

US EPA ARCHIVE DOCUMENT

REGISTRATION REVIEW

Report from PPDC Workgroup

Presentation to PPDC

October 29, 2003

Registration Review Background

- FIFRA sec. 3(g) provides for periodic review of pesticides registrations
 - goal of every 15 years
 - establish a procedure via regulation
 - use data call-in authority to require data as necessary
 - other provisions of FIFRA apply
- Advanced Notice of Proposed Rule-Making (April 2000) –
EPA's initial concept and solicit comments
- EPA presentation at April 2003 PPDC meeting
- Charge to form workgroup to make recommendations on key issues
- Workgroup formed in June 2003

Background continued

- PPDC Workgroup organized in June 2003
 - 23 members; diverse membership
 - Series of public meetings held June – October 2003 to discuss and make recommendations for three key issues:
 - Criteria for scheduling registration reviews
 - Should there be multiple levels of the rigor of review depending on the pesticide and its issues?
 - What should be the stakeholder participation process?

Background continued

- Other topics included:
 - What constitutes a registration review decision?
 - How to ensure that a pesticide's registration is kept up to date – registration review should be a safety net, not a catch-all
 - Accounting for inert ingredients in registration review.

Workgroup Mission and Operation

- Mission: provide advice and recommendations on design and development of procedural regulations for registration review
- Three key issues:
 - How should pesticides be scheduled for review?
 - Should there be different levels of review?
 - How should the public participate?
- Four public meetings June - October 2003
- Discussion led to recommendations; did not seek group consensus

ISSUE 1

How Will Pesticides be Scheduled for Registration Review?

Considerations:

- 1200 Pesticides / 20K Products subject to registration review
- Universe of pesticides continually changing
- Many chemically related pesticides
- Work group considered other alternatives, e.g., “worst first”

Scheduling continued

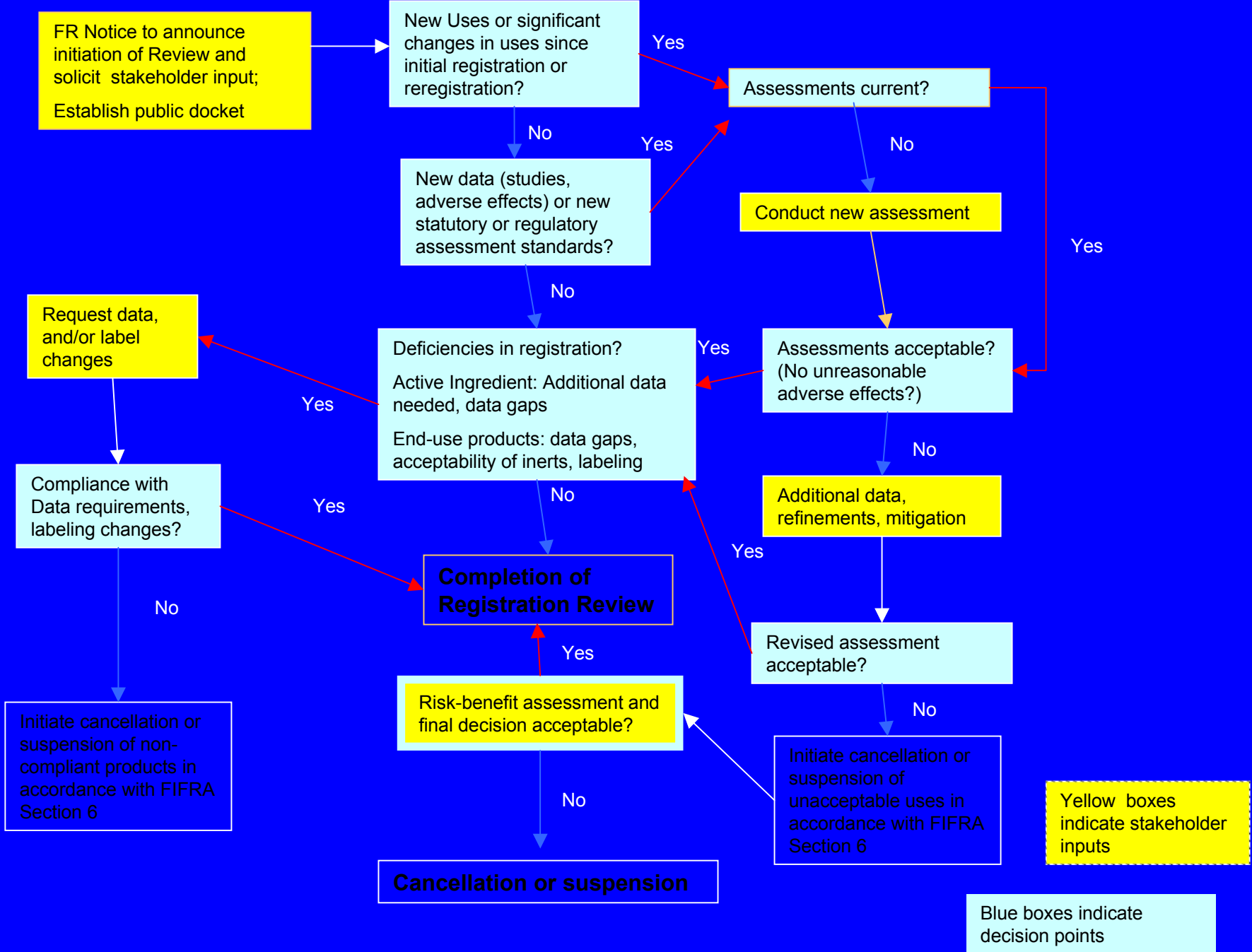
- **Recommendations:**
- The administrative procedures for scheduling registration review should not be subjective, resource-intensive or time-consuming.
- Predictable schedule generally based on 15 years from date of registration, reregistration, or other major risk assessment
- Specific criteria for departure from scheduling should be established by regulation.
- Comprehensive schedule published in federal register and on EPA's website with regular updates

Issue 2

Different Levels of Review

Considerations:

- Not all chemicals pose the same risks
- Scope of the program mandates efficient use of resources
- Changes in data requirements, database, adverse effects data, science policies, and use and usage profiles



Level of Review continued

Recommendations:

- Registration Review process should allow for a streamlined review for relatively “simple” pesticides e.g., low toxicity, minimal usage
- Streamlined process for pesticides with stable regulatory history and science
- Pesticides with major complex issues would require a more robust assessment

ISSUE 3

How can meaningful public participation be accomplished?

- Considerations:

- Registration review would benefit from early participation by all stakeholders.
- Stakeholders need a predictable schedule to prepare for and participate in registration review.
- Stakeholders need an understandable process where opportunities and expectations for public participation are clear.

Public Participation continued

- Recommendations:
 - Stakeholder input would be sought on use profiles, risk assessments, risk/benefit analyses, and risk mitigation measures.
 - Stakeholder process should be tailored to the level of review.
 - Modern electronic technology should be used to facilitate stakeholder access to information
 - Use of a comprehensive e-docket should be expanded to provide a continuum of information including history, status, public comments and all previous regulatory decisions of a pesticide
 - Publish a Federal Register Notice to initiate chemical specific registration review

General Recommendations

- The review does not supersede or replace EPA's other authorities under FIFRA (data call-ins, special review, suspension, cancellation, etc.).
- Registration review can be considered a "safety net" so that every registration is reviewed periodically to assure that no administrative deficiencies or risk-related issues are overlooked.
- The degree of reassessment should not be a "one-size-fits-all" process

GENERAL RECOMMENDATIONS - continued

- FRN should be published to announce annual or biannual updates to the schedule.
- Schedule should be made available on the EPA website well in advance.
- A predictable process and schedule for the submission of data by stakeholders
- Ensure the review of chemicals with outstanding issues (data call ins, etc.) will be completed in a timely manner

Additional Issues

- What constitutes a registration review decision?
 - Whether a pesticide meets the requirements of FIFRA section 3(c)(5)
- How to ensure that a pesticide's registration is kept up to date – registration review should be a safety net, not a catch-all
- Accounting for inert ingredients in registration review.

Additional Issues

- What constitutes a current assessment?
- Possible criteria:
 - Dietary assessment: includes all current food uses
 - For assessments that are not dietary (residential, ecotox, endangered species concerns, occupational) includes uses that are the significant sources of exposure
 - No indications of significant new or increased adverse effects

PPDC Discussion:

- Questions
- Discussion of key issues and workgroup's recommendations
- PPDC recommendations