

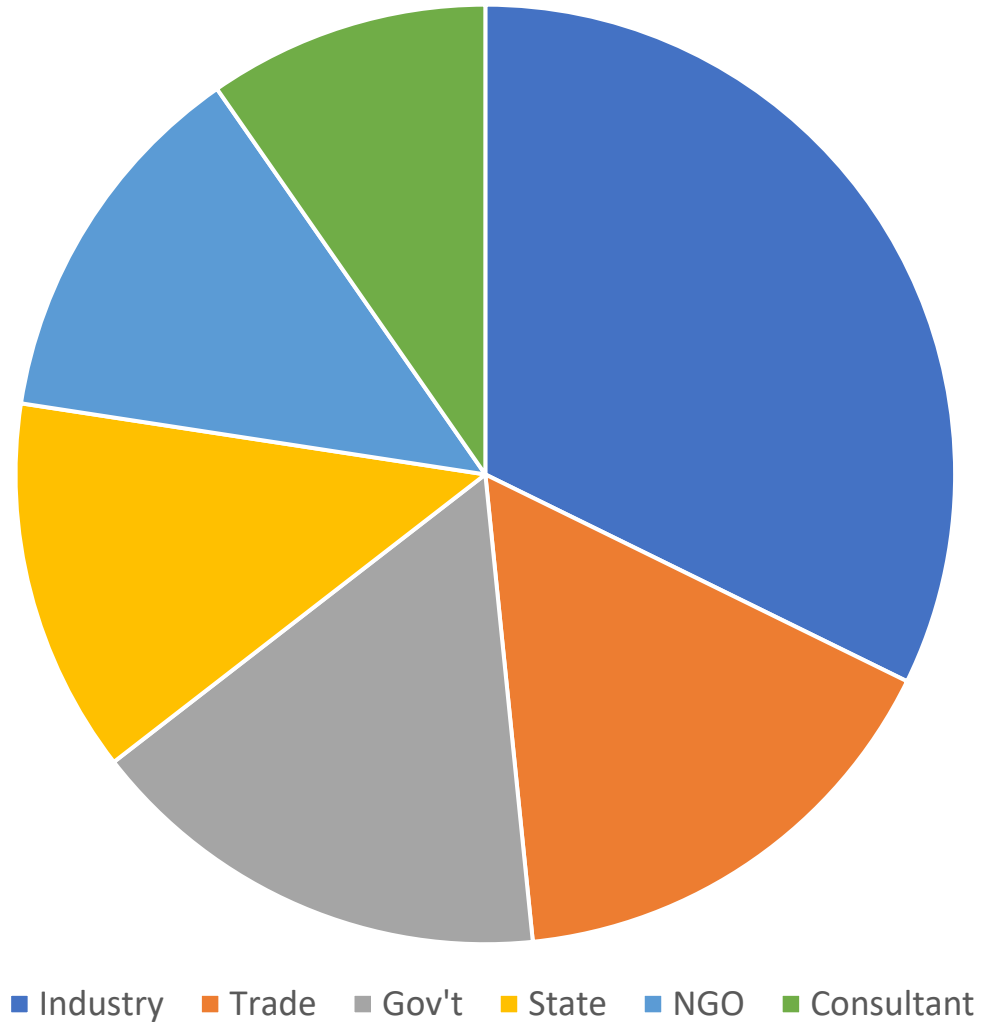
# PPDC Label Reform Workgroup Update

November 15, 2023

# Workgroup Members

- Lisa Dreilinger (Co-Chair) - Arxada
- Manojit Basu (Co-Chair) - Crop Life America
- Michelle Arling (Co-Chair) - EPA
- Charles “Billy” Smith - EPA
- Christian Bongard - EPA
- Gretchen Paluch - Iowa Agriculture
- Steve Bennett - HCPA
- Stephen Schaible - EPA
- Robert (Bob) Schultz - EPA
- Liza Fleeson Trossbach - Virginia Department of Agriculture and Consumer Services
- Anastasia Swearingen - Center for Biocide Chemistries– CBC
- Karen Reardon - RISE - Responsible Industry for a Sound Environment)<sup>®</sup>
- Amanda Burwell - Stepan
- Claire Paisley-Jones - USDA
- Amy Asmus - Asmus Farm Supply
- Garrett Goins - John Deere
- Wendy Sue Wheeler - Washington St.
- Diana Stoyanova - Bayer
- Bill Jordan - Environmental Protection Network
- Monty Dixon/ Kristian Paul - Syngenta Crop Protection
- Dennese (Flores) Grimm -Gowan Company, LLC
- Rhonda Jones / Tony Herber - Scientific & Regulatory Consultants (SRC)
- Shannon Whitlock - Corteva (CLA/Rise Label working group Chair)
- Joseph G. Grzywacz -Florida State University
- Diane Boesenberg - Exponent
- Mayra Reiter - Farmworker Justice
- Ray McAllister - RSM Consulting LLC
- Daniel Skall - LANXESS Corp.
- Sarah Hovinga - Bayer US – Crop Science
- Erik Janus - Vive Crop
- Paul Enwerekowe - Crop Life America
- Tasha Lott – Albaugh LLC
- Terry Kippley – CDPA
- Julie Schlekau - Valent
- Walter A. Alarcon MD MSc. – CDC NIOSH

# Summary of Member Participation



# 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**

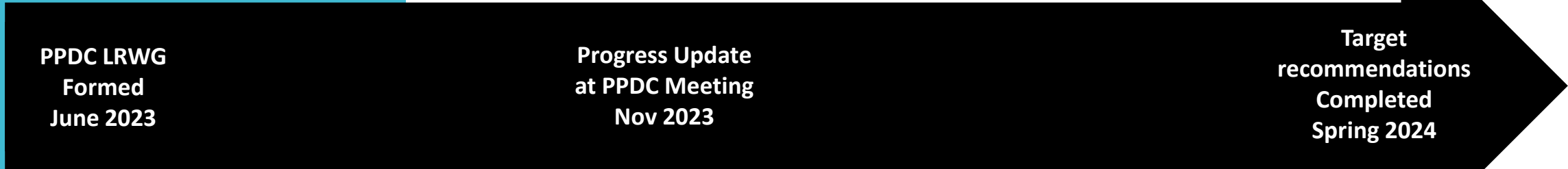
- Short term: Are there tools that could be utilized for improving/maximizing efficiency during the label submission and review process? (e.g., PDF comparison tools, new software, e-CSF; structure/layout of labels; might distinguish between types of product labeling; recordkeeping/information within 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

## 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 issues:
  - Display issues
  - End user experience/accessibility
  - Directions for use (temporary)

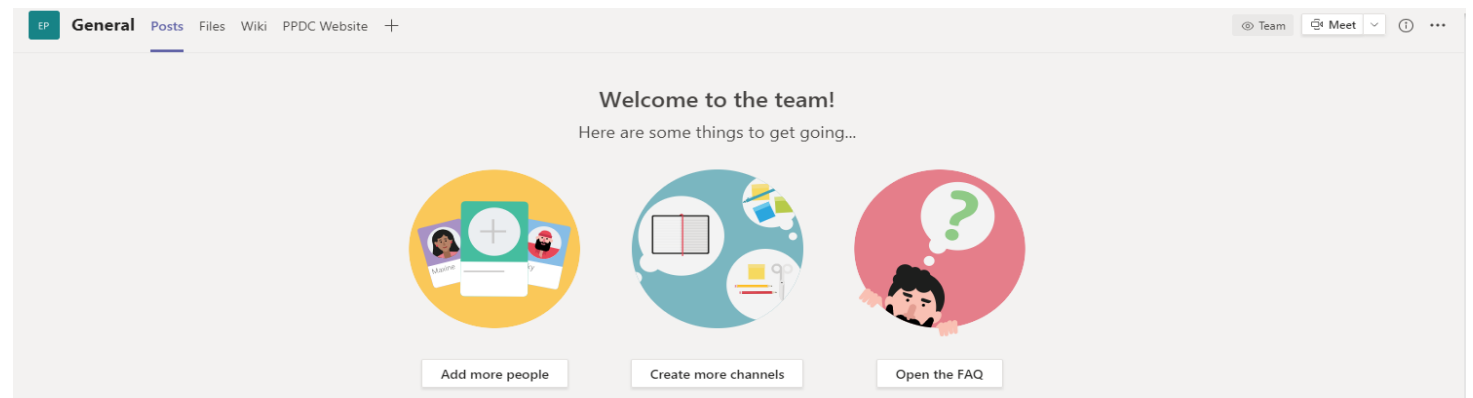
# Timeline & Tools



Weekly Meetings



Teams Site



## Recommendations to PPDC (As of Nov 2023)

### Big picture - Electronic Labeling is necessary to optimize labeling process

Short term – voluntary label template necessary (information shared with EPA in consistent order and similar words)

- 'Data elements' identified
- Goal to have 1 template for all pesticide types
- Creating template, the source information (regulation/Label Review Manual/PR notice)
- Identify data elements that could have a “pick list” for harmonization
- Recommend data elements that could have representative/placeholders to minimize submissions that don't add value to public health (e.g., QR codes and websites to be representative)
- Recommend that EPA use compare document technology
- Recommend that EPA cease de novo reviews when previously reviewed in the last {insert time frame} (e.g., 1 year/2 years)

Long term – ability for EPA to capture labeling as “digital data”

- Use short term template to confirm data elements for digital labeling
- EPA to determine what system is necessary (in current parking lot)
- Determine what parts of the label can be auto populated by e-CSFs
- Determine how data for Master Label can be shared for risk assessments
- Information on automating the label where applicable (e.g., auto programming tractors etc.)

# EPA Digital Labeling Whitepaper

- EPA published a FRN announcing a whitepaper on digital labeling today
- Describes EPA's vision for structured labeling and structured digital labeling and discusses the potential benefits
- Structured labeling – a voluntary template
- Structured digital labeling – a voluntary template with all information captured as data rather than as a static file (e.g., PDF)
- Lays out potential steps to adoption
- Requesting public comment on all aspects of structured digital labels, including:
  - anticipated benefits
  - risks and challenges
  - key information fields (such as pesticide use site, formulation, and maximum application rate), and
  - potential phases of adoption



# Whitepaper Overview

- Benefits of Structured Labels and Structured Digital Labels
  - Consistency
  - Streamlined submission and review process
  - Easier for users to find information
  - Efficiency in reviews, submissions, and label updates
- Timing
  - OPP's Digital Transformation efforts
  - Lessons learned from previous efforts
  - Technology development
- Phases
  - Test digital submission tools
  - Propose standardized format for public comment
  - Allow voluntary submission of structured labels
  - Pilot submission of structured digital labels
  - Refine and launch structured digital label builder

## Overlap Between Label Reform Workgroup Activities and Whitepaper

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# Next Steps

- Review the EPA's Label Reform Whitepaper for integration into recommendations
- Create the “pick lists” for Data Elements
- Help create a Master Label Template that can be used universally for document compare
- Consider what technology information could be utilized by the Agency

Thank you!