Environmental Protection Agency

§155.53 Conduct of a pesticide's registration review.

The Agency will review data and information described in §155.50(a), (b), and (c) or submitted in response to a Data Call-In notice that it believes should be considered in the pesticide's registration review.

(a) Assess changes since a pesticide's last review. The Agency will assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data or information on the pesticide, including any data or information submitted under §155.50 or in response to a Data Call-In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under §155.50 or in response to a Data Call-In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration.

(b) Conduct new assessments as needed. (1) Active ingredient(s) in the registration review case. If the Agency finds that a new assessment of the pesticide is needed, it will determine whether it 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.

(2) 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.