



## **The Value of Process Evaluation:**

# **Risk Mitigation Measures for Pesticide Products Could Be Implemented Sooner**

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# Evaluation Purpose

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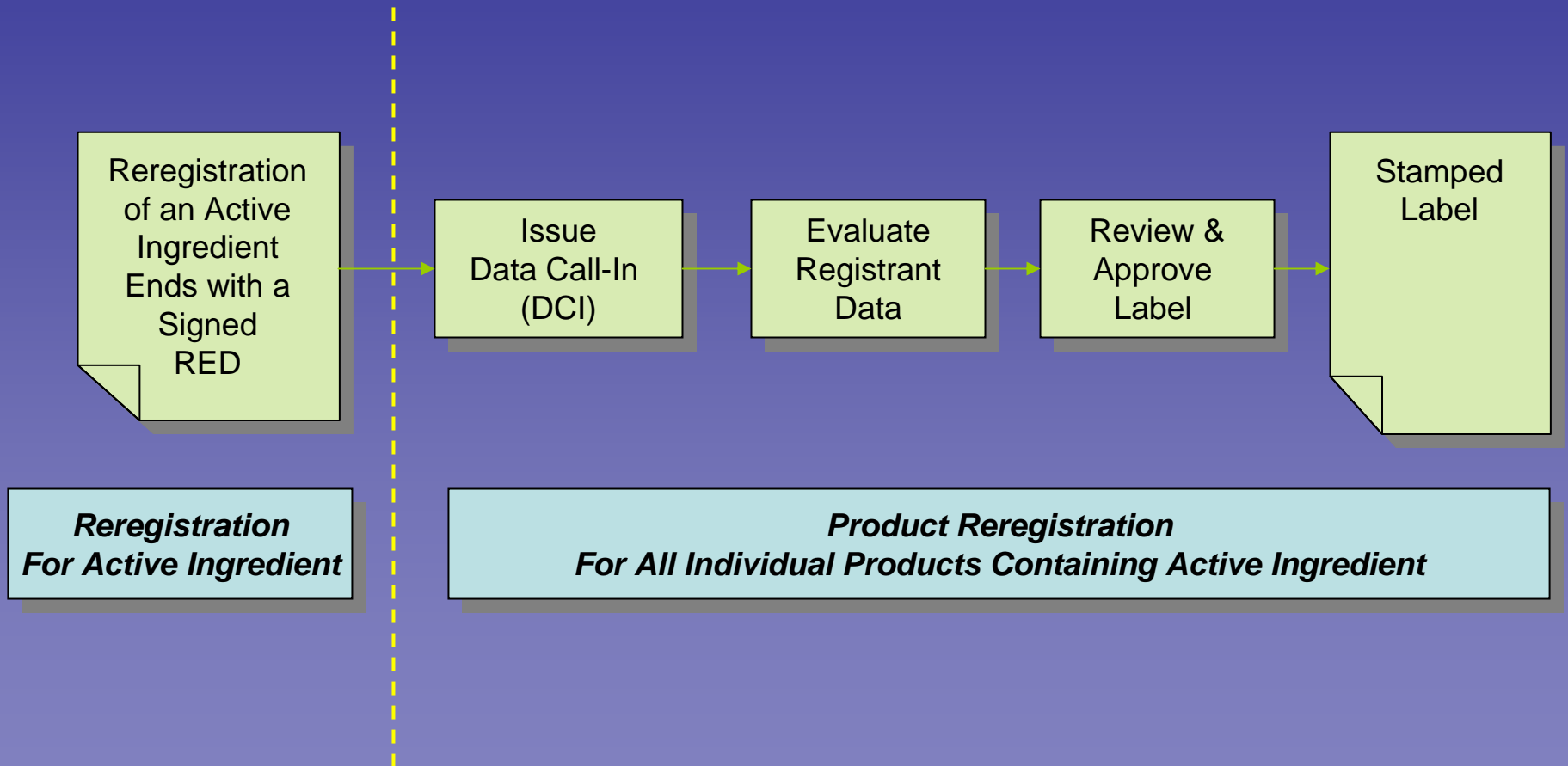
- Identify causes of delay in the product reregistration process
- Identify opportunities for innovation and streamlining to make process more efficient
- Ensure more timely implementation of the required risk mitigation measures for pesticide use

# Background

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- Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  - Requires comprehensive review of all pesticide active ingredients registered before November 1984
- Reregistration Eligibility Decision Documents (REDs)
  - Document decisions on necessary mitigation for each active ingredient
  - 600 active ingredients subject to reregistration
  - Deadlines for completion of REDs in statute
- Once a RED is completed, all individual products that contain that active ingredient must be reregistered
  - Universe of products subject to reregistration > 20,000
  - No statutory deadline for completion of product reregistration

# Overview of Process



# Methodology

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- Identify evaluation questions
- Develop logic model
- Review related evaluations
- Conduct 30 interviews
- Conduct audit of acute toxicity and product chemistry reviews
- Analyze program data on reregistration times, product types, and related parameters
- Develop case studies on specific REDs

# Duration of Process

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- Universe of Products:
  - ~7,300 completed (38% of universe)
  - Almost 12,000 products pending
  - >6,000 more expected based on FY06 REDs
- Average time to reregister products
  - Median = 30 months
  - Mean = 54 months
    - ~41 months for DCI approval and data receipt/review
    - ~14 months for label review and approval

# Evaluation Findings

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- Identified delays/inefficiencies in most steps of process
- Identified broader issues relating to:
  - Data management
  - Communication
  - Management and staffing
- Four streamlining initiatives piloted by OPP
  - Establish “SWAT Teams” to reduce backlog
  - Batch data requirements where feasible
  - Implement RED-specified mitigation prior to product reregistration
  - Provide streamlined packages for label review

# Conclusions of Evaluation

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- Delays associated with REDs
  - Known, unresolved issues
  - Errors, issues raised in comments, and new data
- Problems, bottlenecks, duplications of effort
  - DCI process
  - Label reviews
  - Information management
  - Resources and priorities
- Delays from external entities or considerations
  - Registrant-submitted data
  - Several OPP divisions participate, in addition to others



# Recommendations

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- OPP adopted 17 out of 21 recommendations
- Example recommendations:
  - Revise approach for DCI justification
  - Improve transition of cases through streamlined label packages
  - Maintain management attention through regular meetings
  - Incorporate product reregistration into performance standards
  - Prioritize an information tracking system

# Recent Increase in Product Reregistration Decisions

Decision	FY'02	FY'03	FY'04	FY'05	FY'06	FY'07	FY'08
Products reregistered	77	53	78	104	169	529	680
Products amended	51	40	35	63	40	80	205
Products cancelled	186	213	14	342	297	370	309
Products suspended	0	5	0	0	0	0	3
<b>Total</b>	<b>314</b>	<b>311</b>	<b>127</b>	<b>509</b>	<b>506</b>	<b>979</b>	<b>1,197</b>

# Value to EPA OPP

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- Expect to complete product reregistration sooner than previously estimated
  - Implement risk mitigation measures on label sooner!
- Information to help better allocate resources and staff
- Improved communication

# Evaluation Report

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- Evaluation of the U.S. EPA Pesticide Product Reregistration Process
  - <http://www.epa.gov/evaluate/reports.htm>
  - Under "Office of Prevention, Pesticides and Toxic Substances"

*Questions or Comments?*