Updating labels in the marketplace

- Overview of Registration Review
  - Process and statutory deadline
  - How many pesticide labels must be revised in next year or two?
  - Implications for states and registrants
- What is the Existing Stocks Policy?
  - Challenges for states and registrants
- Goals
  - Alert states to the large number of label updates coming
  - Seek feedback on challenges (timeline, predictability)
  - Work with regulatory authorities to develop solutions

Registration Review

- EPA issued updated schedule December 2021
  - FY2021 EPA had **51** ai Interim Decisions published
  - FY2022 EPA expects to publish **75** ai Interim Decisions
- 9/30/2022 deadline for first round of Registration Review will require EPA to finalize a large number of cases
- States can expect a LARGE numbers of revised labels due to label change requirements in Interim Decisions

Existing Stocks Policy

- Following approval of a label amended at registrant's initiative, registrant may sell and distribute "old label" product for 18 months (normally).
- Label changes required by EPA under Registration Review may impose shorter time limit for sale & distribution of "old label" product (typically 12 months but may be 18 months; inconsistency leads to confusion).

Challenges

- Routine label amendments and Reg Review changes may be pending simultaneously, and not coordinated.
- Unpredictable timing of EPA finalizing and stamping labels
- The 12- or 18-month period must accommodate (sequentially):
  - Possible delays by EPA in notifying registrant of label approval
  - Review and approval process in some states
  - Additional rounds of approval by EPA, if states request changes
  - Recording of revised approved labels by all state regulatory agencies
  - Create and print new labels for multiple package sizes
  - Manufacture and package product – production schedule may not align with label approval
  - Distribution/sale of product with revised label
- Sometimes it doesn’t all fit!

More Challenges

- One EPA label can become many products and many labels in each state, e.g., sub/split labeling, alternate brand names, supplemental distributors
- Variability in review processes for revised labels
  - From state to state, and within a state
  - All states are affected whether reviewing labels or simply recording revised labels
- Managing multiple labels versions for different states is extremely complex and challenging.
- Huge & concentrated workload coming under Registration Review
- This adds to an already large backlog of pending label approvals
- If products cannot be sold in a state because of pending label versions, they are unavailable to GROWERS
- The situation leads to difficult choices for registrants

Example active ingredients

- Supplemental distributor labels not included below
- For California, data search below finds 164 imidacloprid labels; CDPR says there are 238
- Label registrations per state range from mere handful to hundreds

	Imidacloprid	Fipronil	Tebuconazole
Interim Decision	**Q4 FY2022**	**Q3 FY2022**	**Q4 FY2022**
EPA Registered Products	**741**	**265**	**253**
State Registrations (37 states only)	**5,045**	**1,801**	**2,026**

Path Forward

- Regulatory authorities and industry jointly develop solutions to handle the workload
  - Propose formation of ad hoc work group with representatives from States, CLA, EPA
  - Feedback welcome
- Possible solutions
  - Consistent 18-month timeline for updating labels with registration review changes in the marketplace.
  - Coordinate timing of EPA and State processes for review of labels.
  - EPA specifies date by which registrant must submit revised labels for state review.
  - Timeline for updating labels would begin at completion of state reviews.

Thank you!