

Environmental Protection Agency

§ 155.42

a previously registered active ingredient for which the Agency has determined that a substantially complete chronic health and teratology data base exists. Following the comment period and issuance of the Registration Standard, the Agency will issue in the FEDERAL REGISTER a notice of availability of the Registration Standard.

Subpart C—Registration Review Procedures

SOURCE: 71 FR 45732, Aug. 9, 2006, unless otherwise noted.

§ 155.40 General.

(a) *Purpose.* These regulations establish procedures for the registration review program required in FIFRA section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

(1) Among other things, FIFRA requires that a pesticide generally will not cause unreasonable adverse effects on the environment. Registration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment.

(2) If a product fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA.

(b) *Applicability.* This subpart applies to every pesticide product registered under FIFRA section 3 as well as all pesticide products registered under FIFRA section 24(c). It does not apply to products whose sale or distribution is authorized under FIFRA section 5 or section 18.

(c) *Limitations.* (1) At any time, the Agency may undertake any other review of a pesticide under FIFRA, irrespective of the pesticide's past, ongoing, scheduled, or not yet scheduled registration review.

(2) When the Agency determines that new data or information are necessary

for a pesticide's registration review, it will require such data under FIFRA section 3(c)(2)(B).

[71 FR 45732, Aug. 9, 2006, as amended at 73 FR 75595, Dec. 12, 2008]

§ 155.42 Registration review cases.

(a) *Establishing registration review cases.* A registration review case will be composed of one or more active ingredients and all the products containing such ingredient(s). The Agency may group related active ingredients into a registration review case when the active ingredients are so closely related in chemical structure and toxicological profile as to allow common use of some or all required data for hazard assessment.

(1) *Existing pesticides.* The Agency will assign each pesticide registered on or before the effective date of this regulation to a registration review case.

(2) *New pesticides.* The Agency will assign each pesticide registered after the effective date of this regulation to an existing registration review case or to a new registration review case.

(3) A pesticide product that contains multiple active ingredients will belong to the registration review cases for each of its active ingredients.

(b) *Modifying registration review cases.* New data or information may suggest that a registration review case should be modified. The Agency may modify a registration review case in the following ways:

(1) Add a new active ingredient to a registration review case. The Agency may determine that a new active ingredient is chemically and toxicologically similar to active ingredients in an existing registration review case and should be grouped with the ingredients in the existing registration review case.

(2) Split a registration review case into two or more registration review cases. For example, new data or information may suggest that active ingredients in a registration review case are not as similar as previously believed and that they belong in two or more separate registration review cases.

(3) Move an ingredient from one registration review case to another. For example, new data or information might suggest that an ingredient

§ 155.44

should not be grouped with the other ingredients in the registration review case and that it belongs in a different registration review case.

(4) Merge two or more registration review cases into a single registration review case. For example, new data or information might suggest that the active ingredients in two or more registration review cases should be grouped together for registration review.

(5) Delete an active ingredient from a registration review case. For example, the Agency will remove the ingredient from the case if the registrations of all products containing an active ingredient in a registration review case are canceled.

(c) *Closing a registration review case.* The Agency will close a registration review case if all products in the case are canceled.

(d) *Establishing a baseline date for a registration review case.* For the purpose of scheduling registration reviews, the Agency will establish a baseline date for each registration review case. In general, the baseline date will be the date of initial registration of the oldest pesticide product in the case or the date of reregistration, whichever is later. For the purpose of these procedures, the date of reregistration is the date on which the Reregistration Eligibility Decision or Interim Reregistration Decision was signed, whichever date the Agency determines to be more appropriate based on the comprehensiveness of the review.

(1) The Agency generally will not change the baseline date for a registration review case when it modifies a case by adding or deleting ingredients or products.

(2) When the Agency splits a registration review case into two or more cases, the new case(s) generally will have the baseline date of the original registration review case.

(3) When the Agency merges two or more registration review cases into a single case, the Agency generally will use the earliest baseline date as the baseline date for the new case.

(e) *Announcing registration review cases and baseline dates.* The Agency will maintain a list of registration re-

40 CFR Ch. I (7–1–13 Edition)

view cases, including baseline dates, on its website.

§ 155.44 Establish schedules for registration review.

The Agency will develop schedules for registration review that are generally based on the baseline date of the registration review case or on the date of the latest registration review of the registration review case. The Agency may also take into account other factors, such as achieving process efficiencies by reviewing related cases together, when developing schedules for registration review. The Agency will maintain schedules for the current year and at least two subsequent years on its website.

§ 155.46 Deciding that a registration review is complete and additional review is not needed.

The Agency may determine that there is no need to reconsider a previous decision that a pesticide satisfies the standard of registration in FIFRA. In such cases, instead of establishing a pesticide registration review case docket as described in § 155.50, the Agency may propose that, based on its determination that a pesticide meets the FIFRA standard for registration, no further review will be necessary. In such circumstances, the Agency will publish a notice in the FEDERAL REGISTER announcing the availability of the proposed decision and provide a comment period of at least 60 calendar days. The Agency will publish a notice in the FEDERAL REGISTER announcing the availability of a final version of the decision, an explanation of any changes to the proposed decision and its response to any comments. The date of the final notice of availability would be used as the date of the latest registration review for the purpose of scheduling subsequent registration reviews.

§ 155.48 Data Call-In.

The Agency may issue a Data Call-In notice under FIFRA section 3(c)(2)(B) at any time if the Agency believes that the data are needed to conduct the registration review. The provisions in FIFRA section 3(c)(1), (c)(2)(B), and