed on the label; what are the opportunities for modernization of claims and content? And how would we communicate this to stakeholders?

Parking Lot topics (partially addressed in Structured Label and Optimal Electronic Experience work products):

- Display issues
- End user experience/accessibility
- Directions for use (temporary)
- Software/tools (need to define needs first)

Antimicrobial Division Structured Label Example

Appendix

Data Element	Reference	Requirements/Notes
1. Product Name	LRM Ch 12, Sec VI / 40 CFR 156.10(b)	Required Front of Pack
2. Active Ingredient	LRM Ch 5, Sec III	Required Front of Pack
3. Net Contents	LRM Ch 17	Front of Pack
4. Signal Word & KOOROC	Signal Word: LRM Ch 7, Section IV; 40 CFR 156.60 KOOROC: LRM Ch 7, Section IV; 40 CFR 156.60	Required Data Elements. First aid for Danger products are required on front of pack unless a variance is granted. Front of Pack
5. Restricted Use Pesticide Statement	See LRM Chapter 6, Section III for specific RUP requirements.	Required only for RUP products. A brief reason for RUP classification should follow. No words can appear above the phrase and it should be enclosed in a box. Front of Pack
6. EPA Number	LRM Ch 14 Sec II	Required Front or Back of Pack
7. EPA Establishment Number	LRM Ch 14 Sec IV	Required Front or Back of Pack
8. Company Logo		Front or Back of Pack
9. Website Information	LRM Ch 3 Sec II, Part J	Front or Back of Pack
10. Contact Information	LRM Ch 15	Front or Back of Pack
11. Made in Country		Optional Front or Back of Pack
12. Lot Batch Number	LRM Ch 13	Front or Back of Pack
13. First Aid	LRM Ch 7, Sec IV; CFR 156.68	
14. Precautionary Statements	LRM Ch 7 and Ch 9	
15. Use Directions	LRM Ch 11	
16. Storage and Disposal	LRM Ch 13	
17. Pest Information (Date Table)		
18. Emerging Pathogens Statement		
19. Voluntary Ingredient Disclosure	Policy on Voluntary Disclosure of Antimicrobial Ingredient Information on Company Websites or Labels	
20. Market Claims (Including use sites & surface types and icons)	LRM Ch 12 and Ch 16	

Table of Data Elements

1. General Information- Front of Pack (Product Name, Active Ingredient, Net Contents, Signal Word & KOOROC, Restricted Use Pesticide Statement)

2. General Information Con't – Front or Back of Pack (EPA Number, EPA Establishment #, Company Logo, Website Information, Contact Information, Made in Country, Lot Batch Number)

3. First Aid

4. Precautionary Statements

Registration Division, Conventional (Agricultural) Structured Label Example

Agricultural Structured Label Template

1.10. Child Hazard Warning / KOROC Statement

mandatory statement:

KEEP OUT OF REACH OF CHILDREN

MANTÉNGASE FUERA DEL ALCANCE DE LOS NIÑOS

Note: See LRM Chapter 7, Section IV, Part A, Point 3

See 40 CFR 156.60/ [40 CFR 156.60(a)]

1.11. Signal Word

Danger-Poison Peligro - Veneno

<Controlled vocabulary pick list – dependent on Tox Category>

DANGER-POISON (PELIGRO-VENENO) *Skull & Crossbones required*

Note: See LRM Chapter 7, Section IV, Part A

See 40 CFR 156.60 / [40 CFR 156.60(a)]

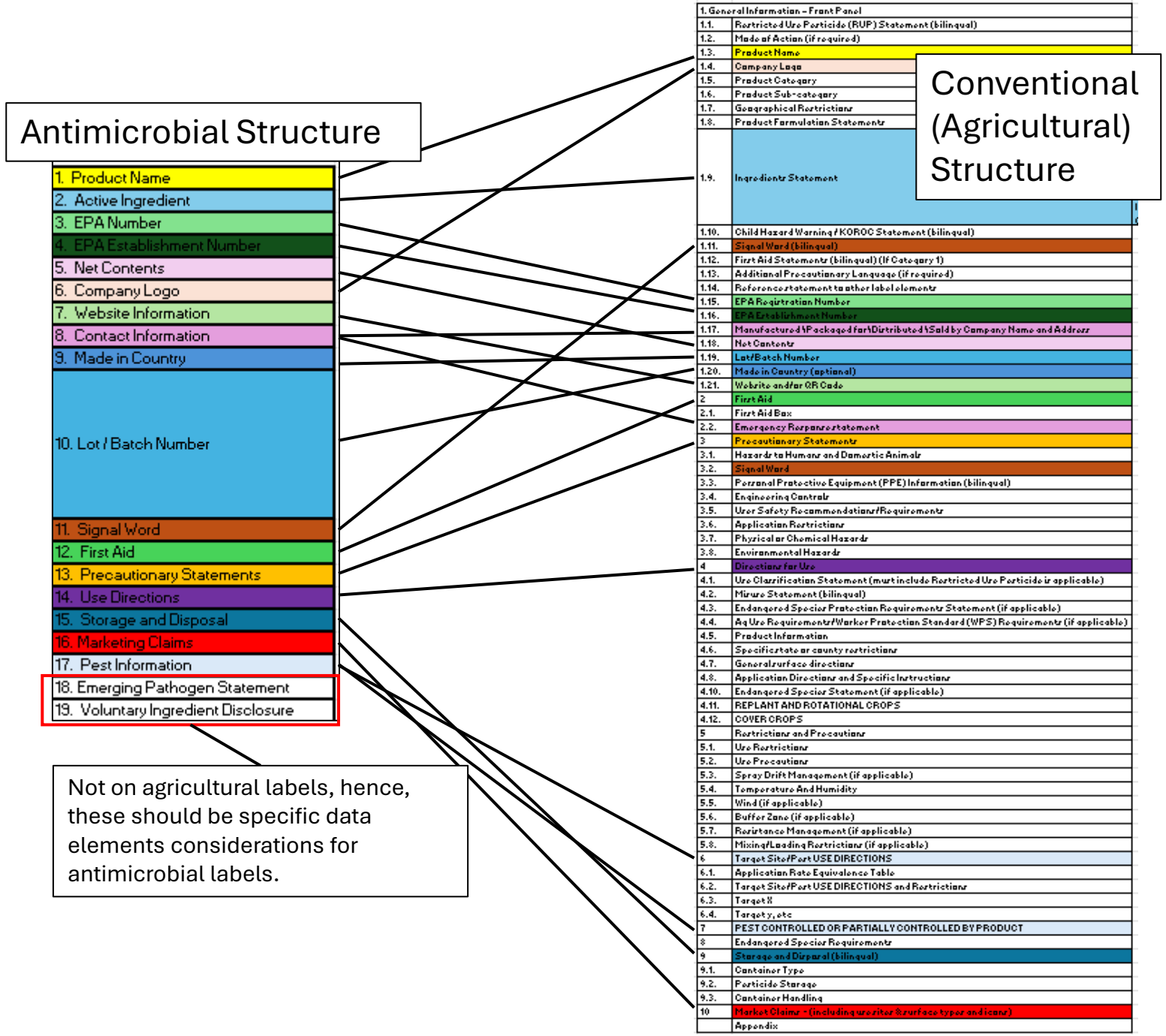
Conditionally required on front panel. Only exception is for products with category IV in all endpoints and negative for dermal sensitization.

Skull & crossbones symbol (if applicable)

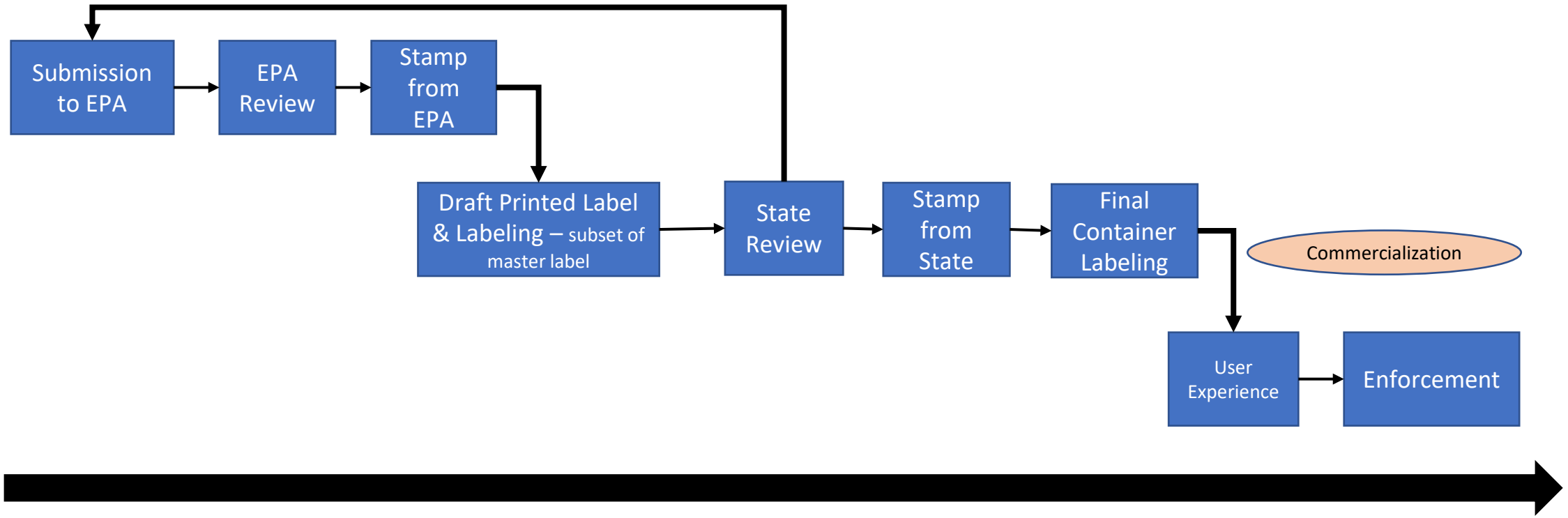
Pesticides share *some* common data elements

- After a mapping analysis of different pesticide types (example to the right), **one common structure is likely achievable** with additional label elements/modules depending on the pesticide type (i.e., the unique data elements and needs of different pesticide types)

- Registrant industry groups such as CropLife America [CLA], Responsible Industry for a Sound Environment [RISE], Household and Commercial Products Association [HCPA], Center for Biocide Chemistries [CBC], American Chemistry Council [ACC], Biological Products Industry Alliance [BPIA], should be considered as stakeholder groups for further refinements of the structured label for their specific pesticides types



Submission & Approval / Technology: What does the optimal electronic experience look like?



Stakeholder Categories	Registrants	EPA	States	Physical Location (e.g. Retailer/Distributor)	Vendor (e.g. Label Information Provider/Manager)	Label Information Users

Overall System Requirements

- Data needs to be FAIR (Findable, Accessible, Interoperable, Reusable)
- Project needs dedicated resources (including funding and staff)
- Structured content authoring (for the registrant) and submission (to EPA)
- Structured content should be compatible with different platforms and applications
- Voluntary initial approach (Goal is to incentivize users to adopt digital approaches, be inclusive to all stakeholders)
- Use encouraged by incentives (i.e., faster review times or lower PRIA fees, etc.)
- Harmonize, as much as possible, with any structured digital labeling system used by other national regulatory entities and/or international organizations (e.g., USA, CAN, MEX, OECD, ISO, etc.) – primarily through standard data elements
- Align with stakeholder requirements and needs (e.g., States, registrants, users)

Short-term Recommendations

- A **structured labeling approach** is proposed as a **voluntary first step** to improve **label creation, review, and comprehension**
  - This involves establishing **consistent data elements and standardized phrases** to create a uniform backbone for all pesticide labels, while allowing for differentiation through templates and modules for different product types
  - The PPDC LRWG has made progress by identifying example **core data elements, regulatory sources, feasibility of pick lists, and interoperability with databases**
  - Initial comparisons between **Antimicrobial and Conventional (Agricultural) product labeling** have helped define an example minimum set of **common data elements** and an **exercise that can be repeated** to identify similarities and differences **for other pesticide types**
- Outstanding work includes **evaluating other pesticide types**, refining **controlled vocabularies and standardized phrases**, and **piloting structured label submissions** to assess efficiency gains.
  - This approach should enable **automation, minimize errors,** and **ensure consistency** while maintaining **flexibility for different pesticide types**
- A **central label guidance location** (potentially within the **Label Review Manual**) should house the structure, templates, pick lists, and validation rules, ensuring long-term **maintenance and adaptability to technological advances**
- This structured approach aims for **faster submissions, improved accuracy, easier comprehension across stakeholders** and **structured content authoring** to enhance usability
- Allow for placeholders for future integration of tools like **QR codes, websites, etc.**

Long-term Recommendations

- **Structured Digital Labeling** is essential for achieving comprehensive label reform
- By transitioning from a document-centric approach to a **data-centric** model, the **EPA** would capture and communicate label elements as **digital data**
  - This shift involves working with stakeholders to define **pick lists, standardized phrases, controlled vocabularies**, and **interoperability** for data elements across all pesticide types
  - Comparison is necessary for various pesticide types to establish a **minimum set of common data elements** and explore opportunities to enhance **comprehension** with label stakeholder groups
  - Monitoring tools will need to be implemented to track benefits from digital label transitions, with **pilot programs** to identify further improvement areas
- The effort also involves collaboration with **States and Tribes** to understand their **electronic system needs** and enable **interoperability** across **Federal, State**, **Tribal**, and other **local authorities**
  - The goal is to establish an **end-to-end digital system** for submissions, registration, and label distribution, supporting **two-way data flow** between users and regulators.
- The system needs to incorporate **workflow definitions** for **human processes**, **document management**, and **system interoperability** while enabling **automation** to reduce the need for repetitive reviews
- Utilizing advanced **document/section comparison technologies/AI**, the EPA could potentially streamline label reviews, creating efficiencies that improve compliance and regulatory processes

Recent Agency Advancements

EPA Registers New Pesticide Metamitron and Uses a New Structured Label

Released on March 11, 2025

Today, the U.S. Environmental Protection Agency (EPA) registered one technical and two end use plant g
containing the new active ingredient metamitron for use on apple and pear trees. Metamitron is a chem
apple and pear tree leaves shortly after the blooming stage to thin excess fruit. This allows the remainin
contribute to higher quality fruit and plant health giving farmers an additional tool to help manage crop
country.

The metamitron registrations are supported by human health and ecological risk assessments as well as
pesticide under the Endangered Species Act (ESA). No human health risks of concern were identified wh
to the label. EPA conducted an ecological risk assessment and biological evaluation under the ESA and c
consultation with the U.S. Fish and Wildlife Service (FWS). FWS concurred with EPA's determination that
and pears being registered is not likely to adversely affect endangered species or critical habitats.

In response to stakeholder feedback regarding a lack of clear and uniform format in labels, making it dif
information and to use this information correctly, EPA worked with the registrant, ADAMA AGAN c/o Mak
Inc. (ADAMA), and representatives from the Weed Science Society of America (WSSA) to implement a nev
product. On its own initiative, WSSA has been soliciting feedback from their membership and contacts a
labels easier to use and presented that information as a proposal to EPA. The two end use labels being r
the first labels implementing the vision of this proposal. These labels are one step towards increasing th

To read more about the registration of metamitron, see docket ID EPA-HQ-OPP-2022-0575 at www.re
structured labels will soon be available in the docket.

Last updated on March 11, 2025

Read EPA Registers New Pesticide Metamitron and Uses a New Structured Label.

EPA Launches Updated Pesticide Registration Tracking App for Companies

Released on April 18, 2025

The U.S. Environmental Protection Agency (EPA) has launched the latest version of its MyPest application. MyPest allows registrants of pesticide products to monitor the status of their pesticide registration submissions in real-time. Updates to MyPest include an enhanced dashboard page with information about the registrant's cases and products, the ability to drill down into a highly detailed view of each application, and the capability to communicate with EPA staff directly within the application page.

MyPest gives pesticide registrants greater insight into the registration process and provides an easier way for them to communicate with EPA on registration packages under review. This update represents a significant step forward in making the regulatory process more efficient and transparent. This work is part of EPA's overall digital transformation strategy and lean process streamlining which will improve the timeliness of pesticide registration decisions, supporting Administrator Zeldin's Pillar Three of Powering the Great American Comeback initiative to advance permitting reform.

Over 1,200 registrants have already signed up for MyPest. Additional updates planned for later this year include further enhancements to the user experience and detailed information on the progress of registration review cases and data call-ins.

Additional information from EPA on pesticide registration is available on EPA's website.

Last updated on April 18, 2025

Read EPA Launches Updated Pesticide Registration Tracking App for Companies.

Next Steps

- The LRWG has provided fundamentals, across diverse stakeholder needs, from EPA submission until Label Information Users, for an overall approach to structured pesticide label information
- The LRWG recommends that a new PPDC Working Group be established utilizing PPDC LRWG work as a foundation. Charge questions can be considered around the themes:
  - Provide value to EPA during work towards structured labels & labeling
  - Provide value to EPA during its registration digitization implementation
- The LRWG thanks the PPDC for consideration of this final report, which recommends formally sunsetting the LRWG and to establish a new group
  - The LRWG requests a vote from PPDC on approving the report and sunsetting the LRWG
  - The LRWG requests a vote from PPDC on approving the establishment of a new PPDC Working Group

THANK YOU!