can base the new assessment on available data or information, including data or information submitted under §155.50 or in response to a Data Call-In notice. If sufficient data or information are available, the Agency will conduct the new risk assessment or risk/benefit assessment. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(2) Individual product registrations. If the Agency finds that additional review of an individual product’s registration is needed, it will review the pesticide product label, confidential statement of formula, product-specific data, or other pertinent data or information, as appropriate, to determine whether the registration of the individual product meets the FIFRA standard for registration. If the Agency determines that additional data or information are needed to conduct the review, the Agency will issue a Data Call-In notice under FIFRA section 3(c)(2)(B).

(c) Public participation during a pesticide’s registration review. The Agency will generally make available for public review and comment a draft risk assessment for a pesticide if a new risk assessment has been conducted. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the draft risk assessment and provide a comment period of at least 30 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments. If the revised risk assessment indicates risks of concern, the Agency may, in the notice announcing the availability of the revised risk assessment, provide a comment period of at least 30 calendar days for the public to submit suggestions for mitigating the risk identified in the revised risk assessment.

(1) The Agency might not request comments on a draft risk assessment in cases where the Agency’s initial screening of a pesticide indicates that it has low use/usage, affects few if any stakeholders or members of the public, poses low risk, and/or requires little or no risk mitigation. In such cases, the Agency will make a draft risk assessment available for public review and comment when it issues a proposed decision on the registration review case. If the Agency finds that it is not necessary to conduct a new risk assessment, it will issue a proposed decision on the registration review case as described in §155.58.

§ 155.56 Interim registration review decision.

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in §155.58 when issuing an interim registration review decision.

§ 155.57 Registration review decision.

A registration review decision is the Agency’s determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

§ 155.58 Procedures for issuing a decision on a registration review case.

(a) The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place in the pesticide’s registration review docket the Agency’s proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:
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(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency’s response to significant comments. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.

(d) If the registrant fails to take the action required in a registration review decision or interim registration review decision, the Agency may take appropriate action under FIFRA.

PART 156—LABELING REQUIREMENTS FOR PESTICIDES AND DEVICES

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Subpart A—General Provisions

§ 156.3 Definitions.

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this part, the following terms shall have the meanings set forth below.

Dilutable means that the pesticide product’s labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use.

Transport vehicle means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank