Dated: July 7, 2005.

Jeannette Owings-Ballard,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 05–13742 Filed 7–12–05; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 155

[OPP–2004–0404; FRL–7718–4]

RIN 2070–AD29

Pesticides; Procedural Regulations for Registration Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Food Quality Protection Act (FQPA) of 1996 amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to require periodic review of pesticide registrations to ensure that over time they continue to meet statutory standards for registration. FIFRA section 3(g) specifies that EPA establish procedural regulations for conducting registration review and the goal of the regulations shall be Agency review of pesticide registrations on a 15–year cycle. This proposal describes the Agency's proposed approach to the registration review program. The proposed regulation is intended to ensure continued review of pesticides using procedures that provide for public participation and transparency in an efficient manner.

DATES: Comments must be received on or before October 11, 2005.

ADDRESSES: Submit your comments, identified by docket ID number OPP–2004–0404, by one of the following methods:

- *Federal eRulemaking Portal*:*http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *Agency Website*:*http://www.epa.gov/edocket/*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- *E-mail*: Comments may be sent by e-mail to*opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0404.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0404.
- *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0404. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID numberOPP–2004–0404. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL–7181–7).

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket/*. Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Vivian Prunier, Field and External Affairs Division (7506C), 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 proposed procedural regulation. As such, the Agency is soliciting comments from the public in general. 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 stablilizer 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 proposed § 155.40 of the regulatory text. 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 EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 155 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, regulations.gov, or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Purpose of the Proposal

With this Proposal, the Agency presents its proposed procedural regulations for the registration review program. The Agency describes:

- 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.

The Agency also presents the results of reviews required by statutes and other required analyses.

III. Background

A. Statutory Authority

1. *EPA's authority to license pesticides.* FIFRA section 3(a) generally requires a person to register a pesticide product with 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 section 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).

2. *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.

B. Legislative History

The Agency examined the legislative history for FIFRA section 3(g) to further its understanding of Congressional intent for this program. A discussion of registration review appears in House Committee Report 104–669, Part One (104th Congress, House of Representatives, Committee on Agriculture, July 11, 1996 to accompany H.R. 1627) which states:

The bill requires the Administrator of EPA to periodically review the registration of each pesticide. It has become apparent that the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment is not only important but continuing to evolve. The goal of establishing ongoing scientific look-back procedures will enable the important process of registration review to be considered every 15 years during a product's market life. This creates a continuous reregistration process that both the Agency and the registrant can plan for, rather than creating the need for another complete, resource-intensive reregistration of all pesticide products at one time in the future.

IV. Agency's Goals for the Registration Review Program

A. Review Each Pesticide Every 15 Years to Assure That Each Registration is Based on Current Scientific Knowledge Regarding the Pesticide's Effects on Human Health and the Environment

The science underlying the risk-benefit assessments of pesticides is continually evolving. Research may show hazard endpoints that may not be observable with available methods. Accordingly, the Agency might adopt new methods to assess these endpoints. Models used to estimate exposures may become more accurate as the Agency refines these methods in light of additional data. Risk assessment procedures may be revised to reflect new knowledge regarding mechanism of toxicity, pharmaco-dynamics or pharmaco-kinetics. If the Agency periodically reviews the information and risk assessments for each pesticide consistent with new scientific developments, it can better ensure continued protection of human health and the environment.

B. Develop a Credible and Manageable Program to Review the Registration of All Pesticides Every 15 Years

Using a credible and manageable process, the Agency completes its review of approximately 50 chemical cases a year in the near term.

Credible--using an open and transparent process and basing its findings on sound science, the Agency reaches a regulatory decision for each pesticide in the chemical case.

Manageable--using an efficient and flexible process, the Agency produces 50 decisions per year.

C. Attributes of a Credible Program for Conducting Registration Review

1. *Constructive stakeholder and public participation*. To accomplish this goal, the Agency should have a reliable schedule so stakeholders and the public can decide how best to participate in the review process and to plan their own level of involvement. The Agency should make information available to stakeholders and the public early in the process, i.e., before the Agency has begun its registration review analysis. The Agency should provide opportunities for stakeholder and the public participation at several stages in the process generally at key decision points. For example, the Agency will ask for comment on draft risk assessments and proposed risk mitigation measures. Finally, broad public participation will help the Agency develop effective strategies for communicating pesticide risk to the public.

2. *Transparent decisions based on sound science*. The Agency has published the standards that it uses for characterizing pesticide risk by establishing data requirements and issuing generic guidance regarding its data requirements. Data requirements are codified in 40 CFR part 158. The Agency has also issued guidelines for conducting the tests required in part 158. On a case-by-case basis, the Agency may require data not required under 40 CFR part 158.

It is the Agency's practice to publish generic guidance explaining risk assessment methods. The Agency expects to continue this practice in the future.

The Agency will continue to make decisions using its published standards, policy guidance, and risk assessment methods. The Agency will explain its reasoning when it makes exceptions.

3. *Risk management decisions that protect human health and the environment*. The Agency intends to use States' and Tribes' field, compliance monitoring, and enforcement experience to assess the efficacy and practicality of risk mitigation measures previously adopted to address a risk of concern. When new risks are identified, the Agency will adopt appropriate, effective, and enforceable risk mitigation measures. The Agency's registration review decisions will describe risk mitigation requirements, including time frames and procedures for assuring compliance, among other things.

4. *Timely implementation of risk reduction measures*. Pesticide product labels communicate and put into effect risk mitigation decisions that might be made in a pesticide's registration review. In order to accomplish the Agency's goals of protecting human health and the environment, it is essential that registration review decisions be implemented as soon as practicable. The Agency intends to take prompt action to assure compliance with such requirements. Such actions might include tracking submission and initiating regulatory or enforcement action for failure to comply with requirements.

Because the pesticide product label is the primary means to communicate the safe and legal uses of any pesticide product, the Agency also intends to reduce the lag time between label approval and the commercial availability of products with new labels. The Agency plans to continue to work with stakeholders to improve distribution of updated labels to users.

5. *Accountability*. Registration review decisions should be documented, promptly made available for public review, and remain accessible for future reference. Schedules should be publicly available and updated regularly. The Agency should provide timely and accurate reports on the progress of individual registration reviews and of the registration review process.

6. *Quality assurance and process improvements*. The Agency expects to maintain the quality of its work products. The Agency expects to periodically evaluate its decision processes to improve, for example, the process used to decide the scope and depth of a pesticide's registration review. The Agency expects to evaluate the program to identify vulnerabilities in the registration review process.

7. *Meaningful environmental outcomes*. Under the Government Performance and Results Act, the Agency is required to measure the effectiveness of programs such as the registration review program. To meet this requirement, the Agency will develop measures for assessing the environmental outcomes of the registration review program.

D. Attributes of a Manageable Process for Conducting Registration Review

1. *Promote process efficiencies by applying the knowledge gained through experience with other programs*. For example, in such programs as the reduced-risk pesticide program and the tolerance reassessment program for inert ingredients and other chemicals with low toxicity, the Agency learned to gauge the scope and depth of a pesticide chemical's review. This knowledge should be applied in the registration review process to help the Agency accurately and reliably ascertain which pesticides need intensive review.

2. *Promote process efficiencies through harmonization and work-sharing with other authorities*. The Agency may also be able to achieve efficiencies by harmonizing its data requirements and risk assessment methods with those used by foreign governments, international bodies, or State agencies. The Agency is involved in cooperative work with the Organization for Economic Cooperation and Development (OECD), an intergovernmental organization consisting of 30 industrialized countries in Europe, North America, Asia, and the Pacific, to harmonize pesticide data requirements, focus test guidelines on pesticide regulatory needs, and harmonize industry data submissions and governments' data review formats and content. The OECD's Vision

Document, which outlines the objectives of its harmonization program, specifies that individual countries will continue to conduct their own risk assessments, make their own regulatory decisions, and meet their own legal requirements. In January 2005, the EPA Acting Administrator and his Canadian counterpart announced their commitment to the Vision Document. More information about this harmonization program is available on the Agency's website at *http://www.epa.gov/oppfead1/international/harmonization.htm*.

The Agency may be able to leverage its resources through other work-sharing with its State or international partners. The Agency works with its counterparts in Canada and Mexico under the North American Free Trade Agreement (NAFTA) in the NAFTA Technical Working Group on Pesticides.

Additionally, EPA and the California Department of Pesticide Regulations began in 1999 a workshare program for reviewing residue field studies and assessing dietary exposure to support minor use actions and FIFRA section 18 actions which are of interest to California agriculture. This joint program has benefitted the Federal and State regulatory agencies by shortening the processing time of key pesticide registrations.

3. *Promote efficiencies through improvements in information management systems.* One of the Agency's primary objective is to assemble, develop, and manage the documents needed to conduct the registration review of a pesticide. The objectives are easy access by EPA staff and availability for public review. Agency staff would have electronic access to documents that they will examine during a registration review. The public would be able to access the documents by means of the EDOCKET.

V. Evaluating Approaches to Registration Review

This unit describes the information the Agency gathered and evaluated in developing possible approaches to registration review. First, the Agency evaluated its current programs for assessing the safety of existing pesticides to see whether lessons learned from those programs would apply to registration review. Secondly, the Agency published an Advance Notice of Proposed Rulemaking (ANRPM) (65 FR 24585, April 26, 2000) (FRL–6488–9) to solicit public input on its preliminary interpretation of the statutory requirements and on its initial concept of registration review. In addition, the Agency consulted a stakeholder group regarding the design and implementation of the registration review program. Finally, the Agency conducted a feasibility study to test the decision process that it developed with the advice of the stakeholder group. This feasibility study also provided information the Agency used to estimate the cost of the registration review program to both the regulated community and EPA.

A. Evaluate Experience Gained from Reregistration and Tolerance Reassessment Programs

The registration review program is a brand new program to replace the tolerance reassessment program mandated by section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the rereregistration program mandated by FIFRA section 4. These programs will be completed in 2006 and 2008, respectively.

The 1988 amendments to FIFRA required the Agency to reregister all pesticides registered before November 1984, prescribed procedures, and established deadlines for accomplishing various activities. In contrast to the 1988 legislation, the 1996 amendment to FIFRA requiring registration review does not specify procedures or deadlines. Nonetheless, the Agency evaluated the reregistration program to see whether any of the procedures used in reregistration could be used in the new program.

1. *Identification of pesticides that were subject to reregistration.* FIFRA section 4(c) required the Agency to publish lists of pesticides that were subject to regregistration. To accomplish this requirement, the Agency developed criteria for deciding whether two or more structurally related active ingredients could be assigned to the same reregistration case. Over the 16–year course of reregistration, the Agency applied new information about the chemical or biological properties of active ingredients assigned to a case when deciding whether to add or remove an active ingredient from a case. The Agency proposes to use the knowledge gained in implementing FIFRA section 4(c) when it creates and maintains a list of pesticide cases that will be subject to registration review.

2. *Applications for reregistration.* FIFRA section 4(d) required registrants to notify the Agency whether they intended to seek reregistration for their products, and if so, to identify the data required by regulation to support the registration of the products, cite the data that the registrant would rely on to satisfy the applicable requirements, and commit to provide studies to satisfy outstanding data requirements that the registrant identified. FIFRA section 4(e) required registrants to summarize and reformat the studies that they intend to rely upon to support reregistration of their products. In developing this proposed rule, the Agency considered whether to adopt similar procedures in registration review, but decided that reliance on the Data Call-In (DCI) authority of FIFRA section 3(c)(2)(B), as required under FIFRA section 3(g), would be sufficient.

3. *Identification of outstanding data requirements (data gaps).* FIFRA section 4(f) required the Agency to review the registrants' submissions, independently identify data gaps, and issue DCI notices under FIFRA section 3(c)(2)(B) for submission of any outstanding data. The Agency's experience with these aspects of the reregistration program showed that registrants did not always correctly identify the data requirements that applied to their product registrations and that the data registrants intended to rely upon were not always adequate. The Agency identified multiple data gaps for virtually every pesticide in the reregistration program.

Because the Agency made significant effort in the reregistration and tolerance reassessment programs to ensure that data requirements were identified and satisfied with appropriate data, pesticide databases now meet or exceed the standard established in 1984. Although the Agency anticipates that it will identify data gaps for many pesticides in the registration review program, it believes that the scope of the DCI effort in this program will be smaller than that of the reregistration program. The results of an Agency's feasibility study of the proposed registration review decision process supports this expectation.

4. *Quality of the submitted studies.* In the early 1990's, the Agency frequently found that the studies submitted in response to DCI notices did not meet applicable requirements and could not be used to support a risk assessment. Because the Agency was concerned about the delay and expense that accrue when studies must be repeated, it conducted rejection analyses to determine why so many studies were inadequate. Among the outcomes of these analyses were improved guidance for the design, conduct, and reporting of studies.

The Agency believes that improvements in the guidance for designing, conducting, and reporting studies will carry forward into the registration review program. The Agency anticipates that few studies submitted in this program will suffer

from inadequate design, conduct, or reporting.

5. *Late submission of pertinent information.* The Agency found that data and information affecting pesticide exposure and risk were frequently provided after the Agency had drafted its risk assessments. The Agency was obliged to redo the risk assessments. This problem eased somewhat after the Agency began to consult more regularly with stakeholders before conducting the review. The Agency hopes to avoid or minimize this problem in registration review by proposing procedures that would promote early submission of pertinent information.

6. *Complex issues.* A major challenge in the reregistration program was the number and complexity of the issues presented by many of the older pesticides subject to reregistration. Many new studies reported new hazards and raised new questions about the potential risks posed by the pesticide. The Agency often required additional studies to further characterize the risks.

As a result of the work accomplished since 1984 in the registration, reregistration and tolerance reassessment programs, the Agency identified and resolved significant issues regarding human health and the environment. In the short-term, human health issues encountered in registration review are likely to be less complex than those confronted in the reregistration and tolerance reassessment programs. Overall, because scientific knowledge continuously evolves, the Agency will encounter new scientific or regulatory issues arising as the registration review program proceeds.

7. *Public participation in reregistration.* The Agency gained significant experience in stakeholder consultation and public participation processes during reregistration. While not required by FIFRA section 4, the Agency found value in consulting stakeholders before beginning a reregistration review. In particular, such consultation clarified use practice and usage patterns and identified uses that were no longer economically viable. As a result, the Agency was able to reduce the amount of effort and rework required to complete a reregistration eligibility decision.

Public participation is also critical for achieving transparency of the decisions made in the reregistration program. Under procedures adopted in 1998 and formalized in a notice published in the **Federal Register** of May 14, 2004 (69 FR 26819) (FRL–7357–9), the Agency provided an opportunity to review draft preliminary risk assessments. When the Agency released the refined risk assessment, it also provided a document explaining how it had responded to the comments. The Agency also invited public comment on draft risk management decisions.

The Agency has modified its public participation procedures for reregistration so that it can tailor public participation in accordance to the complexity of the issues and the degree of stakeholder interest in the pesticide. Although the public participation process adds to the time frame for making reregistration decisions particularly in complex or controversial cases, the process leads to better decisions and more efficient use of Agency resources. In addition, the public benefits from the transparency and openness of the decision process. For these reasons, the Agency proposes to include ample opportunities for public participation in the registration review process.

8. *Reregistration Eligibility Decision Document.* The Agency found that a highly structured decision document did not always provide flexibility in addressing the range of issues presented by the diverse pesticides that were reviewed in reregistration. In particular, the reregistration report format and the process used to create such reports did not provide flexibility for expediting review of pesticides that pose low hazard and risk. The Agency proposes to incorporate such flexibility in the registration review process and in registration review decision documents.

9. *Scheduling reregistration decisions.* For much of the reregistration program, the Agency did not have published procedures for scheduling completion of Reregistration Eligibility Decisions (REDs). FIFRA section 4(c)(1) provided general guidance for prioritizing reregistration reviews which the Agency accomplished early in the reregistration process when it published lists A, B, C, and D within the mandated time frames. However, the Agency appeared not to have criteria for setting priorities for reviewing pesticides within each list. Later, FFDCA section 408(q) established a 10–year time frame for reassessing tolerances and exemptions. This section generally instructed the Agency to give priority to reviewing tolerances or exemptions that appear to pose the greatest risk to public health. Initially, the Agency did not have schedules for conducting tolerance reassessments.

The Agency now has a priority ranking for reregistration and tolerance reassessment and publishes schedules well in advance. These scheduling procedures provide stakeholders ample opportunity to share information, data, and concerns to aid the Agency in making well-informed and balanced decisions.

The Agency proposes to use chronologically based criteria to establish priority of review and to provide advance notice of registration review schedules. The Agency's experience in reregistration and tolerance reassessment shows that adopting these practices will help the Agency meet its objective of having a predictable and reliable schedule.

10. *Implementing reregistration decisions.* FIFRA section 4(g)(2) specifies procedures for reregistering individual pesticide products. A criticism of this aspect of the program is the lag time between issuance of a RED and the appearance, at the retail level, of products with labeling that put into effect the risk mitigation measures identified in the RED. This issue is significant because the pesticide label is the Agency's chief means of communicating risk management procedures to pesticide users. Because one of the objectives for the registration review program is to ensure timely implementation of risk reduction measures, it is important to develop a process for timely submission and review of pesticide product labels.

B. Advance Notice of Proposed Rulemaking (ANPRM)

The Agency published an ANPRM in the **Federal Register** of April 26, 2000 (65 FR 24585) that presented the statutory requirement for registration review and alerted its stakeholders that the Agency was initiating the development of rulemaking to establish procedures for a registration review program. The Agency explained its preliminary interpretation of the statutory provisions and its preliminary ideas regarding goals, objectives, and how registration review might operate. Soliciting public input on critical issues about registration review early in the planning process helped the Agency to identify potential problems as early as possible.

C. Summary of Comments on the ANPRM

The Agency received eight comments on the ANPRM, primarily from pesticide manufacturers or other persons with commercial interest in the sale or use of pesticides. These comments are available for review in the public docket for the ANPRM under docket control number OPP–36195. The Agency has placed a summary of these comments and EPA's response to the issues discussed in these comments in the docket for this proposed rule.

The four issues that stimulated the most discussion were:

1. *Standard for registration under FIFRA*. Some commenters asserted that compliance with data requirements in 40 CFR part 158 would be sufficient to satisfy the FIFRA requirements for registration. Other commenters advocated that the Agency use a checklist approach to see whether a pesticide continued to meet the FIFRA standard for registration. Commenters agreed that the Agency should use existing data and data reviews and avoidre-review where possible.

2. *Predictable schedules*. Industry commenters generally stated that they sought predictable schedules and advocated using the date of the last comprehensive review as the basis for scheduling a pesticide's registration review. Most asserted that the risk-based priority system described in the ANPRM would not produce a predictable schedule because priority-setting would require too many resources and schedules that rank pesticides by perceived risk would be contentious. Commenters advised the Agency to handle emerging risks such as actions based on information on adverse effects that must be reported under FIFRA section 6(a)(2) information outside of the registration review process.

3. *Public participation*. Most commenters wanted to be able to participate throughout the registration review process. However, some commenters want to limit public participation in various ways. Other commenters acknowledged the value of public participation but cautioned that it could slow down decision-making.

4. *Registrant's role in registration review*. In general, commenters asserted that the Agency should not expect registrants to provide studies or other information unless the Agency specifically requires it.

D. Stakeholder Consultation

After reviewing the issues raised in the comments to the ANPRM, the Agency reconsidered its initial approach to the design of the registration review process. Before issuing a proposed rule, however, the Agency decided to consult with stakeholders to gain additional views on the design of the registration review process. The Agency chose to present its revised approach to the registration review process at a public meeting of the Pesticide Program Dialogue Committee (PPDC) held in Arlington, VA in April 2003.

The PPDC is an advisory committee established in 1995 under the Federal Advisory Committee Act. Its charter was renewed in November 2001 and 2004. This Committee provides a forum for a diverse group of stakeholders to discuss and provide advice to the pesticide program on various pesticide regulatory, policy, and program implementation issues. Topics of discussion at past meetings have included, among other things, implementation of the FQPA.

Membership to the PPDC includes environmental and public interest groups, pesticide manufacturers and trade associations, user and commodity groups, public health and academic institutions, Federal and State agencies, and the general public. The PPDC meets two to three times a year and all meetings are open to the public. Background materials along with a summary of each meeting held to date are kept in a public docket at the Docket facility identified under **ADDRESSES**. Meeting summaries for the PPDC are also available electronically at the following internet address: *http://www.epa.gov/oppfead1/cb/ppdc/*.

In response to the Agency's April 2003 request for stakeholder input into the design of the registration review program, the PPDC agreed to form a workgroup to develop recommendations for the Agency.

In June 2003, the PPDC chartered the PPDC Registration Review Workgroup. The workgroup was composed of 23 members representing a broad and balanced range of interests who were drawn from the PPDC membership and other stakeholders who were not currently serving on the PPDC. Its mission was to develop an assessment of key registration review issues as a basis for the full PPDC to provide EPA advice and recommendations on issues and topics related to developing the Agency's registration review program.

The workgroup held several public meetings and teleconferences during the summer and fall of 2003. At the PPDC meeting in October 2003, the PPDC Registration Review Workgroup presented its recommendations on three topics. The PPDC endorsed these recommendations and asked the workgroup to continue to meet and to present additional recommendations at the spring 2004 PPDC meeting. The PPDC Registration Review Workgroup resumed its deliberations in January 2004. The PPDC endorsed a second set of recommendations at the April 2004 PPDC meeting. Meeting minutes and background information for the workgroup's activities in 2003, including a copy of the October 2003 presentation to the PPDC, may be found in Docket OPP–2003–0252; meeting minutes and background information for the workgroup's activities in 2004, including a copy of the April 2004 presentation, may be found in Docket OPP–2004–0014. You may access these dockets electronically at the following internet address: *http://docket.epa.gov/edkpub/index.jsp*.

E. Summary of PPDC Recommendations

The PPDC considered a number of procedural and implementation issues, as follows:

1. *How should pesticides be scheduled for registration review*? The PPDC took into consideration that approximately 1,200 active ingredients and 15,000 products would be subject to registration review and that new pesticides will be added in the future.

The PPDC recommended that the administrative procedures for scheduling registration review should not be subjective, resource intensive, or time-consuming. There should be a predictable schedule generally based on a date 15 years from the date of registration, reregistration, or other major risk assessment. Specific criteria for departure from scheduling should be established by regulation. The Agency should publish a comprehensive schedule in the **Federal Register** and on the Agency website with regular updates.

The PPDC considered whether scheduling procedures could be based onrisk--''worst first''--but concluded that scheduling procedures based on this criterion would be resource intensive and time-consuming.

2. *Should there be different levels of review*? The PPDC recommended that the degree of assessment not be a ''one-size-fits-all'' process. The workgroup took into consideration that: (a) Not all chemicals pose the same risks; (b) the scope of the program mandates efficient use of resources; and (c) changes in data requirements, database, adverse effects data, science policies, and use and usage profiles could affect the scope or depth of a pesticide's registration review.

The PPDC developed a flow chart for the registration review process that identified points in the review process where the Agency could determine whether further review was needed. Specifically, the process should focus on identifying what has changed since the last review and determining whether existing risk assessments could be used as the basis of a risk-benefit analysis.

The PPDC recommended that the registration review process allow for a streamlined review for pesticides judged to be low risk and for pesticides with a stable regulatory history and science. Pesticides with major complex issues should receive a more comprehensive assessment.

3. *How can meaningful public participation be accomplished*? The PPDC took into consideration that a pesticide's registration review would benefit from early participation by all stakeholders. It noted that stakeholders need a predictable schedule to prepare and participate in registration review and an understandable process where opportunities and expectations for public participation are clear.

The PPDC recommended that the Agency seek stakeholder input regarding use profiles, risk assessments, benefit assessments, risk/benefit analyses, and risk mitigation measures and that stakeholder participation should be commensurate with the level of review. The PPDC recommended that the Agency use modern electronic technology to facilitate stakeholder access to information and asked the Agency to establish and maintain an electronic docket for each pesticide that would include comprehensive information about the pesticide, including history, status, public comments, and all previous regulatory decisions.

4. *How does registration review relate to other pesticide program activities*? Because registration review does not supercede or replace EPA's other authorities under FIFRA, the PPDC recommended that EPA manage risk issues as they arise rather than relying exclusively on registration review for resolving these issues. To the extent possible, registration review should be a safety net to help assure that no risk-related issues have been overlooked.

5. *How should EPA initiate a pesticide's registration review*? The PPDC found that there is no need for a registrant to submit an application for registration review because payment of annual maintenance fees attests to a registrant's willingness to support a pesticide through the registration review process. The PPDC advised the Agency to publish a**Federal Register** notice to initiate a pesticide's registration review. The notice would announce the public availability of the documents that the Agency intends to review in its assessment of the pesticide. During the comment period, registrants and other persons could submit additional information for the Agency to consider during registration review.

6. *How should EPA encourage early submission of test data and other information to support a pesticide's registration review*? Before the Agency begins its assessment, registrants and other stakeholders should be allowed to comment on the information that the Agency had placed in the registration review docket for the pesticide. At this point, stakeholders could submit data and other information that would be pertinent to the review. However, the PPDC noted that registrants need a clear understanding of the Agency's requirements, guidelines, and issues of concern to assess what additional information would be useful. The Agency should explain how the data will be used. When necessary, the Agency should issue DCI notices under FIFRA section 3(c)(2)(B). The Agency should support stakeholder efforts to provide information by providing a framework for communicating information needs and by creating an electronic listserve for use by stakeholders who wish to participate in the registration review.

7. *What is a registration review decision*? The PPDC identified seven potential outcomes of a registration review:

- Registration review concluded—no changes in current registration are needed.
- Registration review concluded—risk mitigation or other action required.
- Registration review concluded—confirmatory data requested.
- Registration review cannot be concluded until additional data are submitted.
- Registration review concluded, but there is ongoing generic DCI or other action—registration review decision may be revisited if necessary.
- Registration review concluded—active ingredient voluntarily canceled.
- Registration review concluded—FIFRA section 6 cancellation or suspension action.

F. Feasibility Study

The Agency conducted a feasibility study to test certain aspects of the registration review decision process that the PPDC recommended. The Agency randomly selected 30 pesticides from among the likely candidates for review in the first 5 years of the program. The Agency assembled data that it would consider in a registration review and then simulated the review and decision process described in the proposed procedures. A detailed description of this study is presented in the economic analysis for this proposed regulation. A copy of the economic analysis is available in the public docket for this proposed regulation. Unit VIII. of this preamble describes how the Agency used the study to learn how the proposed registration review decision process might work and to identify aspects of the proposed process that need further development.

VI. Factors Considered in Designing a Registration Review Decision Process

A. Pesticides Subject to Registration Review Should Have Already Met the Data Requirements for Registration Established in 1984

Registration decisions made since 1984 and reregistration decisions made since 1988 are based on data requirements and risk assessment methods that were current at that time. In addition, by August 2006, the Agency will complete tolerance reassessment to assure that pesticides with food uses meet the requirements of FFDCA section 408 with respect to human health risks from aggregate and cumulative exposures. In general, the Agency believes it will not be necessary to redo reviews of studies because it has already determined that studies supporting current registrations meet requirements established in 1984.

B. FQPA Requirements Have Transformed Pesticide Risk Assessment into a Dynamic and Iterative Process

Before FQPA, EPA considered the incremental dietary risk posed by each new use and generally did not reexamine risk from existing uses. When establishing a tolerance for a new food use, the Agency now must conduct a new assessment of aggregate non-occupational exposures and assess cumulative risk, if necessary, using the most recent procedures for conducting such assessments. This assessment would update the non-occupational human health risk assessment performed during tolerance reassessment and would provide the Agency another opportunity to evaluate previously approved uses. Accordingly, the non-occupational human health risk assessments for some pesticides may be updated during the 15–year registration review cycle as a result of the review of any applications for new uses.

C. Emerging Serious and Urgent Risk Issues Will Be Identified, Characterized, and Managed as They Arise and Generally in Processes Other than Registration Review

It is the Agency's practice to investigate reports of pesticide incidents or findings of adverse effects as expeditiously as possible. The Agency intends to continue this practice.

VII. Design Options for Registration Review

This unit describes and evaluates options for various aspects of a registration review program. The program aspects discussed in this unit are:

- What should be the unit of review?
- How should the Agency account for inert ingredients in registration review?
- How should the Agency schedule pesticides for review?
- What event should be used as the basis for developing a chronological schedule?
- What approach should the Agency use in conducting the review?
- What is the optimal way to assemble the materials that the Agency will consider in its review?
- How should review of individual product registrations be managed in registration review?
- How should the Agency communicate the results of the registration review?

A. What Should Be the Unit of Review?

The statute requires the Agency to review ''the registrations of pesticides,'' but did not further describe in FIFRA section 3(g) the unit of review. Accordingly, the Agency must determine the unit of review for the purpose of this program. The Agency has identified the following three options: (1) Individual pesticide products; (2) individual active or inert ingredients; or (3) registration review cases composed of chemically related active ingredients and the products that contain one or more of these ingredients. For the reasons discussed in this unit, the Agency is proposing to use the third option and review registration review cases in the registration review program. This is reflected in proposed § 155.42 of the regulatory text.

1. *Review each product separately*. Under longstanding practice, EPA bases its decision to register a product on its assessment of the hazard characteristics of the active ingredient in the product (and its metabolites and degradates) and the risk posed by potential exposures to these substances that would result from the proposed uses of the product. The Agency also considers the possible benefits from the proposed uses of the pesticide. The Agency makes its registration decisions on a pesticide chemical and then applies this decision to a pesticide product.

Under this option, the Agency would conduct a risk assessment on each individual product. Such an assessment would not be a complete assessment of the exposure to the active ingredient(s) in the product because it does not consider exposures from other products that contain the same active ingredient(s). Accordingly, this approach might not be scientifically sound and might not meet FIFRA requirements.

2. *Review of pesticide ingredients*. The Agency currently makes decisions on ingredients and applies them to products. Comments on the ANPRM agreed that the unit of review should be a pesticide ingredient. Congress intended that EPA review a pesticide's registration in light of advances in science (i.e., data and other information relating to hazard, exposure, and risk). Because ''science'' is generally developed on a generic basis, the Agency believes conducting registration review on ingredients would be consistent with Congressional intent. However, a product that contains multiple active ingredients could belong in two or more cases and could undergo registration review more than once in a 15–year cycle. The Agency believes that the statute does not preclude the Agency from reviewing a pesticide product more than once in a 15–year cycle.

3. *Review of chemical cases that include one or more structurally similar pesticide ingredients and the products that contain these ingredients*. Under FIFRA section 4, the Agency established reregistration cases that contain either a single active ingredient or two or more structurally related active ingredients. In the reregistration program, the Agency uses data on one member of the case to support other members of the case. Significant resource savings are achieved when chemically related pesticide ingredients are grouped in the same chemical case and are reviewed together. Decisions made on the active ingredients would apply to products in the case. The Agency finds that because FIFRA section 3(g) does not stipulate the unit of review, the Agency may continue its current practice of forming cases consisting of one or more active ingredients and the products that contain these ingredients. The Agency believes that this unit of review is consistent with Congressional intent that a pesticide be reviewed in light of advances in science, which are developed generically. As stated in Unit III.A., a product that contains multiple active ingredients could belong in two or more cases and could undergo registration review more than once in a 15–year cycle.

B. How to Account for Inert Ingredients in Registration Review?

When the Agency evaluates an application to register a pesticide product, it examines the product's composition and product-specific toxicity data as part of its consideration of the potential risks posed by the product. Accordingly, the Agency believes that a review of a pesticide's registration must include a consideration of the inert ingredients as well as the active ingredients in the product.

Options for managing the review of inert ingredients include:

1. *Option 1--Establish registration review cases for inert ingredients*. Such cases would be composed of one or more inert ingredients and the products that contain the ingredient(s). The Agency would conduct either a comprehensive review of each inert ingredient, as is being done for active ingredients in reregistration or tailor the scope and depth of the review, as is being proposed for the registration review of active ingredients.

2. *Option 2--Review individual inert ingredients in a process that is separate from registration review*. During registration review, examine product composition to assure that any inert ingredient used in the product has been cleared for use in pesticides, and, if the pesticide is used on foods, to assure that a tolerance or tolerance exemption for the chemical has been established and reassessed.

The Agency may establish a program for periodically reevaluating inert clearances, tolerances, or tolerance exemptions. If the Agency does so, it would be able to use this new information in the registration review program. During a pesticide's registration review, the Agency would review the composition of a product and then check to see whether there are issues of concern associated with any of the inert ingredients in the product.

3. *Option 3--Focus on product hazards rather than reviewing individual inert ingredients*. After making findings on the active ingredients, base an assessment of the safety of end-use products upon a review of the product's acute toxicity data without separately considering each inert ingredient in the product.

The Agency proposes to adopt option 2. It would not establish registration review cases for inert ingredients as would be done under option 1. Safety of inert ingredients will continue to be evaluated in a separate process. During registration review, the Agency will check to see whether there are any issues concerning the inert ingredients in a product that is undergoing registration review. This approach would produce product assessments that reflect current knowledge about the ingredients in the product. Additionally, the PPDC registration review workgroup endorsed this approach.

The Agency believes that option 1, conducting a registration review of inert

ingredient registration review cases, could support the Agency's goals regarding sound science. However, the Agency believes that this approach would not be practical and may not be appropriate. For example, the procedures proposed for establishing registration review cases, such as the proposed criteria for establishing the baseline date for a registration review case, would not work well for inert ingredients because it is often difficult to determine when registrants began to use an inert ingredient in registered products. Other proposed procedures, such as public identification of the products that belong in a registration review case, would not be appropriate for a registration review case composed of inert ingredients. Registrants consider the identity of the inert ingredients in their products to be trade secret, so the Agency must not disclose the products that belong in an inert ingredient registration review case. Thus, the Agency finds that it may not be practicable to establish a chemical case for an inert ingredient when it is not possible, for trade secret reasons, to identify products belonging to the case. The PPDC identified additional issues with this approach. It believes that because inert ingredients are ''cleared'' for use in pesticides and not registered, they are not subject to registration review. Accordingly, they believe it would be inappropriate to establish registration review cases for inert ingredients.

The Agency believes that option 3, basing a product's registration review on acute toxicity data rather than on a review of individual inert ingredients, might not meet Agency goals relating to efficient use of resources and sound science. Review of product-specific acute data is unlikely to provide insight into potential hazards posed by chronic or repeated exposure to the inert ingredients in a pesticide product. Because such a review may not provide new understanding of the potential hazards posed by a product, the review would not be an appropriate use of Agency resources.

C. Approaches for Scheduling Registration Review Cases for Review

The Agency believes that an optimal scheduling approach would enable the Agency to meet the following goals:

- Achieve a 15–year review cycle with a predictable and reliable registration review schedule (emphasized in ANPRM comments).
- Set schedules for review that promote protection of human health and the environment.
- Promote efficient use of resources to develop and implement the schedule and provide flexibility for managing the registration review caseload.
- Be perceived as fair and objective. For example, avoid stigmatizing a pesticide by alleging that concern for the pesticide's potential risk warrants scheduling its registration review early in the registration review cycle (emphasized in ANPRM comments).

The Agency has evaluated three basic approaches to scheduling registration reviews:

(1) Chronological. Commenters on the ANPRM and PPDC Registration Review Workgroup recommended scheduling registration review based on the date of the last comprehensive review.

(2) Risk-based ''worst first.'' Under the Agency's ''initial concept'' published in the 2000 ANPRM, registration reviews would be scheduled on the basis of known or suspected risk.

(3) Random. Use randomizing procedures to develop a schedule for registration review.

Under the proposed procedures, any of these approaches could be modified to address the need to revise a pesticide's registration review schedule to balance workload (both EPA's and industry's), group related cases together, or to achieve process efficiencies, among other things.

Because FIFRA does not prescribe any approach to scheduling registration review, all of the scheduling approaches would be consistent with FIFRA section 3(g), as long as they are implemented in a way that strives to attain the 15–year review goal. For the reasons given in this unit, the Agency proposes to base its schedule on option 1. This is reflected in proposed § 155.44 of the regulatory text.

1. *Chronological, based on date of registration or reregistration.* This approach has the advantage that after initial effort to ascertain registration or reregistration dates, this schedule could be constructed and maintained with minimal resources. Because the criteria for scheduling are objective, a chronological listing of pesticides would not stigmatize any pesticide. The Agency would be in a better position to achieve the 15–year review of each pesticide's registration with this scheduling scheme than with a risk-based scheduling scheme because, in any given year, this approach is likely to produce a mix of heavy and light registration review cases.

The date of a pesticide's registration or reregistration may be a general indicator of potential risk in that older pesticides could potentially have data gaps, outdated risk assessments, and unrecognized risks. Previously unrecognized risks from older pesticides could be identified earlier in a registration review program using this scheduling scheme than one which uses a scheduling scheme based exclusively on risk potential. The Agency's feasibility study described in Unit VIII. showed that older pesticides often lacked assessments that have become routine in the last 8 years or so, such as ecological, occupational, and residential risk assessments. Accordingly, the Agency believes that the date of the last comprehensive review is a reasonable indicator for potential risk.

As discussed in Unit VI.A., the Agency will have performed a comprehensive review on all pesticides that will undergo registration review and will have determined that all pesticides meet, at a minimum, standards established in 1984. In the last 5 years or so, the Agency used its most up-to-date methods to evaluate high risk pesticides. The Agency made regulatory judgments about the acceptability or reasonableness of the risks posed by these pesticides. The public health or environmental benefit of reviewing these pesticides early in registration review would be marginal because the Agency's understanding of the risks or the societal benefits of the pesticides probably would not change much since the Agency's last evaluation of the pesticides.

However, without appropriate modification, a strictly chronological approach lacks flexibility to group related pesticides or balance the workload. Moreover, because risk factors such as hazard or exposure are not included in a chronological schedule, registration review of pesticides with known or suspected risks might occur later than registration review of pesticides that pose less risk.

In proposing this approach, the Agency recognizes that, in order to protect human health and the environment, it must rely on other procedures for identifying, assessing, and managing new risks from existing pesticides.

2. *Risk-based, relying on exposure, hazard, or other recognized expression of risk.* This approach has the advantage of early review of pesticides that are recognized to have greater potential to pose risks of concern. Additionally, pesticides with similar risks are likely to be scheduled for review at approximately the same time. Grouping such pesticides for review would promote efficient use of resources.

However, identifying and describing the risk criteria to be used in prioritizing pesticides could be controversial and

difficult. For example, should the criteria give greater weight to carcinogenic potential than to potential developmental toxicity? It would be difficult to make such judgments in an objective way. Furthermore, applying risk criteria to generate a schedule would be extremely resource intensive because of the effort needed to develop criteria, see whether each pesticide in the registration review caseload meets the criteria, and to apply a scheme for ranking pesticides that meet the criteria. The resulting schedule might be challenged by stakeholders who believe that particular pesticides should be placed higher or lower on the schedule.

As risk-based priorities change over time, the schedule would need to be modified repeatedly to advance some cases and defer others. Because the schedule would be ''front-loaded'' with the most difficult and time-consuming cases, the Agency would be less likely to stay on schedule and meet the statute's goal of reviewing each pesticide's registration every 15 years.

As described in Unit VIII.B., the feasibility study showed that older pesticides often lacked assessments that have subsequently become routine. When the Agency performs such assessments during a pesticide's registration review, it may find risks that it had not recognized before. Under the risk-based approach for scheduling registration review, the Agency might not review an older pesticide until later in the cycle and, as a result, the Agency would discover any unrecognized risk associated with the pesticide later than it might have under another approach.

3. *Random assignment*. The sole advantage of this approach is that the criteria are completely objective and incontrovertible. This scheduling approach would require the least resources. The schedule would be predictable and easily ascertainable. However, because no indicators of potential risk would be taken into account when developing a schedule, the public would not receive the public health or environmental protection benefits associated with the other approaches.

D. Establish a Baseline Date for Each Registration Review Case

Since the Agency is proposing to schedule registration review on a chronological basis, it must decide what event or events should be used to establish a baseline date for each registration review case. The options include: (1) Registration date of oldest product in the case or date of reregistration whichever is later; or (2) date of latest registration action.

Option 1 would list in chronological order pesticides registered or reregistered after the November 1984 effective date of the Agency's data requirements for pesticides. Under this option, the Agency would give priority to pesticides with the oldest post-1984 data.

Under option 2, the Agency would use the date of the most recent approval of a new use as the basis for scheduling the review. The disadvantage of this approach is that the review of the new use would have focused on the exposures that would result from the proposed new use and might or might not have led to a comprehensive review of the pesticide. Although aggregate exposure from all dietary and non-occupational exposures might have been assessed in the review of the new use, occupational or ecological risks from earlier registration actions might not have been considered.

The Agency believes that registration review schedules should generally provide for reviewing the oldest decisions first to see whether the pesticide continues to meet current standards for registration. The Agency proposes to use the earliest post-1984 registration or reregistration decision as the initial basis for scheduling registration reviews. The Agency proposes to use the date of the latest registration review as the basis for scheduling subsequent registration reviews. This is reflected in proposed § 155.42 of the regulatory text.

For the purpose of registration review procedures, the Agency must decide which event constitutes ''reregistration.'' The options include: (1) Signature date of the Registration Eligibility Decision (RED) or Interim Registration Eligibility Decision (IRED); (2) date of issuance of DCI notices for product-specific data and labels specified in the RED; and (3) date of approval of submitted labels. The Agency prefers the signature date of the RED or IRED because this is the date of the latest comprehensive risk assessment of the pesticide. Other events in the reregistration process might not be useful as a baseline date. For example, the date of the DCI notice for product-specific data is significant for compliance purposes and the label approval date signifies the completion of regulatory action in the reregistration process.

The Agency must also decide what should be the baseline date for reregistration cases for which REDs or IREDs have not been completed by the time the registration review program begins. The Agency could use either the date of initial registration or the projected date of the registration eligibility decision as a baseline date or it could wait until reregistration is completed before establishing a baseline date. The Agency believes it is simpler and more practical to wait until it issues a reregistration decision before establishing a baseline date for such cases. Consequently, the initial list of registration review cases would not include baseline dates for such cases.

E. Approaches for Conducting a Pesticide's Registration Review

The Agency has identified three approaches for conducting a pesticide's registration review: (1) A comprehensive approach modeled on reregistration; (2) a checklist approach suggested in comments on the ANPRM; and (3) a tailored approach where the scope and depth of the review are tailored to the circumstances of the registration review case. Variations of a tailored approach to registration review were presented in the Agency's initial concept described in the ANPRM, the revised concept that the Agency presented to the PPDC in 2003, and the approach recommended by the PPDC.

In evaluating these approaches, the Agency finds that the comprehensive approach and the checklist approach do not satisfy the Agency's policy objectives. The underlying assumption in the comprehensive approach is that existing risk assessments and the studies upon which they are based do not meet current standards. The studies must be reviewed again and replaced if necessary and the risk assessments must be redone. This process would redo the work performed in registration and reregistration without significantly adding value. Accordingly, this approach would not satisfy the objective of avoiding unnecessary rework. Because a comprehensive review is likely to be resource-intensive and time-consuming, the Agency would not be able to complete reviews within a 15–year cycle. Under the comprehensive approach, the Agency also would not be able to provide review decisions and impose data requirements on a predictable schedule.

The checklist approach also would not meet the Agency's objectives for a registration review process. Because this approach does not address the adequacy of existing risk assessments, it might not reveal risks that could be discovered if new risk assessments were performed. This approach would not address deficiencies in previously accepted data or changes in policy or assessment methods. In successive 15–year cycles, the original risk assessments would fall further behind the standards of the day.

Also, this approach does not include an assessment of new information that could affect the risk assessment. Accordingly, a decision based on such a review would not be based on sound science. Furthermore, under this approach, the Agency might not review new use or usage or other information on benefits that could affect the risk/benefit assessment for the pesticide.

As a practical matter, it would be extremely difficult for the Agency to develop a core assessment scheme, as suggested in comments on the ANPRM, that would apply to all pesticide products. The Agency has always made case-by-case decisions on pesticides and expects to continue to do so. For these reasons, the Agency believes that a checklist approach might not meet the requirements of FIFRA section 3(g).

The tailored approach differs from the other approaches in that scope and depth of the review would be commensurate with the complexity of the issues presented by the pesticide. The scope/depth decision and any accompanying DCI notice that might be needed is a critical output of the registration review process. By using a tailored approach, the Agency believes it will be able to make such decisions on approximately 1/15th of the total registration review workload each year. As a result of registration activity that will continue to occur during the 15–year registration review cycle, the Agency will receive new data and conduct new risk assessments for many pesticides. The Agency expects that the scope/depth decision that the Agency would make as part of registration review is likely to show that very little additional work would be needed to complete the registration review for such pesticides, at least in regard to non-occupational human health assessments.

The Agency finds that an approach that tailors the scope and depth of a pesticide's review according to the circumstances of each case is more likely to meet the Agency's goals than the alternative approaches. Accordingly, in § 155.53 of the regulatory text, the Agency is proposing this approach for the conduct of registration review.

F. What is the Optimal Way to Assemble the Materials That the Agency Will Consider in its Review?

For example, should the Agency require registrants to submit registration review applications that include or cite material for the Agency's consideration? Alternatively, should the Agency identify and assemble the material it will consider in its review? Or should the Agency and stakeholders work together to prepare for a pesticide's registration review?

1. *One option for assembling material to be considered in a pesticide's registration review would be to adopt procedures used in reregistration.* As discussed in Unit V.A.2., FIFRA section 4(d) required registrants to notify the Agency whether they intended to seek reregistration for their products, identify the data required by regulation to support the registration of the products, and the studies that satisfy the applicable requirements, and commit to provide studies to satisfy data gaps that they identified. In addition to the notification requirements in FIFRA section 4(d), FIFRA section 4(e) required registrants to summarize and reformat previously submitted studies that they intended to rely upon to support reregistration of their products.

In the ANPRM, the Agency raised the possibility of requiring registrants to submit a registration review application. The registration review application could indicate which uses the registrant intends to support, identify applicable data requirements, and cite the studies used to satisfy these requirements. The registration review application could include additional information and data on the pesticide that has not already been submitted. The Agency hypothesized that requiring registrants to assemble information needed in the review could save the Agency's resources.

Comments to the ANPRM did not object to the idea of requiring registration review applications. In fact, several comments supported the idea and made suggestions regarding the required contents of a registration review application.

However, the PPDC believed that a requirement to submit registration review applications would be burdensome to registrants. Members of the PPDC stated their belief that registrants should not be required to identify data and other information they have already submitted and that the Agency has already accepted to support a pesticide's registration.

The Agency believes that administering a registration review application process could be quite resource intensive. The Agency would have to identify who is required to submit an application, notify them of the requirement, verify receipt of such notification, track submissions, and process submitted registration review applications. Additionally, the Agency would have to follow-up when a registrant fails to submit an application as required.

The Agency has considered the burden that requiring a registration review application would impose on registrants and the costs the Agency would incur to process such applications and finds that these costs outweigh the possible benefits of such a requirement. Accordingly, the Agency will not propose to require registration review applications.

2. *The Agency might decide to base the scope/depth decision on a review of the material it has on hand.* This may be sufficient in some cases, particularly for pesticides that pose minimal risk and for which there appears to be no information that would cause the Agency to reconsider its previous registration decision. However, the feasibility study showed that in many cases, early input from registrants or other stakeholders could help clarify the Agency's understanding use practices. Accordingly the Agency will not propose to forgo public participation at this stage of registration review.

3. *In comments on the ANPRM and in public meetings, stakeholders expressed their need to participate in the registration review process before the Agency makes a scope/depth decision.* The Agency agrees that stakeholder input early in the process could improve the quality of the scope/depth decision and improve the efficiency of the review process. The Agency might also use submitted information when it conducts any new risk assessment that might be needed.

The PPDC has developed a number of recommendations as to how to manage various aspects of stakeholder participation at this stage--assembly of information for the registration review--such as:

- Advance notice of schedules so stakeholders can plan.
- Early consultation to clarify pesticide use and usage patterns.
- Early determination by Agency of data or information that might be useful in refining exposure assessments.
- Early determination of outstanding data requirements so that DCI notices can be sent out and studies required to be submitted in time for use in the registration review.

The Agency is proposing in § 155.50 of the regulatory text to provide opportunity for stakeholder participation in the information assembly stage of the process.

G. Managing the Registration Review of Individual Products

Consideration of individual products could occur at various stages of registration review. Before initiating a registration review, the Agency would

examine some or all product labels to ascertain the uses of the pesticide.

There are approximately 15,000 registered pesticide products subject to registration review. However, the Agency does not believe it is practical to conduct a comprehensive review of the composition, labeling, and product-specific data for each product. Clearly, it is necessary to assure that specific product labeling is consistent with the risk assessment regarding use directions and precautionary statements. Because pesticides undergoing registration review were registered or reregistered after 1984, the Agency expects that many pesticide products currently display up-to-date labels. As a result of reregistration, the current generation of product labels conform to labeling policy and are adequately supported by appropriate product-specific data. As discussed in Unit VII.B., the Agency would review a product's composition to confirm that the inert ingredients in the product have appropriate clearances for use in the product. The Agency might conduct a detailed review of a product if there are circumstances, such as a product registration that had not been amended in many years, that indicate that a review might be warranted.

The Agency expects to involve stakeholders in its decision regarding the scope and depth of product review in registration review. As described in Unit IX.I., the Agency will establish a docket for information that it intends to consider in a pesticide's registration review. This information may include product labels. Images of product labels are already available to the public on the Agency's website at: *http://www.epa.gov/pesticides/pestlabels/*. When commenting on the information in a pesticide's docket, stakeholders may advise the Agency of any issues that they have identified regarding the registration of products in the case, based on their own assessment of the information in the docket, and describe what they believe should be the scope and depth of the Agency's review of the products in the case.

H. Communicating the Results of a Registration Review

FIFRA section 3(g) does not specify how the Agency should communicate the results of a registration review to pesticide registrants or the public. The options range from publication of a comprehensive review document, modeled on the RED used in the reregistration program, to private communication with individual registrants, as is the current practice when the Agency reviews applications for registration actions. In order to satisfy its objectives for an open and transparent registration review process, the Agency believes that it should release to the public the results of the review of each registration review case and that the public should have the opportunity to comment on the Agency's draft conclusions before a decision regarding a pesticide's registration review becomes final.

VIII. Feasibility Study: Testing the Proposed Registration Review Decision Process

A. Design and Conduct of the Feasibility Study

The Agency conducted a feasibility study to test certain aspects of the decision process described in this regulation. A detailed description of this study is presented in the economic analysis for this proposed rule which is available in the public docket for this proposed regulation. The following discussion describes how the Agency conducted the feasibility study.

1. *Draft a preliminary list of registration review cases*. Using the criteria described in the proposed regulation, the Agency drafted a preliminary list of registration review cases and provisionally assigned baseline dates for each case.

2. *Selection of cases for the feasibility study*. The Agency randomly selected 30 cases from among the cases that, under the proposed scheduling procedures, would be scheduled for registration review in the first few years of the program. The proportions of conventional pesticides, biopesticides, and antimicrobial pesticides in the sample were roughly the same as the proportion of these categories of pesticides in the pesticide program.

3. *Assess the regulatory status of the pesticide*—a. Assemble information regarding: Current registrations and tolerances, including product labels; decision memos, reregistration eligibility decisions or tolerance reassessment decisions; pending registration actions; bibliography of submitted data; incident information or data submitted under FIFRA section 6(a)(2); and latest risk assessments for the pesticide.

b. Consult with others within the Office of Pesticide Programs (OPP) who review or regulate the pesticide. Because of time and resource constraints, OPP staff was unable to consult with other EPA program offices or other agencies. Under the proposed process, the Agency would consult with other EPA program offices and other agencies.

c. Develop a summary of the information on the regulatory status of the pesticide, including a brief discussion of the risks or other issues identified.

d. Under the proposed registration review process, the Agency would establish a docket for the information on the regulatory status of the pesticide and ask for comment on it. At this stage in the proposed registration review process, the Agency might ask stakeholders to comment on specific issues, such as the use of the pesticide, that the Agency might have identified. The Agency did not seek stakeholder input in the feasibility study. Accordingly, the feasibility study was limited to data available in the Agency's files.

4. *Determine whether the existing risk assessments meet current standards*. Ask: What do we know and what do we need to know, and what would be the value of the new information?

a. Clarify the uses of the pesticide, using information on product labels without attempts at detailed interpretation. Determine whether there is a risk assessment to support each use of the pesticide. Account for the data requirements for all the uses. Determine whether there are any on-going studies required under a DCI or conditional registration.

b. Identify the changes in requirements, risk assessment methods, science policy, and regulatory policy that have occurred since the last regulatory decision. For the feasibility study, the Agency identified changes since the publication of 40 CFR part 158 data requirements for pesticide registration in 1984, including: Introduction of a new paradigm for ecological risk assessment, 1993; introduction of short-term and intermediate-term human health risk assessments, 1995; worker protection standards in 40 CFR part 170, 1995; science policy changes arising from the passage of FQPA in 1996; EPA begins joint regulation of indirect food additives with FDA, 1996; introduction of probabilistic dietary risk assessments, 1998; and ''counterpart'' regulations regarding endangered species risk assessment, 2004.

c. In evaluating the risk assessment, consider the following factors, among other things: Are any existing data waivers still appropriate? Has the Agency established new data requirements for these uses? Has the Agency adopted new risk assessment methodology? Is there new information that suggests that the risk assessment should be revised?

d. In deciding whether to conduct a new risk assessment, consider the following factors, among other things: Is it likely that data from other sources--open literature, other government agencies--could address the uncertainties? Are new data or a new risk assessment likely to change a regulatory endpoint?

e. In the feasibility study, the Agency did not review new studies or conduct new risk assessments. Nor did it attempt to locate additional data or information by conducting searches of the open literature or consulting with other government agencies.

5. Prepare a document summarizing the findings of each review conducted under the feasibility study.

B. Lessons Learned in the Feasibility Study

The Agency evaluated the results of the feasibility study to improve its understanding of how the registration review process might work. Some of the findings are described in this unit. The Agency anticipates that the registration review decision process would continue to evolve as the Agency implements the program and gains experience in conducting registration reviews. Accordingly, the feasibility study illustrates the kinds of issues that might occur in registration review but by no means identifies all the issues that could arise.

1. *Case formation*. To develop a list of candidates for the feasibility study, the Agency applied the procedures it is proposing for forming registration review cases, thereby testing the assumptions that it made in developing these procedures. Before releasing a draft list of registration review cases, the Agency will continue to refine the information that it will use to generate such a list.

2. *Consultation with stakeholders*. The feasibility study demonstrated the usefulness of early consultation with stakeholders. Such consultation would help resolve issues such as questions regarding formulation of the pesticide, ambiguous label language, and use and usage of the pesticide. Examples include:

a. In one case, an ambiguous statement on a product label implied that a pesticide could be used either indoors or outdoors. There were insufficient data to support the outdoor use. In another case, an ambiguous statement on the label implied that the pesticide might have residential exposures. Consultation with the registrants and other stakeholders could help to clarify whether the registrants intended the pesticides to be used outdoors or in the home and whether users actually used or intended to use the pesticides in these ways.

b. A pesticide was registered for greenhouse and shadehouse uses. When the shadehouse use was registered (or reregistered), the Agency considered use of a pesticide in a shadehouse to be an indoor use. Since then, the Agency has reclassified shadehouse use as an outdoor use. Much additional data would be required to support this outdoor use. Consultation with the registrant could help to clarify whether the registrant intends to support the outdoor use of the pesticide.

3. *Determine whether the existing risk assessments meet current standards*—a. Determine whether there is a risk assessment to support each use of the pesticide. In some cases, the Agency found that there was no assessment of occupational or residential exposures or ecological risk posed by one or more uses of the pesticide. In order to conduct a registration review, the Agency would need additional data to assess the risk posed by such uses.

b. Evaluate the risk assessment to see whether the methods used to perform the risk assessment meet current standards. As expected, the Agency found that human health risk assessments were generally acceptable and complete for pesticides for which tolerance reassessments had been completed. In such cases, there generally was no need for further analysis. In other cases, the Agency found that a new risk assessment method had supplanted the method used in the existing risk assessment. In these cases, the Agency performed further analysis to determine whether it would need additional data to conduct a new assessment.

c. Check whether there are incident reports or data submitted under FIFRA section 6(a)(2). In one case, incident reports underscored the Agency's concern that a metabolite or degradate of the pesticide may be more toxic than the parent. The Agency would require additional data to characterize the effects of the metabolite or degradate.

In several cases, the Agency found that studies had been submitted under FIFRA section 6(a)(2) but were judged as not needing expedited review and had not yet been reviewed. Such studies would be reviewed in registration review to confirm the Agency's finding, made when the studies were submitted, that the results of the study do not warrant revision of the Agency's regulatory decision.

d. Account for the data requirements for all the uses. In some cases, the Agency had received studies that had been required in a RED or a conditional registration but had not yet reviewed them. In other cases, the Agency identified new data gaps. New data gaps might occur under a number of circumstances, such as:

- The Agency previously determined that a particular study was not needed in order to register or reregister a use, but now finds that the study is required. This might happen because the Agency has developed a new method for assessing the risk posed by a particular use. The data are needed to perform the new assessment and the Agency finds that it must conduct a risk assessment using the new method.
- The Agency finds that, because of changes in risk assessment methodology, a study that was adequate for use in an earlier risk assessment is inadequate for use in a new risk assessment.
- After registering or reregistering a particular use, the Agency reclassified the use into a different use category. The Agency requires more data to support uses in the new category than it does for uses in the former category.

e. Determine whether there are any on-going studies that the Agency required under a DCI or registration action. In some cases, the Agency found that studies needed to conduct a risk assessment were already required to support an application for registration of a new use or as a condition for registration under FIFRA section 3(c)(7). Where appropriate, the Agency would use such studies to support a review of existing uses as well as the new use or conditionally registered use.

f. Determine whether there are other potential sources of information that could address uncertainties identified in the review. Alternative sources of information might exist elsewhere in the Agency (i.e., outside of the Office of Pesticide Programs), other Federal agencies or the open literature. In the feasibility study, the Agency did not consult the open literature or anyone outside of the Office of Pesticide Programs.

g. Assess the value that would be provided by the new data or risk assessment. To conduct this phase of a registration review assessment, the Agency would consider the significance of a data gap or outdated risk assessment in the context of everything else it knows about the pesticide. In many cases, the Agency found that the missing information was essential and that without this information, it would not be able to determine whether the pesticide continued to meet the requirements of registration in FIFRA section 3(c)(5). In other cases, the

Agency found that it could accept the uncertainty that would occur if a particular risk assessment were not redone. For example, in one case, the Agency judged that the surface water exposure assessment did not meet current risk assessment guidance and that assessment as well as the drinking water exposure assessment should be redone. Exposure through drinking water accounted for less than 5% of human health risk, but aquatic species could still be exposed through pesticide residues in surface water. Accordingly, the Agency found that the human health risk assessment was complete, but additional work was needed to complete the ecological risk assessment.

4. *Case studies.* A summary of the results of the feasibility study was presented to the PPDC in 2004 and is available on the Agency's website at *http://www.epa.gov/oppfead1/cb/ppdc/regisreview/regreview-update.pdf.* Three case studies illustrate the effects of changes in requirements, risk assessment methods, and science or regulatory policy on risk assessments conducted before these changes occurred.

a. *Case 1.* This herbicide was registered for cereal crop uses in the late 1980's. Since then no new uses have been granted. The tolerances for this pesticide were reevaluated in accordance with FQPA. The environmental fate and effects of this pesticide were reviewed at the time of initial registration. The feasibility study showed that the dietary risk assessment performed for the FQPA tolerance reassessment is still acceptable. The occupational risk assessment would need to be updated, but no new data would be required for this assessment. Because of changes in ecological risk assessment methods since the late 1980's, a new ecological risk assessment would need to be performed.

b. *Case 2.* This biological insect control agent is a pheromone registered in the 1970's and reregistered in the 1990's. It is always used in a trap at low rates and is not applied directly to food or feed. Although there have been many changes in requirements, risk assessment methods, and policy since this pesticide was reregistered, none of these changes affect the validity of the existing risk assessments for this pesticide and no additional data are needed.

c. *Case 3.* This antimicrobial pesticide was registered in the mid-1980's and a RED was issued in the mid-1990's, before the passage of FQPA. It is used as an indirect food additive and has indoor residential uses such as use in cleaning products and as a disinfectant in ventilation systems, industrial uses, and outdoor uses. Because antimicrobial pesticides used as indirect food additives must now meet the safety standard of FQPA, a new dietary risk assessment would be required. FQPA dietary risk assessments assess aggregate risk from food, drinking water, and residential exposures. No new toxicity data would be required for this assessment, but residential exposure data would be needed. Worker exposure data would be needed for a new occupational risk assessment. Additional environmental fate data would be needed to support a drinking water exposure assessment and ecological risk assessment. Ecological effects data would be needed to support an ecological risk assessment.

IX. Proposed Procedures for Registration Review

A. Purpose of Registration Review

In proposed § 155.40 of the regulatory text, the Agency states that the purpose of a pesticide's periodic registration review is to ensure that each pesticide's registration continues to satisfy the statutory standard for registration in FIFRA.

B. Establish Registration Review Cases

In § 155.42 of the regulatory text, the Agency proposes to establish registration review cases that contain one or more active ingredients and the products that contain those active ingredients. The Agency proposes to continue the reregistration program practice of grouping related active ingredients into cases (e.g., 2,4-D and its salts & esters), where the active ingredients in each case are so closely related in chemical structure and toxicological profile as to allow common use of some or all of the same required data for hazard assessment.

As noted in proposed § 155.42 of the regulatory text, from time to time, the Agency may modify a case by adding or deleting an active ingredient and its associated products, split a case into two different cases, or merge a case with another case.

The Agency would close a registration review case when all the products in the case have been canceled.

C. Establish Baseline Date for Each Case

The Agency proposes in § 155.42 of the regulatory text to use the earliest post-1984 registration or reregistration decision as the point of departure for scheduling registration reviews. The Agency will use the signature date of a pesticide's RED or IRED as the baseline date for a registration review case for a pesticide that was subject to reregistration. If a pesticide's RED or IRED has not been completed by the time the registration review program begins, the Agency proposes to wait until it issues a reregistration decision before establishing a baseline date for such cases.

Once the Agency has assigned a baseline date to a case, it generally would not change this date when it modifies a case by adding or deleting ingredients or products to the case. When a registration review case is split into two or more cases, the new cases generally would keep the baseline date of the original registration review case. When two or more cases are merged, the Agency generally would use the baseline date of the case that had the earliest baseline date as the baseline date for the new case.

D. Maintaining Lists of Registration Review Cases

As provided in § 155.42 of the regulatory text, the Agency would maintain a list of registration review cases on its website.

E. Apply Scheduling Criteria to Create Schedules

Under § 155.44 of the regulatory text, the Agency proposes to base registration review schedules on baseline dates or, for subsequent registration reviews, the date of the latest registration review decision, and other factors. When developing schedules, the Agency would consider clustering cases belonging to the same chemical class to promote efficiency of review for the Agency and provide a ''level playing field'' for industry.

The Agency may take other factors into consideration when developing schedules for registration review. For example, the Agency's economic analysis of this proposed regulation suggested that a small business may be unduly burdened if it holds registrations in two or more registration review cases that are scheduled to undergo registration review in the same year. In such cases, the Agency may take into account when developing a schedule the potential burdens imposed on a small business (i.e., a business that meets criteria established by the Small Business Administration).

The Agency proposes to maintain registration review schedules on its website. The Agency expects to maintain schedules that list registration review cases scheduled for review in the current year and subsequent 2 years.

F. Early Determination That a Registration Review is Complete and Additional Review is Not Needed

When developing triennial schedules or at other times before or during a pesticide's registration review, the Agency may determine that there is no reason to reconsider a previous decision that a pesticide satisfies the standard for registration. Under proposed § 155.46, the Agency may propose that, based on its determination that a pesticide meets the FIFRA standard for registration, no further review will be necessary. The Agency would take comment on this proposal and issue a decision whether the pesticide's registration review is complete.

G. Early Determination of the Need for Additional Data or Information

The Agency and the PPDC agree that the Agency should have all the data and information it needs to conduct a registration review before it performs any new risk assessments or other analyses. The Agency will use a number of approaches to identify and receive data or information that it currently does not have but which it believes would be useful in conducting a pesticide's registration review. Stakeholders have advised the Agency that they could provide necessary data or information if they have advance notice and guidance as to how to prepare and submit such material.

The Agency expects that opportunities for engaging stakeholders in the identification of data needs and in the development of new data or information will become apparent as the program evolves. One such opportunity may occur when the Agency releases registration review schedules. When describing information that it does not have but believes may be useful, if available, in a pesticide's registration review, the Agency would provide guidance on how to prepare and submit such information. The Agency expects that stakeholders will participate in ways that promote a timely and productive exchange of views regarding the data or information needed for a pesticide's registration review.

H. Issue FIFRA Section 3(c)(2)(B) DCI Notices

There may be times when the Agency will be able to identify a data requirement well in advance of a pesticide's scheduled registration review. In such cases, the Agency might issue DCI notices to require the data to be submitted before the Agency begins the registration review. In some cases, the Agency may find in the course of a registration review that additional data or information are needed to complete the review. In other cases, the Agency may find that additional data are needed to confirm findings made in the registration review. Accordingly, in § 155.48 of the regulatory text, the proposed regulations stipulate that the Agency may use existing authority to issue a DCI notice to require data for use in the pesticide's registration review at any time before, during, or after the registration review for a particular case. This proposed rule does not, however, impose any requirements under FIFRA section 3(c)(2)(B).

I. Establish and Maintain a Registration Review Docket

The PPDC advised, and the Agency agrees, that the public should have the opportunity to review the types of information and issues that the Agency may consider in its forthcoming review of a registration review case. Under proposed § 155.50 of the regulatory text, the Agency would establish and maintain a public docket for each registration review case. In general, the docket would contain information to establish the current regulatory status of pesticides in the registration review case and information to indicate what has changed since the last registration decision on the pesticide. The Agency may create a case overview to identify the issues it may consider in the registration review.

The Agency would place in the docket information regarding currently registered uses of the pesticide. Among other things, the docket would list current registrations and tolerances, registrants of record, and documentation underlying current registrations and tolerances such as the most recent risk assessments and bibliography. For pesticides subject to reregistration under FIFRA section 4, the docket might include the RED or IRED and supporting science chapters, an assessment of cumulative risk for pesticides with a common mechanism of toxicity, and risk assessments supporting any new uses or other registration actions that have occurred since the signature date of the reregistration decision.

The Agency would assemble and place in the docket information to address the question: ''What has changed since the last assessment''? This might include generic changes such as new data requirements or risk assessment methods, new statutory mandates, new regulations, court orders, or changes in policy regarding the risks and benefits of pesticides.

There may be changes specific to the pesticide such as pending DCI actions, tolerance petitions, new use applications subject to the notification requirements in FIFRA section 3(c)(4), changes in use or usage, registration of reduced-risk alternatives under FIFRA section 3(c)(10), risk assessments conducted by other agencies or governments, incident data, data submitted under FIFRA section 6(a)(2), new hazard data on a structurally related chemical, or information regarding compliance or field experience.

The Agency would also place in the docket information relating to the registration review of individual product registrations. This information may include copies of product labels or links to a publically available database that contains images of product labels. Images of product labels are already available to the public on the Agency's website at: *http://www.epa.gov/pesticides/pestlabels/*.

To the extent that the Agency can identify questions or issues when the Agency first opens the docket for a particular registration review, the Agency intends to place in the docket questions or issues it identified while assembling information for a pesticide's registration review. For example, the Agency may want to know how users interpret an ambiguous label or it might need more precise information about how a pesticide is used in order to decide what data requirements would apply.

The Agency also intends to place in the docket any new information pertaining to the pesticide's registration review that it receives during the pesticide's registration review, subject to applicable protections like those imposed for CBI.

J. Other Things That Might Happen at this Stage of a Pesticide's Registration Review

When assembling information relating to a pesticide's regulatory status, or at any other time during a pesticide's registration review, the Agency may find information that suggests that the Agency might consider taking action under other existing authorities available outside of the pesticide's registration review. The Agency may find, for example, evidence that a registrant may have failed to complete one of the following actions that were taken under other authorities:

- Comply with a FIFRA section 3(c)(2)(B) notice.
- Submit data required as a condition of registration under FIFRA section 3(c)(7).

• Submit amended labels as required in reregistration or as specified in a notice of intent to cancel.
• Label a product for restricted use if this was a condition of registration or reregistration.
• Make label changes as required in a registration decision.

In such cases, the Agency would take appropriate action under other existing authorities in FIFRA to assure compliance with existing requirements.

K. Invite Review and Comment on the Registration Review Docket

After the Agency has assembled the information it intends to consider in a pesticide's registration review, it proposes in § 155.50 of the regulatory text to open the docket for each registration review case for public review and comment for a period of at least 60 days. Stakeholders may submit comments on the accuracy and completeness of information placed in the docket. At this point, registrants could, among other things, check to see whether the bibliography lists each of the studies they submitted and ascertain whether anything was omitted from the listing of regulated uses.

The comment period for the registration review case docket is the public's opportunity to submit information that responds to the Agency's information needs identified in a notice described above in Unit IX.G. or in the registration review case overview described above in Unit IX.I. Interested persons may also submit information that they believe may pertain to the pesticide's registration review.

L. Standards for Submitting Data or Information in Support of a Pesticide's Registration Review

Registrants may submit data or information in support of a pesticide's registration review. Since such submissions are already governed by existing requirements, the Agency is proposing minimum requirements in § 155.50 of the regulatory text for material submitted in support of a pesticide's registration review. Consistent with existing requirements, the proposed requirements for registration review are as follows:

• Submissions must be on time.
• Submissions must be in a useable and legible form. For example, a written English translation must accompany material not presented in English and a written English transcription must accompany material presented in videographic or audiographic form.
• Submitters must clearly identify the source of the data or information.
• A person may request the Agency to review material that it rejected in a previous review. However, the submitter must explain why he or she believes the Agency should reconsider the data or information in the pesticide's registration review.

In addition to the requirements proposed in this procedural regulation, the Agency has established other procedures or guidance for submitting data or information that may apply to the submissions described in this unit. For example, submitters to the docket should follow the available instructions applicable to the submission method used which are provided in the **Federal Register** notice, and made available at: *http://docket.epa.gov/edkpub/do/NoticeOfUse*. Additionally, the Agency requires that scientific data submitted in support of a pesticide's registration meet the format requirements of 40 CFR 158.32.

M. Quality of Submitted Data or Information

In order to promote efficient use of scarce resources, the Agency would screen all submissions in order to identify data or information it believes should be considered in the pesticide's registration review. In particular, the Agency would look for data or information that may materially affect the Agency's review. The Agency would consider, among other things, whether the submitted material is reliable, relevant, and current.

N. Examples of Information That Could Materially Affect a Pesticide's Registration Review

The Agency expects to use information on use or usage to refine exposure estimates. Other information might be used to assess the adequacy of risk mitigation measures or the benefits of the pesticide. If new and safer alternatives to a pesticide have become available, users might provide quantitative information about the benefits of a pesticide to justify continued registration of a pesticide with known high risks.

The Agency believes that stakeholders might be able to provide several different kinds of information. Registrants might have studies that they conducted for their own needs or to support a registration in another country. Users, especially those with interests in minor or specialty crops, could provide specific information about use and usage. Mosquito control districts or other public health agencies could provide information on the role of a pesticide in controlling pests that spread disease. Commodity groups could contribute information about the role of a pesticide in an integrated pest management program. Labor groups could describe the practicality and effectiveness of the worker protection measures required for the pesticide. USDA could provide survey information developed in the Pesticide Data Program (PDP) and use and usage information. The Interregional Research Project No. 4 (IR-4 Program), in partnership with State lead agencies or public health agencies, could provide residue or other exposure information.

O. Timely Submission of Data or Information

The Agency must receive pertinent data or information early in the registration review process to assure that any risk assessment conducted in registration review is based on the best data and information available. The Agency is particularly concerned that registrants and other stakeholders might not submit relevant data or information until the Agency releases a draft risk assessment. The Agency could then find that it needs to redo the risk assessments to take into account the new data or information. Such rework delays completion of the pesticide's review and ties up scarce resources.

In conducting a pesticide's registration review, the Agency will generally rely on the data or information that it has on hand at the close of the comment period. If data or information that could be used to refine a risk assessment were not submitted by the close of the comment period described in Unit IX.K. or by some other time that the Agency may designate, the Agency would use data and information available (or employ appropriate assumptions) in its risk assessments. The Agency may consider late submissions under exceptional circumstances.

P. Public Participation, Stakeholder Engagement, and Consultation with Other Government Agencies

1. *Public participation*. The PPDC advised the Agency to provide opportunities for the public to review and comment on draft documents that the Agency prepares during the registration review process. The PPDC recommended that the Agency model public participation procedures for registration review on the procedures adopted for reregistration and tolerance reassessment and that the degree of public involvement should be commensurate with the nature and complexity of the issues in a registration review case. In public participation procedures published in the **Federal**

Register of May 14, 2004 (69 FR 26819) the Agency would have discretion to decide when to seek public review and comment on draft documents prepared for reregistration or tolerance reassessment decisions. These documents would include draft risk assessments or draft regulatory decisions.

In proposed § 155.53, the Agency would generally ask for comments on draft risk assessments in cases where a new risk assessment was performed. 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, the Agency might not ask for comments on draft risk assessments at this stage. In such cases, the public would be able to review and comment on the draft risk assessment when the Agency releases a proposed decision for the registration review case.

2. *Stakeholder engagement.* The Agency intends to continue its practice, established in the reregistration and tolerance reassessment programs, of engaging stakeholders in making decisions regarding the continued use of existing pesticides.

Before beginning a registration review, the Agency may convene a meeting of registrants and representatives of pesticide user groups to discuss a pesticide's use and usage. These discussions might guide the registrant's decisions regarding which uses to support and inform the Agency's exposure estimates. The Agency may consult with other Federal, State or Tribal officials at this stage. For example, the Agency may consult with the Centers for Disease Control regarding a public health pesticide.

The Agency may engage stakeholders in the development of risk mitigation measures for a pesticide. The Agency might discuss risk management options with registrants and with pesticide users, public interest groups, or other Federal, State or Tribal officials. The Agency might convene a closure conference for all the interested parties where it reviews the issues and proposes a resolution that is based upon input from the interested parties.

The Agency expects to continue to be available, as it has been during the reregistration and tolerance reassessment programs, to meet with any interested party regarding a pesticide's registration review.

Under proposed § 155.52, the Agency would 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. Under this proposal, the Agency would place minutes of such meetings in the docket when it releases a decision. At its discretion, the Agency may place the minutes of such meetings in the docket sooner.

In the course of a meeting with a person outside of government, the Agency may provide that person with a copy of a document or other written material that the Agency has not yet released to the public. Similarly, a person outside of government may provide the Agency a copy of a document or other written material not previously released to the public. Under proposed § 155.52, the Agency would place a copy of the document or other written material in the registration review docket for the pesticide along with the minutes of the meeting where the documents were exchanged.

The Agency will not place CBI in the docket.

3. *Consultation with other governments.* The Agency may consult at any time with the Departments of Health and Human Services, Agriculture, Interior or other Federal, State or Tribal agency regarding a pesticide's registration review. At its discretion, the Agency may place minutes of meetings with government officials in the pesticide's registration review docket.

Q. Conduct a Pesticide's Registration Review

1. *Assess changes since the pesticide's last review.* The Agency proposes in § 155.53 of the regulatory text to review the data and information it possesses at the close of the comment period described in Unit IX.K. In general, it would assess any changes that have occurred since the Agency's last registration decision on the pesticide in order to determine the significance of such changes and whether additional review is needed to determine whether the pesticide meets the FIFRA standard for registration. In this review, the Agency would take into account, among other things, changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency would consider whether new data or information on the pesticide, including data or information submitted to the docket, warrant conducting a new risk assessment or new risk/benefit assessment. Deciding whether existing risk assessments meet current standards is a key task in registration review.

Under proposed § 155.53, the Agency would assess any changes that may have occurred since an individual product's last registration decision to determine whether the significance of these changes warrant additional review of the product's registration. Changes affecting a pesticide's product registration might include changes in statutes or regulations, pesticide labeling requirements or policy, or product-specific data requirements. The Agency would also consider whether new data or information, such as data or information about an inert ingredient in the pesticide product or other data or information relating to the composition, labeling or use of the pesticide product warrant additional review of the pesticide product's registration. The Agency would also consider whether any new data or information submitted during the comment period described in Unit IX.K. warrant additional review of a product's registration.

The Agency might consider an additional review of some or all of the products in a registration review case under the following circumstances:

- *Age of the label.* It has been the Agency's practice, each time a registrant applies to amend his/her product's registration, to review the entire product label to assure that it complies with all requirements and conforms to applicable guidance. Accordingly, the labels of products with recent registration actions generally conform to current requirements and labeling policy, but the labels of products with no recent registration activity are likely to be outdated. The Agency might review labels that have not been updated since it established new requirements or adopted new policies that might affect products in a registration review case.
- *Concerns about other ingredients in the product.* The Agency may examine the composition of a product to see whether any of the inert ingredients in a product are known or suspected to have risks of concern and to assure that the inert ingredients have appropriate clearances for use in pesticides, including any tolerance or tolerance exemption that might be required. If the Agency has concerns about an inert ingredient, it may require the registrant to remove that ingredient from the product formulation or provide data to show that risks posed by the product are acceptable. If the Agency finds that an inert ingredient has not been cleared for a particular use, the Agency might require the registrant either to petition for clearance, remove the use from the product registration, or remove the ingredient from the product's formulation.
- *Concerns about product-specific data.* The Agency may assess whether

product-specific data submitted or cited to support a product's registration are appropriate. If the data are not appropriate, the Agency would require submission of new data.

2. *Conduct new assessments as needed*. If the Agency decides that a new assessment is needed, the Agency would ascertain whether it can base the new assessment on available data or information, including data or information submitted to the docket. If a new risk assessment can be conducted with available data or information, the Agency would do so. If the Agency believes that additional data or information are needed to conduct the new risk assessment, the Agency would issue DCI notices under FIFRA section 3(c)(2)(B).

R. What Happens When the Agency Finds That it Needs Additional Data to Complete a Registration Review?

As described in proposed § 155.48 of the regulatory text, the Agency would issue DCI notices under its existing FIFRA section 3(c)(2)(B) authority when it finds that additional data are needed to complete a registration review. Among other things, such notices would establish deadlines for submitting the data.

In addition to issuing a DCI notice, the Agency may issue an interim registration review decision when it is unable to complete a pesticide's registration review because it does not have necessary data or information to decide whether the pesticide meets the statutory standard for registration in FIFRA. As proposed in § 155.56 of the regulatory text, the Agency would consider issuing an interim registration review decision when it does not have the data necessary to complete a registration review but it does have sufficient information to determine that new risk mitigation measures are needed. Among other things, an interim registration review decision could utilize existing authorities to require new risk mitigation measures, including interim risk reduction measures that must be adopted until the Agency receives and reviews the data required to complete the registration review and makes a final registration review decision. The interim registration review decision might also include schedules for submitting data, conducting new risk assessments, and completing the registration review. It is important to note that any requirements discussed in the interim registration review decision document are not imposed by this proposed rule. Instead any such requirements would be imposed through other existing authorities.

When issuing an interim registration review decision, the Agency would follow the same procedures it proposes in § 155.58 of the regulatory text for issuing registration review decisions. These proposed procedures are described in Unit IX.U.

S. Deciding Whether to Conduct a New Benefits Assessment

Under proposed § 155.53, the Agency might conduct a new benefits assessment when a pesticide is known to pose high risk and there is new information about the benefits of using this pesticide. The new information might include the availability of reduced-risk alternatives. When a pesticide poses a risk of concern, the Agency would consider the economic benefits of the pesticide under FIFRA section 2(bb). It is important to note that the safety standard in FFDCA section 408(b) precludes consideration of benefits for pesticides used on, in, or around food. Nonetheless, the Agency may estimate the economic benefits of a pesticide that does not meet the FFDCA standard in order to manage transition from the pesticide to safer alternatives.

T. Possible Outcomes of a Pesticide's Registration Review

Under proposed § 155.57, the Agency would complete a pesticide's registration review after it performs all risk assessments or benefit assessments that it deems to be necessary to determine whether the pesticide meets the FIFRA standard for registration. As discussed in this unit, the Agency has identified three possible outcomes of a pesticide's registration review: (1) The pesticide meets the requirements for registration in FIFRA and the registration review is complete; (2) the pesticide does not meet the requirements for registration in FIFRA and the registration review is complete; or (3) the pesticide meets the requirements for registration in FIFRA section (3)(c)(7), the registration review is complete, but may be revisited when certain new data are submitted.

1. *Registration review is complete and the pesticide meets the requirements for registration in FIFRA*. Using other available authorities, the Agency may:

- Specify label changes or other measures or remedies to mitigate a risk of concern and establish deadlines for taking the specified actions;
- Specify label changes to bring the product label into conformance with regulations or applicable policy; and/or
- Require new data to confirm the findings of a risk assessment.

2. *Registration review is complete and the pesticide does not meet the requirements for registration in FIFRA*. Publication of notices specified by other existing authorities in FIFRA section 6 might precede, accompany, or follow the issuance of the registration review decision, as appropriate. This outcome might occur under the following circumstances:

- If previous risk assessments showed a risk of concern associated with uses of the pesticide, but the use remained registered because of the high benefits associated with the use, the Agency might conduct a new benefits assessment under FIFRA section 2(bb). The new benefits assessment may show that decreased benefits of the pesticide or availability of alternatives no longer justify the risks associated with continued use of the pesticide.
- In the course of a pesticide's registration review, the Agency may find that use of a pesticide on food does not meet the safety standard in FFDCA section 408 and that mitigation is neither feasible nor sufficient to ameliorate the risk.
- In the course of a pesticide's registration review, the Agency may find that use of a pesticide poses risks of concern to workers or non-target species. If mitigation is neither feasible nor sufficient to ameliorate the risk, the Agency would conduct a benefits assessment under FIFRA section 2(bb) to determine if risks of continued use of the pesticide outweigh the benefits.

3. *Registration review is complete but may be revisited when new data are submitted; the pesticide meets the requirements of FIFRA section (3)(c)(7).*

- The Agency may conclude a registration review in some circumstances where a general DCI that was previously issued is still in progress. The Agency might revisit the registration review decision if warranted.
- The Agency might use other existing authority to ask for data to confirm a particular aspect of a risk assessment or take any of the other actions described above in Unit IX.T.1.

U. Issuing Registration Review Decisions

Under proposed § 155.58, the Agency would issue a proposed interim registration review decision or a proposed registration review decision. The proposed decision would, among other things, state the Agency's proposed findings with respect to the FIFRA standard for registration, identify proposed risk mitigation, describe any additional data that the Agency believes are needed, specify proposed labeling changes, and identify deadlines the

Agency intends to set for taking the required actions. It is important to note that any requirements discussed in the registration review decision document are not imposed by this proposed procedural rule. Instead such requirements would be imposed through other existing authorities.

The Agency would take comment on the proposed decision and on the data or information it considered in its proposed decision.

The Agency would issue a final decision and also make available the Agency's response to comments on the proposed decision and an explanation of any changes to the proposed decision.

V. Implementation of Registration Review Decisions and Interim Registration Review Decisions

Under proposed § 155.58, the registration review decision or interim registration review decision would specify actions that a registrant must take as prescribed under other existing authorities, and establish deadlines for completing those actions. The docket for the pesticide's registration review would remain open until the registrant has completed the required actions. The Agency may initiate appropriate action under other existing authorities and procedures prescribed under FIFRA if a registrant fails to comply as required.

The Agency will continue to work with its partners in the States and Tribes to assure that pesticides bear new labels as required and that users comply with the directions on the pesticide label.

W. Program Evaluation

The Agency plans to periodically evaluate the registration review process. The Agency will develop methods to analyze various aspects of the registration review program. For example, the Agency intends to assess the extent to which data that it required for a pesticide's registration review affected the risk assessment.

The Agency may also assess guidance it provides to registrants and the public regarding their participation in a pesticide's registration review in order to improve the utility of the information that stakeholders prepare for submission to the Agency.

The Agency might evaluate the information management systems used to receive and store information relating to a pesticide's registration review in order to achieve process efficiencies and improve public access, where appropriate, to information in these systems.

As required under the Government Performance and Results Act, the Agency will develop methods to measure the public benefits of the program. Benefits might include public health and environmental improvements resulting from identification, assessment, and mitigation of previously unrecognized or poorly understood risks; increased public confidence in the safety of pesticides; improvements in pesticide labeling and risk communication; improved information about pesticides for informing market choice; and improved corporate stewardship of pesticides, as follows:

- Public health and environment--periodic review might uncover previously unrecognized or poorly understood risks, determine whether the appearance of new alternatives since the last review would change the risk/benefit balance, and function as a safety net to help assure that nothing important was overlooked.
- Economic benefits--periodic review could maintain a stable market for pesticide users. Continued availability of a variety of products could promote competition and reduce the price of pesticides.
- Improved stewardship--because registration review decisions would be made through transparent procedures with public involvement, the Agency's and stakeholders' practices and positions would also be visible and subject to public scrutiny. The Agency anticipates that this visibility could enhance corporate responsibility and accountability regarding keeping a pesticide's database and product labeling up-to-date. The Agency also anticipates that continual public discourse regarding pesticide use might facilitate an exchange of ideas within the pesticide user community regarding best practices. If this were to happen, the environmental burden might decline.
- Continuous improvement of the reliability of Agency decisions about pesticides--when a registration review decision shows that no changes are necessary, the public is assured that the decision to continue the registration of the pesticide is based on a finding that the pesticide meets current standards and remains current with evolving science.
- Conserve public resources--periodic review would limit or nearly eliminate the need to conduct a resource-intensive comprehensive review of all pesticides such as reregistration or tolerance reassessment.

X. Request for Comment

In the proposed process, the Agency is seeking to balance a registrant's or pesticide user's need for specific standards against the Agency's need for flexibility to revise these standards in light of knowledge gained through evolving science.

The Agency proposes to inform the public of changes in statute, regulations, data requirements, risk assessment methods, and science policy, among other things, that the Agency will consider in its determination whether the pesticide continues to meet the FIFRA standard for registration. Under this proposal, the Agency would judge whether these changes are significant enough to warrant conducting a new risk assessment to use as a basis for determining whether the pesticide continues to meet the FIFRA standard for registration. Under the proposal, such determinations would be made on a case-by-case basis, where the Agency considers what is already known about the pesticide and evaluates whether new information, including a new risk assessment which might be conducted using a new method or data, would change the Agency's regulatory position on the pesticide.

The Agency recognizes it is essential that decisions about the significance of the changes in statute, regulations, data requirements, risk assessment methods, science policy, and other things considered in a registration review be consistent. For example, the public should be able to understand why a change in risk assessment procedures warrants a new risk assessment in one case and not in another. The Agency believes that it would not be practical to anticipate all possible contingencies in order to establish criteria for deciding the significance of the changes described in this unit. The Agency will continue to rely on its internal procedures for peer and managerial review to assure that its decisions are consistent. Additionally, the Agency is proposing a transparent process in which the Agency would show the information that it considered and would produce decision documents that would explain its reasoning. The Agency is proposing an open process in which the public has the opportunity to review and comment on draft risk assessments and draft registration review decisions. The public would have the opportunity to comment on the consistency of a proposed decision. Finally, the Agency intends to monitor and evaluate the registration review program. Such evaluations may include assessments of the procedures used to promote and assure consistency in its decision-making.

The Agency encourages you to comment on its approach for balancing the registrant's or pesticide user's need

for specific standards with the Agency's need for flexibility to revise these standards in light of knowledge gained through evolving science.

XI. Relationship of Registration Review to Other Pesticide Program Activities

Registration review is intended to be a periodic review to assure that a registered pesticide continues to meet the FIFRA standard for registration. However, to the extent practicable, the Agency also intends to use registration review as a context for performing other risk assessment, benefit assessment, and risk management work. For example, the Agency has evolving or new programs concerning existing pesticides such as conducting assessments of pesticide risks to threatened or endangered species, conducting endocrine disruptor screening and testing, or assuring that certain tolerances are reviewed every 5 years as required by FFDCA section 408(b). The Agency will continue to use a variety of approaches to manage these requirements, including incorporating these activities into the registration review program.

In proposing the procedures for implementing the registration review program, this proposed rule does not impose new requirements on the regulated community. Instead, should the Agency determine the need to impose requirements during a registration review, e.g., to generate data or amend the label or registration, the Agency will utilize other existing authorities, e.g., using FIFRA section 3(c)(2)(B) authority to obtain needed data.

A. Relationship to Tolerance Reassessment and Reregistration

The registration review program is a brand new program that will begin after the Agency completes tolerance reassessment in 2006. The Agency will begin implementing the registration review program while it completes the reregistration program. The Agency expects to complete the last reregistration eligibility decision by September 2008.

B. Relationship of Registration Review to Existing Procedures for Managing Emerging Risk Concerns

The Agency has a continuing obligation to respond to emerging risk concerns. 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 give priority to emerging risk concerns. In establishing the requirement to conduct registration review, FIFRA section 3(g) states that nothing shall prohibit the Agency from undertaking any other review under FIFRA. Among other things, this provision means that the Agency must continue to respond to emerging risk concerns and not defer action until a pesticide's regularly scheduled registration review.

FIFRA section 6(a)(2) requires registrants to submit factual information regarding a pesticide's unreasonable risk of adverse effects on the environment. The Agency has codified in 40 CFR part 159 its criteria for identifying information that must be reported under FIFRA section 6(a)(2) and the procedures for submitting such information. The Agency also responds to reports from other sources, such as other governmental agencies or academic researchers. The Agency is continuously seeking to improve systems that capture and report adverse events relating to pesticide risks.

When the Agency learns of new information that could significantly change its understanding of a pesticide's risk, it uses triage systems to evaluate the information to gauge the importance of the issue and the need for urgent response. The process the Agency uses to assess the significance of adverse effects information reported under FIFRA section 6(a)(2) is one example of a triage system. When the Agency receives a (6)(a)(2) report, it reviews the reported results of the study and asks: ''If this study is a scientifically valid study, would the Agency revise its regulatory position on the basis of this report'' If so, the Agency expedites a full review of the study and takes other action as appropriate.

Although the Agency will not postpone responding to an urgent risk concern until the pesticide's regularly scheduled registration review, the Agency may reschedule a pesticide's registration review because of a new risk concern. For example, if the Agency is reviewing a pesticide because of a new risk concern, it may decide to conduct the pesticide's registration review at the same time, even though the registration review would occur several years ahead of schedule. Since the Agency must expend resources to address a pesticide's urgent risk concern, it may opt to review all other aspects of the pesticide's registration at that time.

C. Managing New Data Needs

New data needs may arise from new statutory requirements, such as the screening and testing program for endocrine disruptor effects mandated in FFDCA section 408(p); new regulations, such as amendments to 40 CFR part 158; or changes in science policy. This proposed rule does not change the authority or existing process for identifying new data needs. The Agency will continue to use a variety of approaches, including registration review, to address an identified need for new data requirements for existing pesticides. The following are some of the approaches the Agency might use to manage DCIs issued under existing FIFRA section 3(c)(2)(B) authority.

- Special DCI projects. The Agency may respond to a new data requirement by issuing DCI notices to registrants of all affected pesticides simultaneously, without regard to the registration review schedule. The Agency might use this approach when a data requirement applies to a class of pesticides, i.e., pesticides with particular chemical characteristics or use pattern, and the Agency urgently needs the data to address a risk concern.
- Pipeline DCIs. The Agency might issue DCI notices for new data requirements 2 or 3 years before a pesticide's scheduled registration review so that the data would be required to be submitted in time for the registration review. This approach is particularly useful when a new data requirement applies to virtually all pesticides and is so new and different that it generally cannot be satisfied by previously submitted data. For instance, this approach might be used to obtain endocrine disruptor screening and testing data required under FFDCA section 408(p).
- Conditional registration of new uses. When the Agency identifies a data gap in the course of reviewing an application for a new use, it may make approval of the new use conditional on the receipt of data to satisfy the data requirement. These data would then be available when the Agency conducts a registration review of the pesticide.
- Call-in the data as part of a regularly scheduled registration review. Identifying a data gap generally requires a lot of resources. In most situations, the Agency must conduct a review to determine whether a data requirement applies, and if so, whether it can be satisfied with existing data and who should be required to provide the data. It may be more efficient to conduct such an analysis in the context of a regularly scheduled registration review.

D. Relationship to Reviews of Applications for Registration of New Uses

The Agency will not delay registration of a new use of a pesticide while conducting the registration review of the

pesticide. It will consider, however, whether reviewing the new use and the existing uses together would be an efficient use of resources and produce a better decision. When beginning a pesticide's registration review, the Agency would note any pending applications for registering a significant new use. If an application for registering a new use arrives during the pesticide's registration review, the Agency would post this information in the pesticide's registration review docket. The Agency would, to the extent practicable, include the application for the new use in its registration review considerations.

E. Relationship to Special Review

The Agency expects any current special reviews to be resolved through the reregistration program. As a matter of policy, the Agency does not use special review procedures in 40 CFR part 154 when it receives new information regarding an urgent and serious risk. In such cases, the Agency uses procedures under FIFRA section 6 to resolve the risk concern as expeditiously as possible.

The PPDC suggested that a decision to initiate a special review might be an outcome of a pesticide's registration review. The PPDC believed that special review may be appropriate in cases where further study, possibly including developing new scientific approaches, is needed to resolve questions raised about the pesticide.

If a pesticide presents an issue that is too complex to be resolved in the time frame allocated for a pesticide's registration review, the Agency might issue an interim registration review decision, with a plan for addressing the unresolved issues. The plan could include a schedule for developing a scientifically sound approach for resolving the issue and require periodic reports on progress toward resolution. Because the proposed registration review procedures would provide an open and transparent process for resolving the issue, the Agency believes that may not be necessary to use special review procedures to complete the review.

F. Managing Potential Risks of Substitute Pesticides

In managing the potential risks identified in a pesticide's registration review, one or more of a pesticide's uses might be voluntarily canceled or amended. In addition, the Agency might take action under FIFRA section 6 procedures to cancel a use that poses risks of concern. In either case, there is a possibility that a pesticide posing greater risks could replace the canceled use. Shifting the market to a potentially more harmful pesticide could be an unintended consequence of registration review.

The Agency believes that shifting the market to a potentially more harmful pesticide is less likely to occur under the proposed approach for scheduling registration review than under other scheduling approaches. The Agency proposes to review the oldest pesticides first, i.e., pesticides with the earliest dates of reregistration or post-1984 registration. The pesticides that could be substitutes for these older pesticides are pesticides that the Agency has reviewed more recently through registration or reregistration, based on more recent data requirements and using more recent risk assessment methodology. Additionally, many of the pesticides registered since 1996 are reduced-risk pesticides. The risks of the potential substitutes are, therefore, well characterized and appropriately managed.

As science advances, the Agency may modify its data requirements to add new tests that measure hazard endpoints that may not be captured by current test methods. As discussed in Unit IX.H., the Agency proposes to require submission of such studies during registration review, when necessary to conduct a pesticide's review. A pesticide registrant may choose to cancel a pesticide use rather than conduct the required testing. Or the new test may show that a use must be canceled or amended to mitigate a new risk concern. In either event, it is possible that the market might shift to a pesticide that has not been tested for the new hazard endpoint. However, as the Agency gains experience with the new test method, it may acquire information that it could use to set priorities for testing and conduct a special DCI project to require testing of high priority pesticides. This activity could reduce the tendency of the market to shift to an untested pesticide.

The Agency has several approaches for minimizing the likelihood of a market shift to a more risky or untested pesticide, as follows.

1. *Assessing risks of substitutes*. When the Agency is considering canceling a use under FIFRA section 6, it must assess the benefits of the use to determine whether the risks and benefits of the pesticide warrant cancellation. This assessment generally entails identifying pesticides that could substitute for the canceled use. When analyzing benefits under FIFRA section 6, the Agency checks to see whether any of the substitutes pose higher risks than the pesticide being considered for cancellation.

Although the Agency does not analyze benefits when a registrant requests voluntary cancellation of a pesticide, the Agency provides the public an opportunity to comment on the proposed cancellation under FIFRA section 6(f). Under the proposed procedures for registration review, the Agency would also provide an opportunity for the public to comment on any Agency proposal to place restrictions on the use of a pesticide. Users or other stakeholders may describe any concerns they might have regarding the availability of substitutes if the Agency cancels or places restrictions on a use.

Depending on the seriousness of the potential risk posed by a substitute pesticide, the Agency could take action as follows:

- Issue a FIFRA section 3(c)(2)(B) DCI notice requiring data to characterize the potential risk of the substitute pesticide;
- Advance the registration review schedule for the substitute pesticide; or
- Manage the risk posed by the substitute pesticide generally in a process outside of registration review.

2. *Group pesticides by chemical class or use cluster*. When feasible, the Agency may group pesticides for registration review by chemical class allowing all the chemicals in that class to be reviewed together and making it possible to address any risks posed by pesticides in that class at the same time. This would be most useful when pesticides in a chemical class are used interchangeably. This procedure would reduce concerns regarding unreviewed substitutes.

When feasible, the Agency may group pesticides by use cluster. For example, in the reregistration program, the Agency grouped soil fumigants, wood preservatives, and rodenticides. Since pesticides in a use cluster may be used interchangeably, such a procedure would reduce concerns regarding unreviewed substitutes.

The Agency believes the chronological approach to scheduling registration review cases is even-handed and practicable for managing the program's expected workload. However, EPA also realizes that relying exclusively on such an approach may not work in all cases. When necessary, the Agency may elect to take cases out of the original, chronological sequence for risk concerns or other factors. While doing so would be the exception, rather than the rule, there may arise circumstances that in the judgement of the Agency warrant changes to the schedule and require additional

analysis, including an evaluation of risks to substitute pesticides. Nonetheless, the Agency does not anticipate doing an extensive alternatives assessment as a regular feature of registration review because doing so would disrupt the regular scheduling of registration review that the Agency, industry, and other stakeholders rely upon to plan for a pesticide's registration review.

XII. Phase-in of Registration Review Program

The Agency plans to begin the registration review program in September 2006. To the extent possible, the Agency expects to prepare for transition to this program while completing the procedural rule.

A. Developing Procedures for Establishing Registration Review Cases

This proposal describes procedures for establishing registration review cases and assigning baseline dates for each registration review case. The Agency may use the proposed procedures to create a preliminary list of registration review cases. The purpose of this project would be to develop internal processes for creating a list of registration review cases. The Agency may release this list for public review and comment.

B. Feasibility Studies to Test the Proposed Registration Review Process

As described elsewhere in this preamble, the Agency conducted a feasibility study to test the registration review decision process. This project also produced data to support development of the economic assessment that accompanies this proposed rule.

The Agency may conduct other projects to examine other aspects of the registration review process. For example, the Agency might conduct a feasibility study to see how early consultation might affect the outcome of the registration review decision process.

C. Data Call-In Projects

The Agency may issue DCI notices under existing FIFRA section 3(c)(2)(B) authority to obtain data it believes to be necessary to support the registration of certain pesticides. After the registration review procedural regulations go into effect, such pesticides might become candidates for registration review in the early years of the program.

XIII. FIFRA Review Requirements

In accordance with FIFRA section 25(a), this proposal was submitted to the FIFRA Science Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate Congressional Committees. The SAP has waived its review of this proposal, and no comments were received from any of the Congressional Committees or USDA.

XIV. 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 proposed 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, if implemented as proposed. In addition to the requirements contained in this proposed rule, the Agency analyzed other potential actions that could occur during a registration review using other existing authorities that are not proposed or otherwise changed in this proposed 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 proposed 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 Proposed Procedural Regulations for the Registration Review of Pesticides*. A copy of this Economic Analysis is available in the public docket for this action and is briefly summarized here.

The proposed 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 proposed 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 proposed 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 only about 30 small businesses might be involved in a registration review each year. 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.

B. Paperwork Reduction Act

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 proposed rule, and the Agency's estimated burden increase is presented in the economic analysis that has been prepared for this proposed rule.

Under the currently approved ICR, the Agency estimated the annual respondent burden for information collection activities associated with the registration review program to average

63,780 hours, with an estimated total annual respondent cost of $5,769,960. As detailed in the Economic Analysis prepared for this proposed rule, the annual respondent burden for information collection activities associated with the registration review program is estimated to increase to an average 120,000 hours, with an estimated total annual respondent cost of $10,800,000. The increase in the annual burden and costs for the information collection activities associated with the registration review program (revised as appropriate) will be incorporated into the existing ICR when the final rule is promulgated.

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.

An agency may not conduct or sponsor, and a person is not required to respond to an ICR unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR, after appearing in the preamble of the final rule, are listed in 40 CFR part 9 and included on any related collection instrument (e.g., on the form or survey).

Submit any 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, along with your comments on the proposed rule as instructed under **ADDRESSES**. The Agency will consider any comments related to the information collection requirements contained in this proposal as it develops the final rule. Any changes to the burden estimate for the ICR will be effectuated with the final rule.

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 proposal will not have a significant adverse economic impact on a substantial number of small entities. This proposed 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.

This proposal does not have direct adverse impacts on small businesses, small non-profit organizations, or small local governments. For purposes of assessing the impacts of today's proposed 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 governmental jurisdictions or small not-for-profit organizations.

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 1 year. As described in Unit XIV.A., this proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed rule.

G. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled*Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, 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 XIV.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 proposed rule because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit XIV.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 proposed rule does not impose any technical standards that would require EPA to consider any voluntary consensus standards.

J. Executive Order 12898

This proposed 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.

List of Subjects in 40 CFR Part 155

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

Dated: July 6, 2005.

Stephen L. Johnson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 155—[AMENDED]

1. The authority citation for part 155 will continue to read as follows:

Authority: FIFRA 136a.

2. 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 section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. 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 pesticide or the date of reregistration, whichever is later. For purposes 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.

(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. As indicated in § 155.40, the Agency may change the schedule of a pesticide's registration review if circumstances warrant. 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 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, 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.

§ 155.48 Data Call-In before, during, or after a registration review.

The Agency may issue a Data Call-In notice under FIFRA section 3(c)(2)(B) at any time before, during, or after a pesticide's registration review 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 and opening it for public review.

(a) *Establish a registration review docket for each registration review case.* The Agency will establish a docket which it will maintain for the registration review of the pesticide. 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 will consider including, among other pieces of information:

(1) An overview of registration review case status;

(2) A list of current registrations and registrants, any **Federal Register** notice 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 requesting that interested persons identify within 60 calendar days of publication any additional information they believe the Agency should consider in the course of the registration review.

(c) *Submission of data and other information.* 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 guarantee that the Agency will consider data or information in the conduct of a registration review, interested persons must submit the data or information within 60 calendar days of publication of the notice described in paragraph (b) of this section or by some other time that the Agency may designate. 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.

§ 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 public interest groups 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) *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 a pesticide's registration review.

The Agency will review data and information described in § 155.51 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 registraton. 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.

(1) The Agency might not ask for 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 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 section 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration 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 registration review 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 section 3(c)(2)(B) notice requiring such data may precede, accompany, or follow issuance of 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.

(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.

[FR Doc. 05–13776 Filed 7–12–05; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 22

[WT Docket No. 04–435; DA 05–1712]

Facilitating the Use of Cellular Telephones and Other Wireless Devices Aboard Airborne Aircraft

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of reply comment period.