ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 155

[EPA–HQ–OPP–2004–0404; FRL–8080–4]

RIN 2070–AD29

Pesticides; Procedural Regulations for Registration Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes procedures for conducting the pesticide registration review program mandated by the Federal Insecticide, Fungicide, and Rodenticide Act. Under this rule, EPA will review existing pesticide registrations to determine whether they continue to meet the statutory standard for registration. The registration review program will begin in the fall of 2006. This rule provides for the establishment of pesticide cases for review, the scheduling of reviews, the initiation, completion and documentation of reviews, and associated public participation procedures. The registration review program established by this regulation is intended to ensure that all pesticide registrations are systematically reviewed in a manner that is based on sound science and provides for public participation, transparency and efficiency to protect public health and the environment. In addition, in order to display the OMB control number for the information collection requirements contained in this final rule, EPA is amending the table of OMB approval numbers for EPA regulations.

DATES: This final rule is effective on October 10, 2006.

ADDRESSES: EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2004–0404. All documents in the docket are listed in the docket index at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Drive, Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Vivian Prunier, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: 703–308–9341; fax number: 703–305–5884; e-mail address: *prunier.vivian@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you hold pesticide registrations. Pesticide users or other persons interested in the regulation of the sale, distribution or use of pesticides may also be interested in this procedural regulation. Potentially affected entities may include, but are not limited to:

- Producers of pesticide products (NAICS code 32532).
- Producers of antifoulant paints (NAICS code 32551).
- Producers of antimicrobial pesticides (NAICS code 32561).
- Producers of nitrogen stabilizer products (NAICS code 32531).
- Producers of wood preservatives (NAICS code 32519).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 155.40 of the rule. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using *http://www.regulations.gov* to access this document and other related information in the electronic docket, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

II. Overview of this Document

In this document, EPA presents its response to comments on the proposed rule to establish procedural regulations for the registration review of pesticides. In response to comments, EPA is modifying some aspects of the rule relating to procedures for public participation in the registration review process. The differences between the proposed rule and the final rule are described in Units VI. and X.

In this document, the Agency describes:

- Statutory authority.
- History of this rulemaking.
- Response to comments on the rule.
- Response to comments on the operation and implementation of the program.
- Results of reviews required by statutes or executive orders.
- Changes to the rule.
- Procedural regulations for the registration review of pesticides.

III. Authority

A. EPA's Authority to License Pesticides

FIFRA section 3(a) generally requires a person to register a pesticide product with the EPA before the pesticide product may be lawfully distributed or sold in the U.S. A pesticide registration is a license that allows a pesticide product to be distributed or sold for specific uses under specified terms and conditions. A pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5), as follows:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

FIFRA 2(bb) defines ''unreasonable adverse effects on the environment'' as

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.

The burden to demonstrate that a pesticide product satisfies the criteria for registration is at all times on the

proponents of initial or continued registration. (*Industrial Union Dept.* v. *American Petroleum Institute*, 448 U.S. 607, 653 n. 61 (1980); *Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975).

B. EPA's Authority for Registration Review

The Food Quality Protection Act (FQPA) of 1996 amended FIFRA to add, among other things, section 3(g), ''REGISTRATION REVIEW,'' as follows:

(1)(A) GENERAL RULE. - The registrations of pesticides are to be periodically reviewed. The Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide's registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6.

(B) LIMITATION. - Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this Act.

(2)(A) DATA. - The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) DATA SUBMISSION, COMPENSATION, AND EXEMPTION. - For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

IV. Notice of Proposed Rulemaking

EPA published proposed procedures for the registration review of pesticides on July 13, 2005 (70 FR 40251) (FRL–7718–4). A copy of the proposed rule may be found in Docket EPA–HQ–OPP–2004–0404, which can be accessed electronically at: *http://www.regulations.gov*. The 90–day comment period for this proposed rule ended on October 11, 2005.

The preamble to the proposed rule discussed:

- Statutory authority and legislative history.
- The Agency's goals for the registration review program.
- Evaluating approaches to registration review.
- Factors considered in designing the registration review program.
- Design options considered for the registration review program.
- Testing the proposed registration review decision process.
- Proposed procedures for registration review.
- Relationship of registration review to other FIFRA activities.
- Phase-in of the registration review program.
- Results of reviews required by statutes and executive orders.

V. Overview of Comments

EPA received 23 comments on the proposed rule, as follows:

- One individual.
- Two consultants.
- One public interest group.
- Four registrants.
- One State Pesticide Safety Coordinator.
- Three State Lead Agencies for pesticides.
- Five California water sanitation agencies.
- Six trade associations.

The Agency's analysis of these comments showed that the comments can be organized into three broad topic areas:

- Requests for changes in the procedural regulations. These comments and the Agency's response are discussed in this preamble.
- Operation and implementation of the registration review program. These comments and the Agency's response are discussed in this preamble.
- Issues concerning the licensing of pesticides in general are described in the response to comments document that the Agency has placed in the docket for this rulemaking.

In general, comments on the proposed rule resulted in minimal revisions in the final rule. Early implementation will continue to be discussed with the Pesticide Program Dialogue Committee, a stakeholder advisory committee established under the Federal Advisory Committee Act. EPA may issue additional guidance on the registration review program as it gains experience with these procedures.

VI. Comments on the Procedural Regulations

A. § 155.40--General

This section describes the purpose of the regulations in Subpart C--Registration Review Procedures and states that the goal of these procedures is a review of each pesticide's registration every 15 years. This section also specifies that the regulations apply to pesticides registered under section 3 or section 24(c) of FIFRA, states that the Agency may undertake any other review under FIFRA at any time and that the Agency will use FIFRA section 3(c)(2)(B) to require new data or information that are necessary for a pesticide's registration review.

1. *Authority to establish procedures for registration review.* A trade association questioned EPA's authority to establish the proposed procedures for registration review. They asserted that in the absence of specific procedures in FIFRA for the administration of registration review, EPA must use procedures in FIFRA section 3(c)(8) which specifies procedures for conducting interim administrative review to develop a risk-benefit evaluation of a pesticide. Procedures for implementing FIFRA section 3(c)(8) are described in 40 CFR part 154.

The Agency does not agree with this comment. FIFRA section 3(g)(1)(A), which mandates a periodic review of the registration of pesticides, requires the Agency to establish procedures for conducting such reviews. This provision means that, except for limitations specified in FIFRA section 3(g)(1)(B) and FIFRA 3(g)(2), EPA has the authority to develop procedures for the conduct of this new program. Accordingly, EPA is not required to use procedures in FIFRA section 3(c)(8) to conduct the review mandated in FIFRA section 3(g).

2. *Registration review of pesticides covered under FIFRA section 25(b).* An industry comment asked EPA to assure that products exempted from FIFRA regulation under section 25(b) of FIFRA are reviewed adequately, especially with regards to health claims.

Pesticides that are exempt from FIFRA requirements under FIFRA section 25(b) are identified in 40 CFR 152.20, Exemptions for pesticides regulated by another Federal agency, and 40 CFR 152.25, Exemptions for pesticides of a character not requiring FIFRA regulation. Pesticides covered by FIFRA section 25(b) are not subject to registration review. However, some products that are exempt under FIFRA section 25(b) could be affected by actions taken in registration review. For example, pesticide-treated articles or substances described in § 152.25(a) could be affected if issues arise during the registration review of a pesticide used to treat an article or substance. If the pesticide product or its use on treated articles or substances were canceled, the treated article or substance would no longer meet the requirements of § 152.25(a), which specifies that the pesticide used to treat an article or substance must be registered for that use.

B. § 155.42--Baseline Dates for Registration Review Cases

In § 155.42(d), EPA proposed to establish a baseline date for each registration review case. In general, the baseline date would be the date of initial registration of the oldest product in the registration review case or the date of reregistration, whichever is later.

The date of reregistration would be the date on which either a Reregistration Eligibility Decision (RED) or an Interim Reregistration Eligibility Decision (IRED) was signed, whichever date the Agency determines to be most appropriate.

An industry comment suggested that to avoid duplication of effort, the Agency should amend § 155.42 to use the date of approval of significant new uses as the baseline date for the registration review case.

The Agency intended the baseline date to be the date of the last *comprehensive* review. A review of a new use may not be comprehensive--previously approved uses may not be included in the evaluation of the new use. Generally, when conducting a registration review of a pesticide for which a significant new use was recently approved, EPA would not redo the recent review but would incorporate the risk assessment for the new use into the registration review.

Another commenter asserted that baseline dates should be either the initial registration of a pesticide or the completion of the RED. The commenter stated that the IRED should not be used because it does not include an assessment of cumulative risk that is required for pesticides that have a common mechanism of toxicity with other substances. For such pesticides, the Agency should use the date of the RED (as opposed to IRED) to establish a common baseline date for all the pesticides included in the cumulative risk assessment.

The Agency agrees that the RED would update the comprehensive IRED regarding cumulative risk or other issues but the RED itself may not be a comprehensive review. For cases where there is both an IRED and a RED, the Agency needs the flexibility to decide which document represents a comprehensive review. Accordingly, this final rule allows the Agency to use the date of either document as the baseline date.

C. § 155.44--Establishing and Announcing Schedules for Registration Review

1. *Chronological* vs. *risk-based criteria as basis for establishing schedules for registration review*. In § 155.44, EPA proposed that schedules would be based on the baseline date of the registration review case or on the date of the last registration review of the registration review case. The rule allows the Agency to take into account other factors, such as achieving process efficiencies, when setting schedules. The preamble of the proposal described other factors that the Agency might consider. In July 2006, EPA released draft schedules that were developed using procedures in the proposed rule. Under the draft schedules, EPA would review chemically related registration review cases together.

While most commenters supported the proposed chronological approach, public interest groups and water treatment authorities advocated risk-based approaches for scheduling. Several industry groups did not like the chemical groupings in the Agency's draft schedules, preferring that cases be scheduled for registration review in a strictly chronological order. They argued that grouping cases together undermines the chronological order of the schedule and that the order of groups in the schedule would be based on risk concerns. One industry group asked the Agency to include in the rule criteria for deviating from a chronologically based schedule and to consult registrants regarding the selection of new dates.

While the Agency appreciates that there is a range of views as to how to set schedules for the registration review program, the establishment of schedules is within the Agency's discretion. EPA believes that reviewing similar cases together facilitates decision making for pesticides with similar scientific or regulatory issues and would be an efficient use of resources. Registrants or other stakeholders may notify the Agency regarding particular issues that could impact the schedule. The Agency would consider such issues as appropriate.

2. *Considerations that could change the registration review schedule*. The Agency may consider factors other than the baseline date of the registration review case when developing schedules for registration review. As discussed in Unit IX.E. of the preamble of the proposed rule and as shown on the draft schedule released in July 2005, the Agency plans to cluster identified cases belonging to the same chemical class or group to promote efficiency of review for the Agency and provide a ''level playing field'' for industry. Additionally, because the Agency's economic analysis of this regulation suggested that a small business (i.e., a business that meets criteria established by the Small Business Administration) might face high data generation costs if it holds registrations in two or more registration review cases that are scheduled to undergo registration review in the same year, the Agency may schedule these cases out of chronological order.

The Agency has a continuing obligation to respond to emerging risk concerns (discussed in Unit XI.B. of the preamble of the proposed rule). At any time, the Agency may receive new information that suggests that the Agency should reevaluate a previous decision to register a pesticide. After the registration review program begins, the Agency will continue to address emerging risk concerns. If a pesticide presents an urgent potential risk of concern, the Agency may opt to review all other aspects of the pesticide's registration at that time, rather than only looking at the risk of concern. In such cases, the Agency may update the registration review schedule by announcing the new date of the registration review of this case.

In general, the Agency may consider these and other factors, including issues raised by the public or the registrant when reviewing a posted schedule, to schedule a pesticide registration review, or to modify the schedule of a pesticide registration review as appropriate.

3. *Three-year schedules*. Although the preamble of the proposed rule contemplated maintaining a 3–year schedule, the proposed rule did not specify a timeframe. In response to comments requesting this change, the Agency has modified § 155.44 to specify that the schedules would cover the current year and at least two subsequent years.

D. § 155.46--Deciding that a Registration Review is Complete and Additional Review is Not Needed

Under § 155.46, the Agency may propose that no additional review of a pesticide is needed in order to determine whether the pesticide continues to meet FIFRA requirements for registration. The Agency would announce the availability of such proposals and take comment on them. In response to comments on a proposal made under § 155.46, EPA may reconsider its proposal and schedule a registration review of the pesticide.

The Agency received one comment asking the Agency to clarify the purpose of this provision. The purpose of this provision is to give the Agency flexibility to not schedule a pesticide for registration review if the pesticide has such low toxicity, exposure or risk that another review would not change the Agency's position and would not be an effective use of resources. The Agency may also use this provision for a pesticide that has recently undergone a comprehensive review. In proposed decisions issued under § 155.46, the Agency generally would explain why it believes that no additional review is

necessary and reference, as appropriate, publicly available documentation to support the Agency's position.

To clarify the procedures it will use in § 155.46, EPA is modifying the second sentence to read, ''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.'' EPA is clarifying the status of pesticides subject to this section by adding the sentence, ''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.''

E. § 155.48--Data Call-In

Section 155.48 provides that, as required by FIFRA section 3(g), EPA will use procedures in FIFRA section 3(c)(2)(B) to require submission of data that are needed to conduct a pesticide's registration review. This paragraph stipulates that the data protection provisions of FIFRA 3(c)(1), (c)(2)(B), and (c)(2)(D) apply to the submission, compensation and exemption of data required to conduct a registration review.

1. *Data Call-In procedures*. One comment asked why the proposed rule does not impose any requirements under FIFRA 3(c)(2)(B). The commenter suggested that additional data collection authorities are needed and procedures to ensure all necessary data must be included in this rule.

The Agency finds that it is not necessary to develop new procedures for calling in data for registration review because FIFRA section 3(g) requires the Agency to use section 3(c)(2)(B) to collect the data, and that section provides EPA with sufficient authority to obtain any necessary data.

2. *Data compensation for ''voluntarily'' submitted data*. Industry comments asked that the proposed rule clarify the data compensation status of information voluntarily submitted in response to registration review. Some comments suggested that the rule specify the mechanisms for requesting and obtaining a Data Call-In notice (DCI) before the data are submitted in order to protect data compensation rights. Other comments suggested that studies used in the registration review decision, particularly studies generated under revisions to the data requirements in 40 CFR part 158, be presented in the decision document. Registrants asked that in addition to determining whether a pesticide meets the FIFRA risk/benefit standard, EPA should assure that the registrant of the pesticide is entitled to use data supporting the risk/benefit determination for the pesticide.

The Agency acknowledges the importance of this issue and agrees that this concern should be addressed in the conduct of the registration review program. FIFRA section 3(g)(2)(A) directs the Agency to utilize section 3(c)(2)(B) to require the submission of data when such data are necessary for a registration review. Similarly, FIFRA section 3(g) requires that the data compensation provisions, including those set forth in sections 3(c)(1), 3(c)(2)(B), and 3(c)(2)(D) ''be utilized for and applicable to any data required for registration review.'' Hence, to the extent the Agency requires any data for registration review, such data are eligible for the data protections provided by the statute.

If a company submits data or information to the docket voluntarily (as opposed to providing these data or information in response to a DCI), such data are not ''required'' data eligible for protection under the statute. However, the Agency may evaluate these data or information and find that it must rely on this information to support the continued registration of pesticide products. If the Agency makes such a finding in the course of a pesticide's registration review, this finding would be a determination that the voluntarily submitted data or information are now required. This would be a ''compensable event'' and would trigger the requirement for compensation to be addressed. The competitors to the original submitter would be required to submit their own data or offer data compensation to the data submitter for use of the study. A ''compensable event'' would also arise should the Agency issue a Data Call-In Notice for the same data as were previously submitted voluntarily, but a Data Call-In Notice is not necessary to trigger compensability should the Agency determine and announce as part of its registration review decision that the particular data were required to support the registrations in question.

The Agency's registration review decision document may identify such data or information and the registration review decision document may establish a deadline for registrants whose registrations depend on such data to offer compensation to the owners of the data or submit their own data. The Agency may cancel the product registration of registrants who fail to adequately support a registration.

F. § 155.50--Initiate a Pesticide's Registration Review

EPA proposed to establish a docket for each registration review case, except for cases covered under § 155.46. The docket would describe information that the Agency may consider in the course of a pesticide's registration review and describe information that the Agency does not have that might be useful in the review. The public would be invited to review information in the docket and submit, within 60 days, any other information that they believe should be considered in the pesticide's review. A pesticide's registration review begins when EPA opens the docket for registration review case.

1. *Timeframe for submitting comments*. As originally proposed, the timeframe for submitting comments in response to a notice issued under § 155.50(b) would be ''60 calendar days.'' In response to comments that this time frame would not be long enough, the Agency is modifying this paragraph to specify that the time frame for such comment periods will be ''at least 60 calendar days.''

2. *Late submissions*. Comments from industry and others asked the Agency to clarify its position regarding data or information submitted after the due date established in the notice announcing the opening of the pesticide registration review case docket.

Under § 155.50(c)(1), the Agency will consider late submissions if the Agency believes that the new data or information are critical for the regulatory decision, such as health effects or ecological effects data or exposure data that the EPA could use to refine a risk assessment.

If a person has data or information that he/she believes that Agency should consider during the pesticide's registration review, but the data or information will not become available before the expiration of the comment period, he/she may either request an extension of the comment period, or in accordance with § 155.52, consult with the Agency regarding a submission date for these materials.

3. *Information submitted under § 155.50(c)*. Comments from industry asked the Agency to modify § 155.50(c) to specify the types of information that might be submitted under this paragraph and to reference quality and scientific criteria for data that might be submitted as comments during a pesticide's registration review.

In the preamble of the proposed rule, EPA described the kinds of information that, based on its experience in the pesticide reregistration program, might

be useful in registration review. As the Agency and its stakeholders gain experience in the registration review process, it may become clear what types of information are most useful. EPA could then develop appropriate guidance. In accordance with the Data Quality Act, EPA has already issued guidance regarding the quality of information that it relies upon for regulatory decisions. This guidance is available at EPA's website at: *http://www.epa.gov/quality/informationguidelines/*. The Agency will use this guidance in the registration review of pesticides.

G. § 155.52--Stakeholder Engagement

Under § 155.52, the Agency may meet with registrants or other stakeholders during a pesticide's registration review or to prepare for a forthcoming review. This section explains the procedure for releasing minutes or other material relating to such meetings.

Comments from industry asked that the rule provide an acceptable framework for activities in the pre-initiation stage. Other commenters remarked that non-registrants should have more access to the registration review process and that the public should be able to view all information, including reports from consumers about adverse effects. Additionally, they asserted that EPA should announce consultation opportunities in the **Federal Register**. Other comments from industry emphasized their concern that EPA not release confidential business information.

In this document, the Agency is establishing procedures that provide the public with the opportunity to participate in the review process and to review materials that the Agency uses as the basis of proposed registration review decisions.

The Agency generally does not announce in the **Federal Register** meetings with registrants or other stakeholders because it needs the flexibility to hold such meetings when the need arises. EPA may meet privately with industry to discuss proprietary or other confidential business information. Under § 155.52(a) and (b), EPA will place in the docket minutes of meetings with registrants or other stakeholders. EPA's protection of information claimed to be confidential business information is governed by section 10 of FIFRA and the Agency's regulations in 40 CFR part 2.

H. § 155.53--Conduct of a Pesticide's Registration Review

This section describes how the Agency will assess the significance of changes in statutes and regulations, risk assessment procedures or methods, or data requirements and any new information about the pesticide to determine whether additional review of the pesticide is warranted. If a new review of the pesticide active ingredients or individual products in a registration review case is needed, the Agency will determine whether additional information is necessary to conduct the review. This section also provides for public review and comment during the review process. Under the proposed procedures, the Agency would generally establish comment periods of ''at least 60 calendar days,'' except in § 155.53(c) where the comment period is ''at least 30 calendar days.''

1. *Agency's approach for conducting registration review*. The Agency received several comments that disagreed with the Agency's proposed approach for conducting a pesticide's registration review. An industry trade association reiterated comments made in response to the April 2000 Advance Notice of Proposed Rulemaking (65 FR 24585, April 26, 2000) (FRL–6488–9) that the Agency should use a checklist or decision tree for deciding whether a pesticide continues to meet the requirements for registration. Other stakeholders expressed concern that the proposed approach was not sufficiently rigorous and would lead to relaxed standards.

In the preamble of the proposed rule, the Agency described alternative approaches for conducting a pesticide's registration review and explained why it selected the proposed approach. The comments do not raise issues or concerns that would alter EPA's choice of approach. It is important to note, however, that although the Agency has not chosen to use a pure checklist approach, it is using a decision paradigm that ensures that the process will be transparent while still providing sufficient flexibility to allow for the scope and depth of a particular review to be tailored to the circumstances of the particular registration review case.

2. *Review of individual product registrations*. Some registrants expressed their belief that the Agency should conduct a comprehensive review of individual product registrations to assure adequacy of product labels, product-specific data, and any claims for generic data exemption under FIFRA section 3(c)(2)(D).

As explained in the preamble of the proposed rule, during the comment period on the initial registration review case docket, the public may comment on the need for a new review of individual product registrations. The Agency will continue to comply with its data protection obligations under FIFRA section 3(c)(2)(D).

3. *Public participation procedures*. Several commenters noted that under the Agency's procedures for public participation in the reregistration and tolerance reassessment programs, the Agency may announce the availability of a revised risk assessment and may invite the public to suggest approaches for mitigating the risks identified in the revised risk assessment. The proposed procedures for registration review did not provide this opportunity.

In response to this comment, the Agency is revising § 155.53(c) so that it may provide the public an opportunity to comment on possible risk mitigation when a revised risk assessment shows risks of concern. However, if immediate action is warranted, the Agency may initiate cancellation or suspension procedures under FIFRA section 6. In this event, the Agency would not provide the opportunities for public comment described in § 155.53(c) but would follow procedures in FIFRA section 6, as appropriate.

4. *Length of comment periods*. Several commenters asserted that the comment periods provided in the proposed regulation were not long enough.

Generally, where EPA publishes a document for comment, the Agency considers requests for extension if a reasonable basis for extension is provided. It is not necessary to modify these regulations to provide for extending comment periods.

I. § 155.57--Registration Review Decision

This section states that a registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration under FIFRA.

1. *Goal of registration review*. The California Stormwater Quality Association asserted that the goal of registration review should be to protect water quality and minimize the need to mitigate pesticide impacts through Clean Water Act (CWA) mechanisms.

The Agency believes that the goal of registration review is set forth in FIFRA section 3(g) and reiterated in § 155.40. Registration review is a determination whether a pesticide continues to meet the FIFRA standard for registration, including, among other things, that the pesticide does not cause unreasonable effects on the environment. As part of this review, EPA will assess the effects of pesticides on water quality. However, while meeting CWA standards is important, it is not the only goal of registration review.

2. *FIFRA standard for registration*. (a) Comments from industry strongly oppose EPA's intention to consider a pesticide's benefits during registration review. The comments referred to a discussion in the preamble of the proposed rule where EPA explained that it would evaluate information about the benefits of a pesticide with known high risks during registration review if a new and safer alternative to a pesticide has become available. The comments asserted that it is inappropriate for the Agency to base continued registration of a pesticide on a comparative benefits assessment with other pesticides. The comments cited FIFRA section 3(c)(5) to support their assertion that when pesticides meet the registration criteria of FIFRA, the Agency should not be allowed to make marketplace decisions of one product over another. FIFRA section 3(c)(5) states, ''The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirement of this paragraph, one should not be registered in preference to the other.''

EPA believes the commenter misapprehends the nature of FIFRA's risk-benefit balancing standard. A determination that a pesticide meets the registration standard under FIFRA at one time does not necessarily mean that the same pesticide will meet the standard at all times in the future, even if the science associated with the risks posed by the pesticide does not change. Significant changes in the benefits picture, such as the development of pest resistance or new alternatives, can also affect whether a pesticide continues to meet the FIFRA registration standard. EPA does not intend to compare benefits of two or more pesticides that do not pose risks of concern. As the commenters noted, EPA may not make a determination of essentiality when two pesticides meet the FIFRA requirements for registration. However, when there are risks of concern for a pesticide, FIFRA requires EPA to weigh those risks against the benefits of that pesticide to determine whether the risks are unreasonable. Benefits are the advantages that accrue to the pesticide users or society in general, such as increased production, decreased production costs, pest-free homes, or disease-vector control. The magnitude of those benefits often depends on the availability of alternative pest control measures, whether chemical, biological or cultural. Benefits are, in general, expected to be higher when there are no viable alternatives.

During registration review, EPA may reassess a pesticide that has remained registered even though high risks are associated with the use of the pesticide. In its earlier review, the Agency may have found that the pesticide did not pose unreasonable risk because of the high benefits of the pesticide. In registration review, EPA may find that existing risk assessments that identify these risks of concern are still valid. EPA would then determine whether the pesticide continues to provide sufficient benefits to justify maintaining the registration. The benefits finding could depend on whether new, safer alternatives have been registered since EPA's earlier decision. EPA conducted similar analyses in the reregistration program.

If EPA's review of a pesticide's registration appears to show that the pesticide does not meet the FIFRA standard for registration, EPA would follow procedures in FIFRA section 6 to change, cancel or suspend the pesticide's registration. This section sets out where it requires EPA to assess the benefits of the pesticide and provides opportunities for public hearings on whether the pesticide's registration should be changed, canceled, or suspended. The Agency would not analyze benefits when a registrant responds to the Agency's registration review finding by agreeing to the cancellation of a pesticide or termination of one or more of its uses under FIFRA section 6(f). However, FIFRA provides the public an opportunity to comment on the proposed action.

(b) Another registrant asserted that the registration review regulations should contain language that specifically reaffirms the standard of imminent hazard and substantial risk as the basis for cancelling pesticide registrations. He cited a specific product example to illustrate his belief that the Agency employed a ''zero tolerance agenda'' during reregistration.

The standard of ''imminent hazard'' referred to by the commenter applies to suspensions and emergency suspensions under FIFRA section 6(c). This section sets forth the standard for a suspension or an emergency suspension. This is not the standard that the Agency will use in making registration review decisions. The Agency interprets registration review to be a determination that a pesticide continues to meet the standard for registration in FIFRA section 3(c)(5), or, where appropriate, section 3(c)(7). This standard specifies, among other things, that a pesticide may not pose unreasonable risk to man or the environment.

When a pesticide poses risks of concern to humans or the environment, the Agency must address these risks. The options for addressing such risks include risk mitigation, determining that the risks are justified in light of the benefits of the pesticide, or initiating regulatory options to modify or cancel the registration. EPA generally consults with registrants and other stakeholders when deciding how to mitigate a risk. In addition, EPA has modified the proposed public participation procedures for registration review to generally add a public comment period when a pesticide poses risks of concerns so members of the public can provide suggestions for reducing the risk. This procedure provides registrants and other stakeholders an opportunity to provide input on the Agency's risk management decisions.

J. § 155.58--Procedures for Issuing a Decision on a Registration Review Case

In this section, EPA explains that it will issue proposed registration review decision documents for public review and comment. In comments on the proposed rule, various stakeholders advised the Agency of their expectations and needs regarding the documentation of registration review decisions and suggested how this documentation might be presented. EPA appreciates these suggestions. The Agency has consulted the Pesticide Program Dialogue Committee and has considered their recommendations together with comments submitted on the proposed procedural regulations. Nothing in the comments indicates the need to modify the regulation to specify the format of the registration decision document.

VII. Comments on the Operation of the Registration Review Program

A. Scope of the Registration Review Program

1. *Is registration review a safety net*? In the preamble of the proposed rule, the Agency described how it intended to use registration review as the framework for managing the regulatory status of existing pesticides.

Industry trade associations did not agree with this approach. In their comments, they asserted that EPA should not expand registration review beyond the intent of Congress because to do so risks repeating the Agency's experience with reregistration which began as a 5–year program in 1972 and still has not been completed. They asserted that registration review should not be a catch-all for other programs and actions. For example, special review, actions under FIFRA section 3(c)(8),

FIFRA section 6 or the Pesticide Registration Improvement Act (PRIA) should not be included in the registration review program. They believe that new programs such as endocrine disruptor screening and testing should be conducted independently of registration review. The industry comments advocate that, as far as possible, registration review should be a safety net.

EPA does agree that registration review is not the only mechanism for addressing pesticide registration issues, and will continue to use other provisions of FIFRA to address particular registration issues. However, EPA does not agree with the comment that registration review should function solely as a safety net to discover and resolve issues missed or overlooked in registration, tolerance reassessment, or reregistration activities. While EPA expects that it will occasionally discover issues that were overlooked in previous reviews, the purpose of registration review is to consider the pesticide in light of new knowledge that was not available for previous reviews.

EPA interprets the Congressional mandate for registration review to be a periodic assessment whether a pesticide continues to meet the FIFRA standard for registration in light of new knowledge. Therefore, the scope of a pesticide's registration review includes all aspects of a pesticide's registration specified in section 3(c)(5) of FIFRA with respect to product composition, labeling and other required material, and risks and benefits. Registration of new pesticides or new uses of pesticides under PRIA is a separate program from registration review. However, in evaluating a new use under PRIA, the Agency would consider all relevant information, including information that it might consider during the pesticide's registration review.

2. *Incorporating evolving or new programs into registration review*. As explained in the preamble of the proposed rule, EPA intends to incorporate new requirements, such as endocrine disruptor screening and testing or endangered species assessments into the registration review program as these aspects of risk assessment mature into routine evaluations for pesticides.

Industry commenters advised the Agency to avoid using registration review as the sole process for handling new issues. They asserted that attaching all these assessments (endangered species assessments, endocrine disruptor screening and testing, review of substitutes, etc.) to a program intended to accomplish periodic review of all pesticides will undermine the timeliness of the review process for a great many pesticides. Commenters believe that this may result in an ever-changing schedule that will deprive registrants and users of predictability and lead to significant inefficiencies within the Agency.

Again, EPA does not intend to use registration review as the only mechanism for addressing pesticide registration issues. However, EPA believes it is appropriate to use registration review as the framework for managing its responsibilities regarding existing pesticides. In making a FIFRA section 3(c)(5) decision as required under FIFRA section 3(g), EPA must consider all information that pertains to that decision. EPA regards endangered species assessments required under the Endangered Species Act or endocrine disruptor screening and testing required under the Federal Food, Drug, and Cosmetic Act as part of the risk characterization of the pesticide that is intrinsic to the FIFRA risk/benefit decision. If knowledge exists on these or other scientific issues at the time of a pesticide's registration review, the Agency believes it must consider them when it makes its FIFRA (3)(c)(5) finding.

3. *Managing emerging issues*. In the preamble of the proposed rule, the Agency explained that it will continue to give priority to emerging risk concerns. While reviewing the new risk concern, the Agency may find that it would be more efficient to review all other aspects of the pesticide's registration at the same time. The procedural regulations for registration review provide flexibility to amend the schedule to advance the registration review of a pesticide in this circumstance. The Agency would provide as much advance notice as possible regarding such changes in the schedule.

Commenters took exception to EPA's approach for managing emerging issues arguing that newly discovered risks of potential concern should be dealt with outside of registration review if the risks are urgent. The commenters believe that registration reviews should not be rescheduled under this circumstance.

The Agency does not agree that it should reassess the approach described in the preamble of the proposed rule. EPA fully explained its reasoning in the proposed rule and the comments do not persuade it otherwise. This is not to say that the Agency will not address urgent risks of concern outside the registration review process if the Agency determines that to be the appropriate course of action.

4. *Assessing risks of substitute pesticides*. In the preamble of the proposed rule, EPA explained that it might advance the registration review of pesticides that are potential substitutes for a pesticide or some uses of the pesticide that are being canceled under FIFRA section 6 because of risk concerns.

Industry commenters expressed concern that EPA would even consider using the registration review program to address reviews that might be the outgrowth of cancellation proceedings.

EPA generally would assess risks of substitute pesticides as part of the cancellation process in FIFRA section 6. In the rare event that it is necessary to perform a comprehensive review of a substitute pesticide, such a review might be tantamount to conducting the registration review of that pesticide. In such cases, EPA might find that it would be more efficient to conduct the registration review of the pesticide at the same time.

5. *Review of inert ingredients*. In the preamble of the proposed rule, EPA explained that it would handle inert ingredients in a process that is separate from registration review.

Some commenters agree with EPA's approach of dealing with inert ingredients. However, others question the need to review inert ingredients at all. A public interest group expressed concern that having separate review processes for active ingredients and inert ingredients could result in missing or ignoring synergistic effects of mixtures of ingredients.

The Agency intends to follow the procedures outlined in the preamble of the proposed rule. The Agency recognizes that there may be interactions among the various chemicals in pesticide products. Currently, the Agency requires acute toxicity data for end-use products, i.e., formulations containing active and inert ingredients. These studies address, albeit to a limited extent, potential synergistic effects of mixtures of active and inert ingredients in a pesticide product. However, to test and review all of the potential combinations of ingredients would require significant resources. The Agency will consider new scientific methodologies to identify potential interactions among chemicals, should they become available.

B. Data and Information Collection in the Registration Review Program

In the preamble of the proposed rule, the Agency described strategies for acquiring information to support a pesticide's registration review including issuing Data Call-In notices to require

data necessary to conduct a review and searching the published literature for pertinent information about a pesticide. The Agency explained that early acquisition of data or information that could be useful in refining a pesticide's risk assessment would reduce the time and effort needed to complete the review of a pesticide. As explained in the preamble, EPA might be able to identify data or information needs when it publishes the schedule for a pesticide's registration review. In some cases, data or information needs might become apparent when the Agency assembles the initial docket for the registration review case. In this event, the docket for the registration review case would identify data or information needs. In other cases, the Agency might not be able to identify data or information needs until it evaluates the information in the initial docket.

1. *Identification of information that may be used to refine risk assessments.* An industry trade group acknowledged EPA's concern about redoing risk assessments when, in response to a preliminary risk assessment, a registrant or other stakeholder submits new data or information to refine the preliminary risk assessment. However, they believe that such iteration is inevitable. When registrants conduct their own risk assessments, they may use different assumptions or interpretations of data than the Agency uses in its risk assessments. When the Agency's risk assessment shows higher risks than the registrants found in their own assessments, they must either develop data or information to refine the risk assessment or cancel uses.

EPA agrees that some iteration may be inevitable. However, the Agency publishes its risk assessment methods, including its approach for interpreting data. So it may be possible for registrants to anticipate the Agency's information or data needs in a forthcoming registration review and to reduce the degree of iteration in the risk assessment process.

2. *Information developed under the Clean Water Act.* In public discussions about the proposed rule, EPA received a suggestion from water treatment authorities that the Agency might consider information developed under section 303(d) of the Clean Water Act, which identifies impaired water bodies.

In comments, States raised the concern that they do not have the resources to assemble such data. Registrants expressed their concern that these data not be taken at face value because the criteria and process used to develop these data might affect the reliability of this information.

EPA believes that information on water quality may be useful in registration review and will make efforts to obtain State data for CWA section 303(d) listings due to pesticides. When evaluating such data, EPA will take into account the procedures used to develop the data to assess the quality and usefulness of the data.

C. Work-Sharing

The preamble of the proposed rule described the Agency's intention to develop work-sharing agreements with its partners in the Organization for Economic Cooperation and Development (OECD) or the North American Free Trade Agreement (NAFTA). In comments on the proposed rule, industry trade associations expressed concern that conducting reviews jointly with EPA's NAFTA or OECD partners might cause delays.

EPA continues to believe that harmonization and work-sharing will result in process efficiencies and superior decisions. Since EPA's partners also have programs for reassessing pesticides, all parties could benefit by coordinating their efforts. EPA and its Canadian counterpart have begun discussions for work-sharing during registration review with the expectation that they will develop a work-sharing plan by the December 2006 meeting of the NAFTA Technical Working Group on Pesticides.

EPA gave a presentation on the registration review program at the February 2006 meeting of the OECD Working Group on Pesticides. EPA intends to continue encouraging the OECD community to participate in work-sharing efforts.

EPA may adjust its schedule slightly to take advantage of these potential opportunities for work-sharing.

D. Adequacy of EPA's Methods for Assessing Potential Risk to Water Quality

California water-treatment authorities questioned the adequacy of EPA's assessment of risks with regard to water quality considerations including: Use of aquatic toxicity testing, surface water quality studies, and urban uses of pesticides, particularly when these uses result in pesticide residues in receiving waters for storm sewers or sewage treatment plants. The commenters reported that in some cases, pesticide residues in water released by a sewage treatment plant may exceed its NPDES permit, which would be a violation of the Clean Water Act. They also noted that residues from agricultural uses of pesticides, e.g., rice pesticides and pesticide degradates have been found in drinking water supplies.

The Office of Pesticide Programs (OPP) will manage water-related issues within the framework of the registration review of pesticides. OPP expects that its capacity for characterizing risk will continue to improve as it works with the Office of Water to refine its models for estimating exposures and as more monitoring data become available.

E. Achieving Label Improvement through the Registration Review Program

Several commenters see the registration review program as an opportunity to improve the quality of labels on individual pesticide products. One aspect of label improvement would be to minimize the number of different labels for the same product. According to comments, this situation arises because many States require State registration and impose their own labeling requirements.

The Agency is committed to improving the consistency of labels. EPA already works with States on labeling issues. However, the Agency notes that section 24(b) of FIFRA prohibits States from establishing or maintaining labeling requirements. The Agency agrees that label improvement is a worthwhile goal for the registration review program.

VIII. Implementation Issues

A. Coordination of the Registration Review Rule with the Data Requirements Rule

Industry comments asserted that EPA should delay implementing registration review until the recently proposed revisions to the data requirements in 40 CFR part 158 have been finalized. They stated their belief that EPA cannot make registration review decisions until it has completed revising the data requirements for the registration of pesticides. Industry is concerned that if registration review is initiated before a final rule on data requirements, different standards will apply to cases reviewed early in the program, negating one of the benefits of the review: to reduce market barriers.

The Agency does not believe it is appropriate to delay implementation of the registration review program as suggested in the comments. In the absence of updated part 158 rules, the Agency makes case-by-case data determinations as a standard program practice. Registrants are familiar with this practice. While the Part 158 Data Requirements Rules and registration review decisions are related, they are

not inextricably linked. The revisions to part 158 have benefits but they are not a condition precedent to making registration review decisions.

The part 158 updates may include provisions to codify current practices. The purpose of the part 158 rule is to capture with clarity and transparency changes in data requirements or application of data requirements that the Agency has made on a case-by-case document since it published its data requirements in 1984. This good-government goal will amplify understanding and further enhance consistency. However, the registration review program can operate effectively, as the registration, reregistration, and tolerance reassessment programs have, in the absence of these enhancements. Final promulgation of the part 158 rules will simply improve on that sound foundation.

Science will continue to evolve even after the Agency has completed the current revision of the data requirements in 40 CFR part 158. The Agency expects that it will change its data requirements to reflect this new knowledge. Because one of the goals of registration review is to incorporate evolving science, the Agency fully expects that it might apply new and different risk assessment tools to pesticides reviewed later in the 15–year cycle than it used when it reviewed pesticides early in the 15–year cycle.

The Agency appreciates the commenter's concern about market barriers that might arise if the Agency uses different risk assessment tools when reviewing pesticides later in the 15–cycle than it used earlier in the cycle. Market barriers can be reduced if similar pesticides are reviewed at the same time. This is one of the benefits of the Agency's plan to group chemically related cases for review.

B. Transition from Reregistration to Registration Review

Industry comments asserted that EPA must clarify when the registration review program will begin. EPA should address how it will handle the work of registration actions, reregistration actions, and other mandated regulatory actions before it commits to initiating the registration review program. EPA should clarify the transition process between the reregistration and registration review programs.

The Agency has announced that the registration review program officially begins when these regulations go into effect. The Agency's first actions under the new program will be to issue schedules and to begin to open registration review case dockets. As noted in the comment, some pesticides will still be undergoing reregistration when the registration review program begins. The Agency recognizes that, to avoid confusion during the transition between the reregistration and registration review programs, it must clearly communicate whether action on an existing pesticide is taken under reregistration (FIFRA section 4) or registration review under FIFRA section 3(g).

C. Unresolved Problems from Reregistration Will Affect the Agency's Capacity to Conduct Registration Review

Industry commented that EPA should not implement registration review of end-use products until it fixes the problems with the review of end-use products in reregistration. The review processes in registration review and reregistration are likely to be similar and registration review might duplicate the effort of reregistration, especially when a product may undergo product-specific review several times (e.g., a product that contains two or more active ingredients may belong in two or more registration review cases). The commenters are concerned that if EPA does not achieve efficiencies in the review of end-use products, the 15–year review will extend to 40 years.

EPA expects reregistration to satisfy most product-specific data requirements and achieve many label improvements for end-use products. Although the Agency does not expect it will routinely require product-specific data during registration review, it expects that registration review will be an important vehicle for the continuing update of labels. The Agency agrees that the review of end-use product labels could benefit from process improvements. The Agency believes that registrants and other stakeholders can help develop approaches to make this process more efficient.

IX. Program Costs

A. Impacts on Small Businesses

Registrants commented that EPA has not accurately characterized the effects of registration review on small business. They suggested that per-company costs of $750,000 and 2% gross sales are not insignificant even for large entities and will have a direct adverse effect on small businesses. They believe that the cost projections are misleading because they do not include all costs incurred by a registrant such as existing reporting, recordkeeping, and financial burdens imposed by the Agency's many other on-going programs. Commenters suggested that EPA should re-evaluate the impacts on small business and reduce economic burden on them.

EPA believes it has accurately characterized the impacts of the registration review procedures on the regulated community, including small businesses. The procedures in this rule establish what EPA will do to review a pesticide registration. They do not obligate a registrant to take any action.

As part of the rulemaking process, EPA is required to estimate the economic impacts, including effects on small business, that occur as a consequence of the rule. Because costs resulting from existing reporting or recordkeeping requirements or costs from other Agency programs are not imposed by this rule, these costs are not included in the Agency's assessment of the impacts of this rule.

The regulations do not impose new data requirements. They establish the process by which EPA will decide if additional data are necessary to determine whether a pesticide continues to meet FIFRA standards. That is, data generation costs are only indirectly a result of registration review procedures. It is important to realize that the per-company costs of $750,000 are primarily the cost of data generation; that is, they are not a direct cost imposed by this rule.

The Agency has determined that this rule will not have a significant adverse impact on a substantial number of small businesses. Nonetheless, the Agency recognizes that, from the perspective of a small business whose product is undergoing registration review, the costs of data generation in registration review could be significant. Accordingly, the Agency is willing to work on a case-by-case basis with a small business for whom the requirements for data generation in registration review are burdensome. Data Call-In notices issued under FIFRA section 3(c)(2)(B) allow a registrant to request a data waiver that is based on economic factors. In lieu of a new study, the Agency is generally willing to consider whether substitute data or bridging data would be adequate. If a new study is required, the Agency may consider time extensions so that a registrant can spread the costs of data generation over a longer period of time. The Agency has made these options available to small businesses in the registration and reregistration programs and expects to continue to make them available for registration review.

B. Cost of Product-Specific Data

Industry comments asserted that the economic assessment was incomplete

because it did not include the costs of generating product-specific data, in particular, the costs of repeating efficacy tests for public health pesticides. At public meetings on the proposed rule, the Agency said that it would require new product efficacy tests.

These comments accurately describe the scope of the feasibility study. The purpose of the feasibility study was to test the validity of the registration review decision paradigm and to develop data for estimating the costs of the program. The Agency did not review individual product registrations in the feasibility study to determine whether new product-specific data, including efficacy data, would be required because the Agency believes that, to a great degree, these product-specific data requirements have been satisfied through the registration and reregistration programs and such data would generally not be needed to support a pesticide's registration review.

During the registration review of a public health pesticide, the Agency would determine whether to continue to base the product's registration on existing product efficacy data. The Agency may ask for new product efficacy data if the product's composition has changed so that existing data no longer support the current composition of the product, or the test method is no longer valid, or there is information suggesting that the formulation might not be efficacious as claimed. The Agency did not review product chemistry data in the feasibility study to make case-by-case determinations whether existing product efficacy tests are appropriate for the composition of the product. The Agency has not revised antimicrobial efficacy test methods, so, for purposes of the feasibility study, the existing efficacy tests were considered to be valid. (If the Agency had information suggesting that a product in the feasibility study was not efficacious as claimed, the Agency would not wait until registration review to ask for new efficacy data. The Agency would have issued a DCI or initiated other action under FIFRA, as appropriate.) The Agency believes that the costs of replacing product efficacy data for a few products in a registration review case will be much lower than the costs of generating new generic data to support the active ingredient(s) in a registration review case. In any case, any costs for generating new product-specific efficacy data would not be a direct cost imposed by this procedural regulation.

X. Technical Changes to the Rule

In addition to the changes made in response to comments, the final rule reflects that the Agency made the following technical changes to what was proposed:

1. In § 155.42(d), the Agency added clarifying phrases (indicated in italics) to the second and third sentences, as follows: ''In general, the baseline date will be the date of initial registration *of the oldest product in the case* or the date of reregistration, whichever is later. The date of reregistration is the date on which the Registration Eligibility Decision or Interim Reregistration Eligibility Decision was signed, whichever date the Agency determines to be more appropriate *based on the comprehensiveness of the review*.''

2. In § 155.44, EPA is deleting the sentence, ''As indicated in § 155.40, the Agency may change the schedule of a pesticide's registration review if circumstances warrant,'' because it is not a correct reference.

3. In § 155.48, EPA is deleting the phrase ''before, during or after a registration review'' because it is redundant.

4. The Agency is modifying § 155.50 as follows:

- In the first sentence add the phrase ''except for cases covered under § 155.46.'' The sentence now reads, ''The Agency will initiate a pesticide's registration review by establishing a docket for each registration review case, except for cases covered under § 155.46, and opening it for public review.''
- Change the paragraph heading of § 155.50(a) to ''Contents of the registration review case docket.'' The Agency has deleted the first sentence of this paragraph and modified the last sentence to read, ''The Agency will consider including, but not limited to, the following information: . . .'' The Agency is making these changes to make clear that this paragraph describes the contents of the initial docket.
- Change § 155.50(c) by adding ''during the comment period'' to the paragraph heading and by changing the first sentence in paragraph (c)(1) to read as follows: ''In order to ensure that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information during the comment period established in the notice described in paragraph (b) of this section.'' These changes are for clarity.
- Add paragraph § 155.50(d) as follows, ''For the purposes of this subpart, the provisions of subpart B do not apply.'' EPA is making this change to eliminate any possible confusion as to whether docketing procedures in part 155 subpart B apply to registration review activities. Subpart B describes docketing and public participation procedures for the registration standard program that the Agency conducted before it began the reregistration process mandated in the 1988 amendments to FIFRA. The Agency will eventually issue a housekeeping rule to delete this subpart.

5. In § 155.52, the Agency is making editorial changes for clarity, as follows:

- Substitute ''other persons'' for ''public interest groups'' in the third sentence so that it reads, ''The Agency may consult with registrants, pesticide users, or other persons during a pesticide's registration review . . .''
- Add the phrase ''Minutes of'' to the paragraph heading of § 155.52(a) so that it reads, ''Minutes of meetings with persons outside of government.''

6. In § 155.53, the Agency is making several editorial changes for clarity, as follows:

- Add the preposition ''of'' to the section heading of § 155.53 so that it reads, ''Conduct of a pesticide's registration review.''
- In the first sentence of this section, replace the reference to ''§ 155.51,'' which doesn't exist, with ''§ 155.50(a), (b), and (c).''
- In the first sentence of § 155.53(c)(1), replace the phrase ''ask for'' with the verb ''request.''

7. In § 155.58, the Agency is making an editorial change in paragraph (b)(3) by deleting the phrase ''precede, accompany or follow'' from the second sentence and replacing it with the phrase ''may be issued in conjunction with.''

XI. FIFRA Review Requirements

In accordance with FIFRA section 25(a) and 25(d), this rule was submitted to the FIFRA Science Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

Pursuant to Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has designated this rule as a ''significant regulatory action'' under section 3(f) of the Executive Order because it may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive

Order. This action was therefore submitted to OMB for review under this Executive Order, and any changes to this document made at the suggestion of OMB have been documented in the public docket for this rulemaking.

EPA has prepared an economic analysis of the potential impacts of the registration review procedures. In addition to analyzing the requirements contained in this rule, the Agency analyzed other potential actions that could occur during a registration review using other existing authorities that are not changed in this rule. The Agency's analysis, therefore, considers the potential impact of the registration review process, which includes the costs of a registrant's participation in the public review components of the process described in this rule and other potential requirements imposed by existing authorities such as data generation under FIFRA section 3(c)(2)(B). This analysis is contained in a document entitled *Economic Analysis of the Procedural Regulations for the Registration Review of Pesticides*. EPA placed a copy of this Economic Analysis in the public docket for this action when it published the proposed rule. Comments on the Economic Analysis did not warrant revision of this document and the Agency will rely on this document to support the final rule. The Economic Analysis is briefly summarized here.

The rule does not require registrants to take specific action as part of the review of a pesticide registration, however, the Agency's analysis assumes that registrants will engage in their own evaluation of information provided by the Agency and other stakeholders, and participate in the public process described in this rule. The Agency estimates such industry costs to be around $1.2 million annually.

The Agency recognizes that under other existing authorities a registrant may also need to submit data that they have or generate data as necessary to support the registration. As such, the analysis also considers the potential cost to industry from other anticipated activities under existing authorities that may occur during the registration review process, although such activities are not requirements in this rulemaking. These activities include potential data submission or generation activities related to DCIs, including the paperwork burden, and other activities that might occur under other existing authorities.

Considering these other potential activities, the analysis shows an estimated total annual cost to industry of about $50 million, with the estimates for potential data generation activities accounting for approximately 70% of these costs. The Agency estimates about 68 companies will be impacted each year; thus, per-company costs for the entire registration review process are likely to average less than $750,000 each year, even though some companies may have multiple chemicals under review during the year. Out of the universe of 2,000 small businesses estimated to hold pesticide registrations, the Agency estimates that each year about 30 small businesses that have responsibility for providing data to support the registration of a pesticide would be involved in a registration review. Assuming the same level of participation and potential need to generate data, the estimated average cost of the registration review process is estimated to be less than 2% of the gross sales for small businesses involved in a registration review.

B. Paperwork Reduction Act (PRA)

The information collection activities associated with the registration review program are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. That Information Collection Request (ICR) document has been assigned EPA ICR number 0922.07, and OMB control number 2070–0057. Although this action does not impose any new information collection requirements that would require additional approval by OMB, the Agency expects the approved burden estimate to increase with the full implementation of the registration review process. A copy of the OMB approved ICR has been placed in the public docket for this rule, and the Agency's estimated burden increase is presented in the economic analysis that has been prepared for this rule.

As detailed in the Economic Analysis prepared for this rule, the annual respondent burden for information collection activities associated with the registration review program is estimated to average 120,000 hours, with an estimated total annual respondent cost of $10,800,000. The July 13, 2005, proposed rule invited comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques. No comments were received. Therefore, the Agency has submitted an information correction worksheet request to OMB to amend its existing ICR covering the information collection activities associated with the registration review program so that it reflects the burden estimates in the Economic Analysis.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations codified in Chapter 40 of the CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9. For the ICR activity contained in this final rule, in addition to displaying the applicable OMB control number in this unit, the Agency is amending the table in 40 CFR 9.1 to list the OMB control number assigned to this ICR activity. Due to the technical nature of the table, EPA finds that further notice and comment about amending the table is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedures Act (APA), 5 U.S.C. 553(b)(B), to amend this table without further notice and comment.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this rule will not have a significant adverse economic impact on a substantial number of small entities. This rule defines the procedures that EPA will follow to implement the statutory registration review provision. It does not impose any new requirements on the regulated community. As such, this rule does not have direct adverse impacts on small businesses, small non-profit

organizations, or small local governments.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201, which for the pesticide industry consists of businesses with fewer than 500 to 1,000 employees (range is based on NAICS sector variations); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The regulated community does not include any small not-for-profit organizations. Small local government organizations, such as counties, may register a pesticide under FIFRA section 24(c). However, such registrants generally do not manufacture, distribute or sell pesticides and generally would not be responsible for generating data to support the registration of pesticides. Accordingly, the Agency finds that this rule does not have a direct adverse effect on small local governments.

D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. As described in Unit XIII.A., this rule is not expected to result in such expenditures. In addition, this action will not impact small governments, or local or tribal governments. Accordingly, this rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this rule does not have ''federalism implications,'' because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. Thus, Executive Order 13132 does not apply to this rule.

F. Executive Order 13175

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this rule does not have tribal implications because it will not have any affect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13211

This rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Disribution, or Use* (66 FR 28355, May 22, 2001) because it is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit XIII.A.), nor is it likely to have any significant adverse effect on the supply, distribution, or use of energy.

H. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) does not apply to this rule because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866, (see Unit XIII.A.), nor does it establish an environmental standard, or otherwise have a disproportionate effect on children.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ((NTTAA), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures) that are developed or adopted by voluntary consensus standards bodies. This rule does not impose any technical standards that would require EPA to consider any voluntary consensus standards.

J. Executive Order 12898

This rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency does not need to consider environmental justice-related issues.

XIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

List of Subjects in 40 CFR Part 155

Environmental protection, Administrative practice and procedure, Pesticides and pests.

Dated: August 1, 2006.

Stephen L. Johnson,

Administrator.

■ Therefore, 40 CFR chapter I is amended as follows:

■ 1. Part 9 is amended as follows:

PART 9—[AMENDED]

■ a. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ b. In § 9.1, the table is amended by revising the existing heading for ''Registration Standards''; removing the entry under that heading; and adding a new entry to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control no.
* * * * * .	
Registration Standards and Registration Review	
* * * * *	
Part 155	2070–0057

* * * * *

■ 2. Part 155 is amended as follows:

PART 155–REGISTRATION STANDARDS AND REGISTRATION REVIEW

■ a. The authority citation for part 155 continues to read as follows:

Authority: 7 U.S.C. 1361.

■ b. By revising the heading of part 155 to read as set forth above.
■ c. By adding a new subpart C to read as follows:

Subpart C—Registration Review Procedures

Sec.

Subpart C—Registration Review Procedures

§ 155.40 General.

(a) *Purpose.* These regulations establish procedures for the registration review program required in FIFRA 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. The goal of the registration review procedures is review of each pesticide's registration 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).

§ 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 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 review 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 (c)(2)(D) apply to the submission, compensation, and exemption of data required to conduct a registration review.

§ 155.50 Initiate a pesticide's registration review.

The Agency will initiate a pesticide's registration review by establishing a docket for each registration review case, except for cases covered under § 155.46, and opening it for public review.

(a) *Contents of the registration review case docket.* The Agency will place in this docket information that will assist the public in understanding the types of information and issues that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

(1) An overview of registration review case status;

(2) A list of current registrations and registrants, any **Federal Register** notices regarding pending registration actions, and current or pending tolerances;

(3) Risk assessment documents;

(4) Bibliographies concerning current registrations;

(5) Summaries of incident data; and

(6) Any other pertinent data or information.

(b) *Public review of the registration review case docket.* The Agency will publish a notice in the **Federal Register** announcing the availability for public review of the information described in paragraph (a) of this section and establishing a comment period of at least 60 days. During this comment period, interested persons may identify any additional information they believe the Agency should consider in the course of the registration review.

(c) *Submission of data and other information during the comment period.* The Agency may identify, either in the notice published under paragraph (b) of this section, or at any other time, data or information that it does not have but which may be useful, if available, for consideration in the registration review. Any person may submit data or information in response to such identification. In order to be considered during a pesticide's registration review, the submitted data or information must meet the requirements listed below.

(1) In order to ensure that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information during the comment period established in the notice described in paragraph (b) of this section. The Agency may, at its discretion, consider data or information submitted at a later date.

(2) The data or information must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

(3) Submitters must clearly identify the source of any submitted data or information.

(4) Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

(d) For the purposes of this subpart, the provisions of subpart B do not apply.

§ 155.52 Stakeholder engagement.

In addition to the public participation opportunities described in § 155.50 and § 155.53(c), the Agency may meet with stakeholders regarding a forthcoming or ongoing registration review. For example, before conducting a pesticide's registration review, the Agency may consult with registrants or pesticide users regarding the use and usage of the pesticide. The Agency may consult with registrants, pesticide users, or other persons during a pesticide's registration review with regard to developing risk management options for a pesticide. The Agency may informally consult with officials of Federal, State or Tribal agencies regarding a forthcoming or ongoing registration review.

(a) *Minutes of meetings with persons outside of government.* The Agency will place in the docket minutes of meetings with persons outside of government where the primary purpose of the meeting is to discuss a forthcoming or ongoing registration review. The Agency will place minutes of such meetings in the docket when it takes action under § 155.58. At its discretion, the Agency may place minutes of such meetings in the docket sooner.

(b) *Exchange of documents or other written material.* In the course of a meeting with a person outside of government, the Agency or that person may provide the other with a copy of a document or other written material that has not yet been released to the public. The Agency will place a copy of any such document or other written material in the docket along with the minutes of the meeting where the materials were exchanged.

(c) *Confidential business information.* The Agency will not place confidential business information in the docket.

§ 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.

§ 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:

(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.

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