ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[OPP–36195; FRL–6488–9]

RIN 2070–AD29

Pesticides; Procedural Regulations for Registration Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Advanced Notice of Proposed Rulemaking.

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 safety. FIFRA section 3(g) specifies that EPA establish procedural regulations for conducting registration review and that the goal of the regulations shall be the Agency review of pesticide registrations on a 15–year cycle. This advance notice of proposed rulemaking (ANPRM) alerts stakeholders that EPA is beginning development of procedural regulations for registration review under FIFRA section 3(g). It explains EPA's preliminary interpretation of the authorizing legislation, presents EPA's goals in implementing the statutory provisions, presents the Agency's initial concept of how the registration review program might operate, identifies several issues that should be addressed in developing the program, and invites public comment on these and other issues relating to registration review.

DATES: Comments, identified by the docket control number [OPP–36195], must be received on or before June 26, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–36195 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Vivian Prunier, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; 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 the planned rulemaking described in this document if you hold pesticide registrations or may hold pesticide registrations in the future. Pesticide users or other persons interested in the regulation of the sale, distribution, or use of pesticides may also be interested in these planned procedural rules. As such, the Agency is soliciting comments from the public in general. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document from the EPA Internet Home Page at http://www.epa.gov/. To access this document on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register—**Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number [OPP–36195]. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Public Information and Records Integrity Branch telephone number is 703–305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–36195 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically*. You may submit your comments electronically by e-mail to: ''opp-docket@epa.gov,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–36195. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior

notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

We invite you to provide your views on the various issues we raise, new approaches or options we haven't considered and the potential impacts, including possible unintended consequences, of the Agency's initial concept. You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible and provide any supporting data where appropriate.
- Describe any assumptions that you used.
- Make sure to submit your comments by the deadline in this notice.
- To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Purpose of the ANPRM

With this ANPRM, the Agency presents the statutory requirement for pesticide registration review and alerts its stakeholders that it is initiating the development of rulemaking to establish procedures for a registration review program. Second, the Agency explains its preliminary interpretation of the statutory provisions and its preliminary ideas regarding goals and objectives for this program. Third, the Agency describes its preliminary ideas about how registration review might operate. Fourth, the Agency solicits public input on critical issues about registration review early in the planning process. Finally, EPA solicits public input to identify potential problems as early as possible.

III. Legal Authority

A. EPA's Authority to License Pesticide Products

FIFRA sections 3(a) and 12(a)(1) require a person to register a pesticide product with the EPA before the pesticide product may be lawfully sold or distributed in the United States. A pesticide registration is a license that allows a pesticide product to be sold and distributed for specific uses under specified terms and conditions such as use instructions and precautions. 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.
>
> (D) When used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

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

The proponent of initial or continued registration always bears the burden of demonstrating that a pesticide product meets the statutory standard for registration.

B. EPA's Authority for Registration Review

The FQPA amended FIFRA to add, among other things, section 3(g), ''REGISTRATION REVIEW,'' as follows:

> (1)(A) GENERAL RULE. The registrations of pesticides are to be periodically reviewed. The Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide's registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6.
>
> (B) LIMITATION. Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this Act.
>
> (2)(A) DATA. The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.
>
> (B) DATA SUBMISSION, COMPENSATION, AND EXEMPTION.—For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

IV. What is Registration Review?

EPA believes that ''registration review'' would consist of the review of a pesticide to determine whether the pesticide continues to meet the statutory standard for registration under FIFRA section 3(c)(5). During a registration review, EPA would evaluate elements of FIFRA 3(c)(5) including the composition, labeling and other required material (including studies and other data), risks and benefits of a pesticide, and incident data or other information relating to its use. FIFRA section 3(g) contemplates that EPA may determine whether or not a pesticide meets the statutory standard for registration in FIFRA section 3(c)(5). If EPA determines that a pesticide no longer meets the statutory standard, it should not remain registered. In this event, EPA may need to pursue other actions such as cancellation under other statutory authority.

FIFRA section 3(g) instructs EPA to establish, by regulation, a procedure for accomplishing registration review. The goal of these regulations shall be Agency review of pesticide registrations on a 15–year cycle. EPA believes the activities that should be addressed under the procedural regulations include, but are not limited to: setting priorities for review, establishing a mechanism for setting schedules for reviewing all pesticides every 15 years, and articulating the general approach to conducting and concluding the review.

FIFRA section 3(g) also instructs the Agency to rely on existing authorities for data submission, data compensation, data exemption, or cancellation of registrations. Therefore, the procedural regulations need not be concerned with procedures for acquiring new information, assuring compensation for data developers, data exemption, or canceling a pesticide registration. Authorities and procedures for such activities already exist and FIFRA 3(g) did not require EPA to develop alterative procedures for these activities. Existing regulations such as those concerning good laboratory practice for data generation and FIFRA section 8 recordkeeping requirements would also apply.

EPA has already issued regulations and guidelines under FIFRA 3(c)(2)(A) to specify the kinds of information that are required to support a pesticide registration. EPA modifies this guidance periodically to reflect new developments in science areas such as hazard characterization and exposure assessment. Additionally, as explained in an October 29, 1998 **Federal Register** notice (63 FR 58030) (FRL–6041–5), EPA is in the process of issuing guidance for meeting the new safety standard mandated by the FQPA. Accordingly it is not necessary to specify such information in procedural regulations issued under FIFRA section 3(g)(1)(A).

EPA may determine that reviews accomplished under other authorities, e.g., section 408 of the FFDCA, could potentially contribute to registration reviews. In any event, EPA believes that it would not be necessary to specify procedures for these activities because authorities and procedures already exist for them.

Finally, FIFRA section 3(g)(1)(B) stipulates that EPA retains its authority to undertake any other review of a pesticide under FIFRA. This provision means that EPA may continue to undertake any review that is authorized by FIFRA or EPA regulations such as reregistration or special review. EPA also interprets this provision to mean, among other things, that the Agency may continue its practice of requiring submission of data whenever the Agency believes that such data are needed to support the continued registration of a pesticide.

V. What are EPA's Goals for Registration Review?

EPA's ultimate goal for registration review is to ensure continued protection of human health and the environment throughout the ''life'' of each pesticide's registration. To achieve this goal, EPA will periodically review all pesticide registrations to assure that they continue to meet the FIFRA statutory standard for registration based on the science, policies, and regulations current at the time of the review. EPA will conduct this review efficiently and effectively by building on existing knowledge about the pesticide.

EPA will evaluate any new test data, monitoring data, and field information. EPA will consider the effects of any changes in data requirements, risk assessment methodologies and labeling policies. If the risk assessment changes for any of these reasons, EPA may need to change the regulatory requirements pertaining to the registration. In some cases, EPA may find significant new risks that were not considered when the pesticide was registered or reregistered. This could trigger further review of risks or benefits. In such cases, EPA may determine that the pesticide does not meet the statutory standard for registration under FIFRA section 3(c)(5) and therefore should not remain registered. In other cases, EPA may find that originally it had overestimated risks and it may be possible to ease regulatory restrictions.

A. Keeping a Registration Up-to-Date

EPA has identified several aspects involved in keeping a pesticide registration up-to-date. These include receipt of new data; changes in data requirements and associated test guidelines (or protocols); changes in risk assessment methods; new information gained through use and practical experience with a pesticide; and changes in labeling policy.

1. *Availability of new data.* At any time, registrants or other persons may submit new studies on a pesticide. These studies may be undertaken in response to an Agency request or upon the data generator's own initiative. FIFRA section 6(a)(2) requires submission of certain kinds of data, as specified in 40 CFR part 159.

2. *Changes in data requirements and test guidelines.* From time to time, EPA changes data requirements or testing guidelines to reflect advances in the science of hazard characterization or exposure assessment. When changes are significant, EPA may require registrants to submit new testing to EPA to support registration. New testing may be necessary to evaluate an aspect of toxicity or exposure that was not previously considered, to replace particular studies that are no longer adequate as a result of advances in test design or protocols, or for many other possible reasons.

3. *Changes in risk assessment methodologies.* EPA continually seeks to improve its risk assessment methodologies. Currently, the Agency is reviewing a number of risk assessment methodologies as part of its implementation of the FQPA. Undoubtedly, there will be further changes as science and policy advance.

4. *Use and practical experience with a pesticide.* EPA evaluates whether practical experience from using a pesticide changes our understanding of the risks and benefits of the pesticide. EPA has established registrant reporting requirements for risk/benefit information (see 40 CFR part 159) and has a process for quickly assessing the safety implications of such information. The EPA will also maintain incident databases, sponsor a toll free telephone service that gathers information related to pesticide incident, and obtain incident related information from poison control centers. In addition, EPA is considering the establishment of a Pesticide Field Data Plan for capturing key information about pesticide use or misuse. Under this plan, States would standardize their procedures for collecting and reporting information from State pesticide compliance and enforcement records. EPA would analyze information from thousands of federally-funded investigations and inspections for trends and patterns of problems related to pesticide use or misuse. EPA may eventually be able to use these analyses to shape or confirm regulatory decisions.

5. *Changes in labeling policy.* From time to time, EPA publishes guidance on the format and content of pesticide product labels. EPA would, as part of registration review, evaluate existing labeling to determine whether it needs to be changed to reflect current policies and regulations pertaining to matters such as restrictions in use, requirements for protective clothing, and other precautionary label language associated with reducing exposure and environmental risk. Additionally, EPA may assess alternative ways to communicate risk management information to pesticide users.

B. Incorporate Lessons Learned from Reregistration

FIFRA section 4, established by the 1988 amendments to FIFRA, instructed EPA to review the human health and environmental effects of all pesticide active ingredients originally registered before November 1, 1984, in order to determine whether they are eligible for reregistration. To be ''eligible,'' an older pesticide must have a substantially complete data base, and must be found not to cause unreasonable risks to man or the environment when used in accordance with its approved labeling. As of August 1, 1999, of 612 reregistration cases (composed of a pesticide active ingredient or group of related pesticide active ingredients), 415 cases have completed reregistration (including 231 cases where registrants requested voluntary cancellation of all registrations of the pesticide). That leaves 197 cases awaiting reregistration decisions.

The Agency's experience with the reregistration program offers insights into the construction of an efficient registration review program. Chief among these are the importance of effective organization of large quantities of data for review, the efficient conduct of the review of these data, and the need for flexibility in defining the scope of the review for each pesticide. In addition, public participation at critical junctures helps ensure that the Agency develops practical risk mitigation measures where needed, and that stakeholders better understand the bases for decisions. To the extent possible, EPA plans to:

1. Review first those pesticide registrations for which EPA believes registration review will produce the greatest human health and environmental benefits.

2. Establish methods and approaches for ensuring that it has all necessary

data to make good regulatory decisions on schedule.

3. Standardize data submission by adopting guidance for data submitters such as the guidance developed by the Organization for Economic Cooperation and Development (OECD). Standard submission formats could expedite EPA's review and promote sharing the work of pesticide evaluation with other governments.

4. Review related pesticides simultaneously. This would allow effective use of review resources and promote more practical and comprehensive risk mitigation measures.

5. Tailor the level and nature of the review to the specific facts and concerns of each case.

6. Build on the results of prior review efforts such as reregistration and tolerance reassessment and on updates such as evaluations of applications for registration of new uses. EPA would avoid re-reviewing data to the fullest extent possible.

7. Adopt, or use to the extent practicable, state and foreign governments' reviews of pesticide studies. For several years, EPA has been developing experience in sharing the work of pesticide evaluation with North American Free Trade Agreement (NAFTA) partners. We intend to build on this experience by developing work share relationships with additional countries through OECD initiatives.

8. Standardize its approach to documenting data reviews by adapting OECD guidance for development of government monographs. Standard formats would promote sharing work between countries and can enhance understanding of EPA reviews.

9. Seek stakeholder views and input through an open process that offers the public and the regulated community clearly defined, time-limited, opportunities for input to various aspects of the review process for an individual pesticide.

VI. EPA's Initial Thinking on How Registration Review Might Operate

EPA has developed an initial concept for registration review, which is presented in this document. It is intended to stimulate thought about and comment on all aspects of developing procedures to implement registration review. EPA believes that the conceptual model presented in this Unit meets the statutory requirements and Agency goals and objectives for the registration review program for all pesticides.

EPA intends for registration review to be implemented within the next 5 years. EPA expects that the reregistration program will be completed by then, and the registration review program will become the Agency's primary review program for all pesticide registrations. We anticipate that the registration review program will incorporate the application of the FQPA safety standard and, as appropriate, the use of reviews conducted under other authorities and programs such as reregistration, tolerance assessment and reassessment, and our proposed endocrine disrupter screening program.

VII. EPA's Initial Conceptual Model

This conceptual model has five steps. EPA expects that each pesticide would start registration review at step one and proceed step-wise through the process. At key points in the conceptual model, EPA may decide to omit one or more steps in the registration review of a pesticide. Registrants who are responsible for generating generic data on an active ingredient would likely be involved in all five steps of the process described in this preliminary model. Registrants who are generally not responsible for generating generic data would likely participate in fewer steps.

A. Step 1: Plan and Schedule Candidates for Review

The first step in EPA's conceptual model of a Registration Review Program would be planning and scheduling of pesticides for review. This step might consist of two tasks: (1) Assembling the historic record; and (2) selecting and prioritizing candidates.

EPA would assemble the historic record for a pesticide, including prior reviews and associated documentation (for example, a Registration Eligibility Document (RED) if the pesticide had been evaluated in the reregistration program); use and enforcement history, including information on compliance with Good Laboratory Practice regulations and other FIFRA requirements. The selection and priority of candidates for review would depend on a number of factors such as: (1) The relative importance of benefits to human health and the environment which might accrue by completing the review of a particular pesticide; (2) whether the pesticide is part of a class or group that should be considered together; (3) state of the data base relative to current guideline requirements; (4) length of time since last comprehensive review; (5) incident data, existence of information required to be submitted under FIFRA section 6(a)(2); (6) any compliance issues; and (7) the pesticide's status in the reregistration and tolerance reassessment programs.

B. Step 2: Publish Schedule, Define Initial Scope and Level of Review, and Issue Needed Data Call-Ins and Requests for Applications for Scheduled Candidates

The second step would also consist of two principle tasks: (1) publication in the **Federal Register** of the list of review candidates and the tentative schedule for review; and (2) case-specific determinations of the level and scope of review and the development of needed data call-in notices.

EPA believes that the schedule for registration review candidates should be announced at least 5 years in advance of the review to provide time for generating and submitting new data. In addition to publishing a **Federal Register** notice listing the registration review candidates, EPA could publish the listing in the Code of Federal Regulations (CFR), make the list available as part of a registration review docket, and/or maintain a list electronically on the OPP Internet Home Page.

In making case-specific determinations about the level and scope of review appropriate to any given pesticide, EPA might conduct a preliminary analysis of the completeness of the data base; the potential significance of any real-world monitoring and field data collected since the last regulatory action; the need to revise the risk assessment using updated methodologies; and any applicable labeling policy changes. This analysis would provide an initial characterization of the level and type of risks possibly posed by the pesticide, critical data needs, and an early assessment of the appropriate level and scope of review (e.g., whether tolerances should be reassessed). EPA might then publish a pesticide-specific notice in the **Federal Register** describing the preliminary analysis, the initial assessment of data needs, and the proposed level and scope of review. EPA would invite comment on these issues. After analysis of comments received, EPA would issue notices to registrants to call-in any needed data and establish a deadline for submitting applications for registration review.

EPA expects that the deadline set for the submission of an application for registration review will depend in large part on the scope, level, and focus of registration review for the pesticide and the type of data that are being called in.

The case-specific determination of the level and scope of review may show that the pesticide meets the requirements of FIFRA section 3(c)(5) and that no additional data or review are needed. In

such cases, EPA would issue a preliminary determination, as described in Step 4 below.

C. Step 3: Registrants Submit Applications for Review

The third step would be the registrant's submission of an application for registration review. EPA envisions that the registrant's application for registration review would contain all required data and all needed use and usage information and any relevant data reviews conducted by regulatory officials in the states or other countries. The format for the submission could be modeled after the OECD data submission guidelines noted earlier in this document. The application might also include the registrant's opinion of which hazard, exposure or risk assessments should be updated (possibly including an evaluation of monitoring data and their impact on the assessment), the registrant's assessment of the pesticide's risks, and the registrant's risk mitigation proposals, including proposed label changes. Finally, if the registrant is considering changes in the pesticide registration that would result in changes in tolerances for the pesticide, a tolerance petition might be needed, along with the appropriate tolerance petition processing fees. The tolerance petition processing fees would be based on the new tolerance fee schedule, which EPA proposed to establish as required by FQPA (64 FR 31039, June 9, 1999) (FRL–6028–2).

EPA would screen the application for completeness, identify issues and questions, and decide whether any issues or questions warrant public discussion before proceeding with the review. EPA does not anticipate routinely soliciting public input at this stage in the process and EPA expects that most pesticides will move to Step 4 without a public meeting. However, in those cases where, for example, the registrant's application potentially raises significant risk-related issues or where the registrant is proposing risk mitigation measures which would potentially be of interest to certain stakeholders -- such as protective clothing requirements, establishment of buffer zones, or voluntary cancellation of minor uses, EPA would expect to hold a public meeting before progressing to Step 4.

D. Step 4: EPA Conducts the Review and Issues It for Public Comment

The fourth step would be to conduct the registration review. This review could include evaluation of all new data and data reviews done by other regulatory officials, review and evaluation of the registrant's risk assessments and public comments (including data) submitted in Step 3, revision of the Agency's risk assessments (where necessary), review of pesticide labeling for conformance to current policy, and development of proposed risk mitigation measures. At this step in the process, EPA envisions making a preliminary determination whether the pesticide continues to meet the statutory standard for registration under FIFRA section 3(c)(5). EPA would announce the availability of the preliminary determination for public review and comment.

If EPA preliminarily determines that the pesticide no longer meets the standard for registration under FIFRA section 3(c)(5), EPA would immediately collect and review any benefits information which it believed it needed. If it appears that there would be a significant change in the existing registration, EPA would seek public input on proposed risk management action before taking such action.

E. Step 5: Consider Comments, Issue Final Review, and Review Registrant's Proposed Labels

In the final step EPA would evaluate public comments on its updated risk assessment and proposed regulatory position and issue its final review. EPA would request submission of product-specific data or new labels if the registration review shows that they are needed. In cases where EPA decides that the registration appears to no longer meet the requirements for registration under FIFRA section 3(c)(5), EPA would undertake appropriate regulatory action, including, if necessary, cancellation action under FIFRA section 6.

VIII. Issues for Public Comment

Although EPA is soliciting your comments on all aspects of the discussion presented in this document regarding registration review, EPA is particularly interested in receiving your comments on the following topics. You may submit comments on any other issue related to registration review, including your own views on what registration review procedures should look like.

1. *EPA's interpretation of the requirements in FIFRA section 3(g).* Do you agree with EPA's interpretation of the statutory mandate for registration review as set forth in Unit IV? If not, why? How would you interpret FIFRA section 3(g)?

2. *Interpretation of ''Review of a Pesticide's Registration every 15 years.''* EPA recognizes that there may be various interpretations of ''review of a pesticide's registration every 15 years.'' This term could be interpreted to mean that EPA would complete a registration review of each pesticide within 15 years of the pesticide's registration or reregistration. This term could also be interpreted to mean that the Agency would complete registration reviews of all pesticides within a 15–year period that could begin when EPA's procedural regulations for registration review go into effect.

3. *Commencement of a 15–year registration review cycle.* The Agency believes that the effective date of the procedural regulations for registration review could be a possible starting date of the 15–year period for completing registration review, but recognizes that another date or series of dates may also be possible starting dates for registration review.Do you have any suggestions for designing a system of staggered scheduling for registration reviews?

4. *Goals and objectives for the registration review program.* Do you agree with the goals that EPA has identified? What changes do you suggest?

5. *Relationship of registration review to other mandates.* A key design issue is how registration review fits in with other activities such as the implementation of the new FQPA safety standard, reregistration, registration of new uses, and tolerance assessment or reassessment, and endocrine disrupter screening and testing. In what way could EPA integrate these activities to promote the efficiency of registration review?

6. *Non-conventional pesticides.* Do the Agency's proposed goals, objectives and procedures for registration review work for all pesticides, including non-conventional pesticides such as antimicrobial or biological pesticides? How should the Agency's concepts be modified to accommodate any special issues pertaining to the registration review of non-conventional pesticides?

7. *Criteria for setting priorities and scheduling compounds for review.* In selecting candidates for Registration Review, should the relative risk, length of time since its last review, relationship to a high priority initiative (for example, EPA's current initiative on persistent bioaccumulative toxics), or other similar programmatic activities (e.g., tolerance reassessment schedule) be considered? What additional factors should the agency consider in selecting and prioritizing pesticides for Registration Review?

8. *Process for announcing schedules for registration review.* Should the agency announce its registration review

scheduling priority in the **Federal Register**? The Agency anticipates announcing tentative schedules 5 years in advance of the initiation of the review. Because review priorities or time estimates for preparing for a review may change after a review schedule has been announced, should EPA publish updated schedules, and if so, how frequently?

9. *Scope and depth of registration review*. Should all pesticides undergo the same level of review or should the review be tailored to the level of risk posed, exposure potential, severity of hazard, level of benefits, degree of uncertainty, length of time since its last review, completeness of database and related factors?

10. *Submission of applications for registration review by registrants*. The Agency is considering requiring a registrant to submit an application for registration review of its pesticides. The application could follow a standard format and content and include any required data, risk mitigation proposal if applicable, information on use and usage and related information. Registrants may also include proposed risk assessments as part of their submissions. Do you believe this requirement will be cost effective and contribute to the overall efficiency of the registration review program? Should EPA require, encourage, or discourage the preparation of proposed risk assessments by registrants?

11. *Potential penalties for submission of incomplete applications*. If an application for registration review is ''material required to be submitted,'' the product registration would be subject to cancellation if the registrant fails to comply with the requirement. If a registrant fails to submit required data as specified in the data call-in notice requiring the data, the product registration would be subject to suspension. What could the Agency do to promote compliance with a requirement to submit a registration review application? If submission of an application for registration review were not mandatory, what should the Agency do if a registrant fails to submit a registration review application or submits an incomplete application?

12. *Incentives and opportunities for registrant participation in registration review*. EPA believes that the public may benefit when a registrant takes the initiative to identify and provide data needed for refining a risk assessment. What can be done to encourage and promote voluntary compliance and registrants taking the initiative?

13. *Maximize work sharing opportunities*. In order to avoid duplication of effort, EPA wishes to use existing reviews wherever possible, provided that these reviews are based on current scientific standards. In addition to its own recent reviews, EPA could use data reviews prepared by state or foreign governments that have participated in harmonization efforts. Are there any reasons why harmonized data reviews should not be used in registration review?

14. *Public participation*. EPA envisions public participation at several critical junctures of the registration review process. How can the public have access to sufficient information to participate meaningfully? At which junctures in the process would public input be most valuable? Is a public meeting on the registrant's data and associated analyses a good way to involve stakeholders in the registration review process? If not, how can the agency best involve stakeholders? Would making information available to the public substantially affect any stakeholder's interests? How can efficiencies be achieved?

15. *Role of the Internet in involving outside stakeholders*. EPA intends to publish notices in the **Federal Register** and maintain a docket for registration review actions, but wants to expand its outreach efforts. Is the Internet an effective supplement to the published notice and is it an equitable way of meaningfully involving stakeholders in the registration review program? What other opportunities using electronic and Internet technology should the Agency consider?

16. *Participation of small entities in the rulemaking process*. What can be done to ensure that the rulemaking process is accessible to small entities and that the Agency identifies issues of concern to small entities regarding procedures for registration review?

IX. Do Any of the Regulatory Assessment Requirements Apply to this Action?

The Office of Management and Budget (OMB) has determined that this advanced notice of proposed rulemaking is not a ''significant regulatory action'' subject to review by OMB under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Nevertheless, the Agency provided OMB with an opportunity to review a draft of this advanced notice of proposed rulemaking, and did not receive any comments that resulted in changes to this document.

This advanced notice of proposed rulemaking does not impose any requirements. Instead, it seeks comments and suggestions on possible approaches that the Agency should consider in developing a procedural rulemaking to implement the registration review requirements contained in FIFRA section 3(g). As such, the various other regulatory assessment requirements that apply when an agency imposes requirements do not apply to this advance notice of proposed rulemaking.

As a part of your comments on this document, you may include any comments or information that you have regarding these requirements. In particular, any comments or information that would facilitate the Agency's assessment of the potential impact of a procedural rule on small entities pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.); the Agency's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note); and the Agency's consideration of environmental health or safety effects on children pursuant to Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). The Agency will consider such comments during the development of the procedural rulemaking as it takes appropriate steps to address any applicable requirements.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping.

Dated: April 19, 2000.

Carol M. Browner,

Administrator.

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