COMPLIANCE SERVICES INTERNATIONAL

Industry Perspective on Scientific Evaluation

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Overview

General Considerations for Scientific Evaluation:

- Discuss any agreements made with EPA to fulfilling data requirements
- Review protocols for testing prior to initiating testing
- If submitted to EPA, most likely should be submitted to CA as well
- If active ingredient is in registration review in CA, new product registrations and label changes may be difficult

Human Health Assessment

General Considerations:

- Alternatives to in-vivo testing:
  - In-vitro testing
  - Waiver requests

- Identify Test Article(s) and all synonyms in cover letter

- If test article not identical to formula proposed for registration, highlight similarities, establish bridging arguments

Human Health Assessment

Expect to be routed if:

- New Product
  - For New AI – Pre-submission meeting to recap EPA pre-submission meetings and concur on data requirements and planned testing and waivers.
  - For Existing AI – Highlight what relevant data is on file, and establish bridging arguments if needed.
- Label Amendment
  - Changes to the following can trigger human health branch review:
    - Signal Word
    - Precautionary Statements
    - PPE
    - REI

Human Health Assessment

Additional Responsibilities:

- Review of 6(a)2 Reports
  - Frequency and severity of incident reports can trigger prioritization for risk assessment
- Preparation of Risk Assessments
  - Identify gaps in database of SB 950 required data for existing registered actives

Chemistry

General Considerations:

- Identify chemical composition of all active and inert ingredients in formula, including CAS numbers.
- Identify Test Article(s) and all synonyms in cover letter
- If test article not identical to formula proposed for registration, highlight similarities, establish bridging arguments

Chemistry

General Considerations:

- Storage Stability and Corrosion Characteristics
  - Accelerated testing
  - Follow up if in progress at submission

- Formula data for technical/MUP may be required for new end-use products if not previously registered in CA

- Magnitude and Nature of Residue studies not required (except for Sec 18 and 24(c) product registrations), but Residue Analytical Method, reference standard and tolerance data are required

Chemistry

Expect to be routed if:

- New product with conventional active ingredient
- New spray adjuvant
- First food or new outdoor uses
- Change in formulation
- Revised label with change in ingredient statement

Ecotoxicology

General Considerations:

- Identify Test Article(s) and all synonyms in cover letter
- Discuss plans to use non-EPA guideline studies in advance of submission
- Request protocol review, especially for pollinator studies
- Backlogged review queues can significantly impact registration timelines

Ecotoxicology

Expect to be routed if:

- New active ingredient or major new use product with outdoor terrestrial or aquatic use pattern
- New molluscicide, repellent, rodenticide or other vertebrate control products.
- Fumigant

Ecotoxicology

Expect to be routed if:

- Revised labels with:
  - Change in environmental hazards statement
  - Change in buffer zones
  - New bee attractive crops
  - Change in application rate
    - Increase in rate (Risk Assessment)
    - Decrease in rate (Efficacy)
  - Change in application method
  - Addition of target pest

Summary

- Cover Letter
  - Be detailed!
  - Summarize EPA data results and risk assessment conclusions
  - Identify potential review issues and provide explanations and interpretations of complex and problematic data
- Supporting Data
  - Electronic submission highly recommended
  - Submit EPA and other agency data reviews and summary memos

Thank You!

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