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Process Efficiency Proposals for Post-Patent Products

SIDE BY SIDE VERIFICATION WORKSHOP

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2025 ADJUVANTS, INERTS & CROP PROTECTION CONFERENCE

cpda

Side by Side Verification Workshop Overview

Executive Summary

- CPDA is looking at Best Practices for Me-Too submissions
- Side-by -Side Verification Pilot Program
  - Presentation to Agency prior to execution;
  - Industry and 3rd party Lab participation to help growers get new off patent products quicker
- Program utilizes additional data from Registrants for quicker decisions

Pilot Content

- Analysis of Physical Chemistry for similarity between Me-Too and Target product
- Confident 3rd Party verification of substantial similarity to registered formulation
- Ensure FIFRA criteria is met for registration

Goals

- Save time and money for EPA for “Me-Too” decisions; optimize Agency resources
- Use sound science to increase efficiency of approval process
- Registrants receive PRIA Decisions in accordance with published timelines

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Purpose - FIFRA Section 3(c)(3)(A,B)

Me-Too" Pesticide – Basis for Proposal

- Substantially similar in its uses and formulation to one or more products currently registered
- Differing only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment
- Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other
- New Product “Me-Too” actions relative to total actions (most recent data)

→R300: 185 / 1,590
→R301: 161 / 1,590

22%

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Framework

☑ Workshop Objectives

- Finalize Proposal for presentation to Registration Division
- Align with Contract Laboratories for Logistics
- Gain understanding / optimize process for review
  - What happens during review?
  - How many people are involved in review?
  - What are key constraints to review process?

➡ Follow Up: Meeting with Registration Division Leadership (June 3)

- Presentation of Final Proposal
- Commitment that Registrants participating will receive on-time PRIA decision

Initiation and Completion of Program

- Participant Commitment
- Timelines

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Proposal

Side-by-Side Verification for “Me-Too” products prior to EPA submission

- Submission pathway for Registrants that ensures decision within PRIA timeline
- Product Chemistry data is submitted with a Side-by-Side Verification of the cited “Me-Too” product
  - GLP laboratory will run Product Chemistry and/or Toxicology guideline studies on a “Me-Too” sample concurrently with a sample of the “Me-Too” target (commercially sealed or certified sample)
  - Report will detail results for both samples and issue opinion on substantial similarity between two samples
  - Uniform Report Template – Results Table that facilitates Data Evaluation Record (DER) generation
- Submission of verified studies will by-pass the need for extensive CITAB review of report
- Analytical Analysis (HPLC/DAD; GC) may also be utilized to verify substantial similarity
- Toxicology Side-by-Side Verification is not required
- **Submissions made under Side-by-Side Verification program will result in decision by PRIA Date**

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Flowchart for Decision

Decision based on Weight of Evidence (do not overuse critical resources)

- Basic Analysis: Side-by-Side Product Chemistry
  - GLP Physical and Chemical Properties
  - CSF – substantially similar

- Optional: Analytical Assay
  - Active Ingredient
  - Major Components / Solvents

- R310: Specific Toxicology Studies (Resubmission)
  - Label Information of Target Me-Too details results
  - Acute Oral, Inhalation, Eye Irritation most common concerns
  - DO NOT conduct unnecessary studies (waste of time, money, animals)

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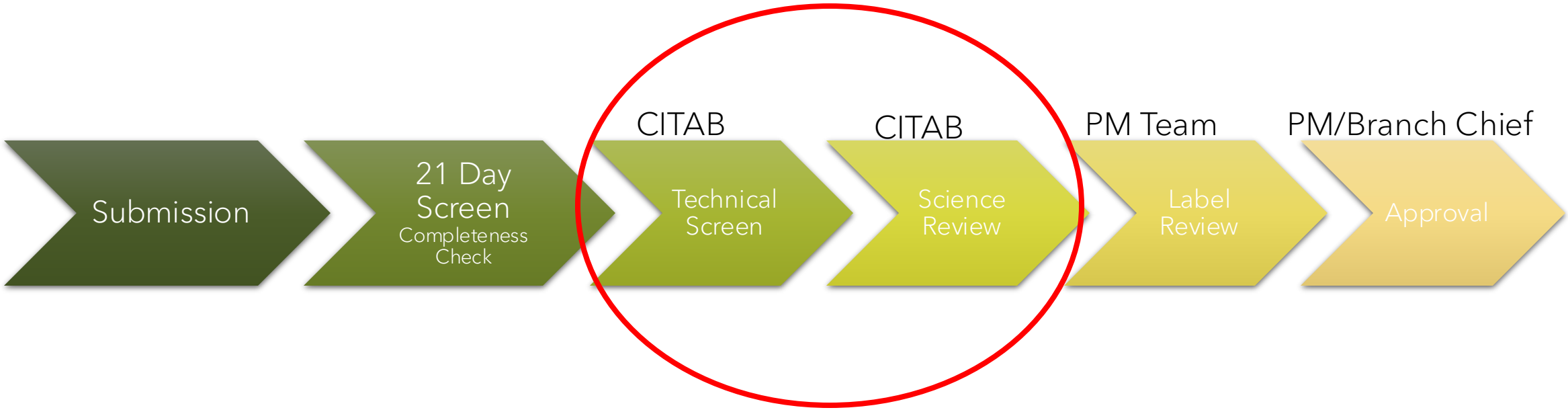
Current Review Process



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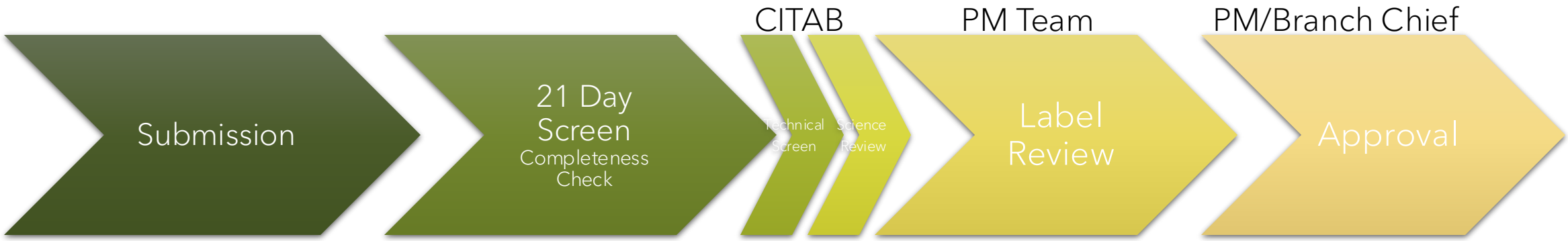
Proposed Improvement



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Considerations

Points for Discussion with Agency

- Find original product to Cite as Me-Too Target
- Me-Too Targets should be approved within past 15 years
- Anonymity / Blinded study not needed. GLP labs operate under scientific principles.
- Acceptance Criteria – Data will demonstrate what is acceptable variation
- RD Leadership feedback - Labs issuing Substantially Similar conclusion / other opinions
- Label Language does NOT equal Product Hazards
- Differences in formulation impact Acute Tox profile

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Expedited Label Review Requirements

Label Review

- Submitted label must “Differ in labeling from such currently registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.”
- Stop excessive editing of Me-Too labels
- Basic product label remains in marketplace unchanged (~90% product)
- No funding / resources required; culture change / training
- If IRRD issued, then draft label must be updated (but not if PID only)
- “Me-Too” drafts based on target labels approved within 15 years only reviewed twice (Primary & Secondary)
- EPA to specify what changes can be incorporated “up front” to make review easier (**DO NOT**, lbs ai / acre, others). General note, do not highlight every instance.
- Build on larger effort to improve consistency in label review

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Details and Logistics

Proposed Timeline

- Have a Me-Too product available for testing prior to 8/1/25.
- Secure a commercial sample of the “Me-Too Target” from marketplace
- Samples shipped to the Testing Lab (Group B studies)
- Target completion by 10/1/25

Confirmation Meeting with Registration Division Leadership - TBD

- Presentation of Final Proposal
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THANK YOU
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