Registration Review: Considerations for Labeling of End-Use Products

Pesticide Program Dialogue Committee

May 12, 2005

Previous Workgroup Recommendations to PPDC (May, 2004)

- Decision on AI and its uses should be followed by review of individual products.
- Product labels must comply with decisions made for AI and particular uses, and with all current label policies.
- Products with multiple AIs may be reviewed and require updating more than once in 15-year period.

Previous Workgroup Recommendations to PPDC (May, 2004)

- Communication of Decision
  - Letters to registrants
  - DCI, when necessary
  - Public communication effort
  - Agreements between registrants/EPA could set conditions
  - Failure to amend labels could lead to cancellation

Options for Individual Product Label Reviews

Similar to current reregistration process:

1).Decisions on required label changes for products containing a given AI and uses are communicated to registrants (via decision document of some sort) with requirement to submit revised labels for review within a given time frame.

2). Registrants submit revised labels for review.

3). Agency reviews labels for compliance with required changes and any other labeling requirements and either approves, approves conditionally, or requires resubmission with additional changes.

Cons: The registrant may overlook label requirements unrelated to the registration review process (e.g., compliance with a PR Notice or other policy change), leading to additional rounds of submission and review, delaying implementation of new labeling. Products with multiple active ingredients may pose complication if registration review time frames for the various active ingredients are similar.

Options for Individual Product Label Reviews

Alternative process:

1). Decisions on label changes required for products containing a given AI and uses are communicated to registrants.

2). Agency reviews current labels and notifies registrants of all labeling changes required, both to comply with RR decisions and all other label policies. Priority could be given to product labels with uses of concern.

3). Registrants submit final labeling and release products for shipment with revised labeling by given date (18 months).

4). Registrants can contest a required change by submitting rationale and, if accepted, receive a stamped, accepted label.

Cons: Compiling current labels may pose difficulty. Products with multiple active ingredients may pose complication if AI time frames are similar. If large numbers of labels have changes that are disputed, this could also delay implementation of revised labels.

Timing for Labeling*

Currently regulations at 40 CFR §152.130 state:

(c) Normally, if the product labeling is amended on the initiative of the registrant, by submission of an application for amended registration, the registrant may distribute or sell under the previously approved labeling for a period of 18 months after approval of the revision, **unless an order subsequently issued by the Agency under FIFRA sec. 6 or 13 provides otherwise**. However, if paragraph (d) of this section applies to the registrant's product, the time frames established by the Agency in accordance with that paragraph shall take precedence.

Timing for Labeling*

Currently regulations at 40 CFR §152.130 state:

(d) If a product's labeling is required to be revised as a result of the issuance of a **Registration Standard, a Label Improvement Program notice, or a notice concluding a special review process,** the Agency will specify in the notice to the registrant the period of time that previously approved labeling may be used. In all cases, supplemental or sticker labeling may be used as an interim compliance measure for a reasonable period of time. The Agency may establish dates as follows governing when label changes must appear on labels:

(1) The Agency may establish a date after which all product distributed or sold by the registrant must bear revised labeling.

(2) The Agency may also establish a date after which no product may be distributed or sold by any person unless it bears revised labeling. This date will provide sufficient time for product in channels of trade to be distributed or sold to users or otherwise disposed of.

Timing for Labeling Changes

- Regulation promulgated May 4, 1988, does not address implications of reregistration, tolerance reassessment, or registration review.
- Time frames can be specified for revisions that are cancellation of uses (subject to FIFRA Sec. 6).

Considerations for time required to implement label revisions

- Product inventories
- Production schedules
- Lead times for new packaging and printing of new labeling
- Complexity of packaging/labeling
- Number of product SKUs (package sizes)
- Disposal of obsolete labeling and packaging
- Costs

Time frames shorter than 18 months are problematic

- Production often is not a continuous process; in some cases products are produced once a year.
- It is most efficient to consolidate multiple changes at one time (once a year is typical).
- Low-sales-volume products may have slow moving inventories.
- State approvals may be required.
- Lead times for packaging may not be flexible.
- Shortening lead times may increase costs significantly.
- Formatting, editing, and review label changes takes significant time; a compressed timeline can increase potential for errors.
- Supplemental distributor products increase the number of entities involved.

Addressing mitigation of risks

- Unless an imminent hazard exists (as opposed to a “concern”), measures to recall, repackage, or relabel products are not warranted.
- It may not be possible to have revised labeled product released for shipment into channels of trade sooner than 18 months.
- Quicker timelines incur significant costs.

Addressing mitigation of risks

If risk mitigation is deemed necessary, interim measures should be considered:

- For agricultural or vector control products for public health programs, when possible (i.e. creates no conflict with current printed labeling), distribution of supplemental labeling is a valid option.

- For consumer products, recommended use changes can be communicated through other means (media, internet).