



## MEMORANDUM

Via E-Mail

DATE: July 28, 2005

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Issues Proposed Registration Review Regulations

On July 13, 2005, the U.S. Environmental Protection Agency (EPA) issued proposed procedural regulations for Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration reviews. According to EPA's *Federal Register* notice, EPA's goal would be review of all pesticide registrations on a 15-year cycle. The Food Quality Protection Act (FQPA) of 1996 amended FIFRA to require the periodic review of pesticide registrations to ensure that they continue to meet the statutory standards for registration. EPA states that the proposed regulations are "intended to ensure continued review of pesticides using procedures that provide for public participation and transparency in an efficient manner." Comments on EPA's proposed rule are due **October 11, 2005**.

EPA will hold public information sessions on **August 23, 2005**, in Washington, D.C., and on **September 1, 2005**, in Chicago, Illinois. According to EPA, the purpose of these meetings is to engage stakeholders in a discussion of the proposed regulations and proposed registration review program and obtain constructive and timely comments on the proposed rule. EPA staff will provide a general explanation of the registration review procedures and discuss EPA's goals and expectations for the proposed program; proposed scheduling procedures; the proposed process for conducting a review; differences and similarities between reregistration and registration review; and stakeholder and public participation in the new registration review process. EPA states that its staff will respond to questions during the meeting. EPA will consider only public comments made during the meeting that are also submitted in writing. More information on the proposed regulations and proposed program is available on the Internet at [http://www.epa.gov/oppsrd1/registration\\_review/](http://www.epa.gov/oppsrd1/registration_review/).

### Background

EPA began evaluating approaches to registration review by first evaluating its current programs to see whether lessons learned would apply to registration review. EPA then



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published on April 26, 2000, an advance notice of proposed rulemaking (ANPRM) to solicit comment on its initial concept of registration review. EPA also consulted a stakeholder group regarding the design and implementation of the registration review program, and conducted a feasibility study to test the decision process that it developed with the advice of the stakeholder group.

### *Experience from the Reregistration Program*

In reviewing the reregistration process, EPA determined that data and information affecting pesticide exposure and risk were often provided after it had drafted its risk assessments. After EPA began to consult more regularly with stakeholders before conducting its review, EPA believes that the problem eased somewhat. EPA states that it hopes to avoid or minimize this problem in the new registration review program by proposing procedures that would promote early submission of pertinent information. EPA states that while stakeholder consultation and public participation in the reregistration program were not required by FIFRA, EPA believes such consultation “clarified use practice and usage patterns and identified uses that were no longer economically viable.” As a result, according to EPA, it was able to reduce the amount of effort and rework required to complete a reregistration eligibility decision (RED). EPA’s proposed regulations “include ample opportunities for public participation in the registration review process.”

### *ANPRM Comments*

According to EPA, four issues in its ANPRM stimulated the most discussion:

- ***Standard for registration under FIFRA:*** Some commenters asserted that compliance with data requirements would be sufficient to satisfy the FIFRA requirements for registration, while others urged EPA to use a checklist approach to determine whether a pesticide continued to meet the FIFRA registration standard. Commenters agreed that EPA should use existing data and data reviews and avoid re-review where possible.
- ***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. Commenters advised EPA to handle emerging risks outside of the registration review process.



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- ***Public participation:*** Although most commenters wanted to be able to participate throughout the registration review process, other commenters wanted to limit public participation in various ways.
- ***Registrant's role in registration review:*** In general, commenters asserted that EPA should not expect registrants to provide studies or other information unless specifically required to do so.

### ***Stakeholder Consultation***

EPA presented its approach to the registration review process and asked for stakeholder input at a public meeting of the Pesticide Program Dialogue Committee (PPDC) held in April 2003. The PPDC agreed to form a workgroup to develop recommendations for EPA and 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 EPA's registration review program. The PPDC's recommendations include:

- ***How should pesticides be scheduled for registration review?*** 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.
- ***Should there be different levels of review?*** The PPDC recommended that the degree of assessment not be a "one-size-fits-all" process. 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, while pesticides with "major complex issues" should receive a more comprehensive assessment.



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- ***How can meaningful public participation be accomplished?*** The PPDC recommended that EPA 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.
- ***How does registration review relate to other pesticide program activities?*** 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, according to the PPDC, registration review should be a safety net to help assure that no risk-related issues have been overlooked.
- ***How should EPA initiate a pesticide's registration review?*** The PPDC advised EPA to publish a *Federal Register* notice to initiate a pesticide's registration review.
- ***How should EPA encourage early submission of test data and other information to support a pesticide's registration review?*** The PPDC noted that registrants need a clear understanding of EPA's requirements, guidelines, and issues of concern to assess what additional information would be useful and that EPA should explain how the data will be used.
- ***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;



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- Registration review concluded, but there is ongoing generic data call-in (DCI) or other action -- registration review decision may be revisited if necessary;
- Registration review concluded -- active ingredient voluntarily canceled; and
- Registration review concluded -- FIFRA Section 6 cancellation or suspension action.

### *Feasibility Study*

EPA conducted a feasibility study to test certain aspects of the registration review decision process that the PPDC recommended. EPA randomly selected 30 pesticides from among the likely candidates for review in the first five years of the program, assembled data that it would consider in a registration review, and then simulated the review and decision process described in the proposed procedures. EPA presents a detailed description of this study in the economic analysis for this proposed regulation, which is available in the public docket.

### **Proposed Regulations**

EPA's proposed regulations include the following provisions:

- Section 155.40, *General*: Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA registration standard. The goal of the registration review procedures is review of each pesticide's registration every 15 years. These regulations apply to FIFRA Sections 3 and 24(c) registrations. If EPA 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).
- Section 155.42, *Registration review cases*: EPA may group related active ingredients into a registration review case. For the purpose of scheduling registration reviews, EPA 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. The date of reregistration is the date on which the RED or Interim



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Reregistration Decision (IRED) was signed. EPA will close a registration review case if all products in the case are canceled.

- Section 155.44, *Establish schedules for registration review*: EPA 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. EPA will maintain schedules on its website.
- Section 155.46, *Deciding that a registration review is complete and additional review is not needed*: EPA may determine that there is no need to reconsider a previous decision that a pesticide satisfies the FIFRA registration standard. In such cases, it may propose that no further review will be necessary, announce in the *Federal Register* the availability of the proposed decision, and provide a comment period of at least 60 calendar days. EPA will announce in the *Federal Register* the availability of a final version of the decision, an explanation of any changes to the proposed decision, and its response to any comments.
- Section 155.48, *DCI before, during, or after a registration review*: EPA may issue a DCI under FIFRA Section 3(c)(2)(B) at any time before, during, or after a pesticide's registration review if EPA believes that the data are needed to conduct the registration review.
- Section 155.50, *Initiate a pesticide's registration review*: EPA will initiate a pesticide's registration review by establishing a docket for each registration review case and opening it for public review. EPA 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. EPA will announce in the *Federal Register* the availability of the information and requesting that interested persons identify any additional information they believe EPA should consider in the course of the registration review. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements: interested persons must submit the data or information within the 60-day comment period or



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by some other time that EPA may designate; data or information must be presented in a legible and useable form; submitters must clearly identify the source of any submitted data or information; and if data rejected in a previous review is submitted, the submitter must explain why EPA should reconsider the data.

- Section 155.52, *Stakeholder engagement*: EPA may meet with stakeholders regarding a forthcoming or ongoing registration review. For meetings with persons outside of government, EPA will place in the docket meeting minutes where the primary purpose of the meeting is to discuss a forthcoming or ongoing registration review. EPA will place minutes of such meetings in the docket when it takes action under Section 155.58. At its discretion, EPA may place minutes of such meetings in the docket sooner. In the course of a meeting with a person outside of government, EPA 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. EPA will place a copy of any such document or other written material in the docket. EPA will not place confidential business information in the docket.
- Section 155.53, *Conduct a pesticide's registration review*: EPA will review data and other information that it believes should be considered in the pesticide's registration review, including changes since a pesticide's last review. EPA will conduct new assessments as needed. During a pesticide's registration review, EPA will generally make available for public review and comment a draft risk assessment for a pesticide, if a new risk assessment has been conducted. EPA may not ask for comments on a draft risk assessment in cases where its 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, EPA will make a draft risk assessment available for public review and comment when it issues a proposed decision on the registration review case.
- Section 155.56, *Interim registration review decision*: EPA may issue an interim registration review decision before completing a registration review. The interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules



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for submitting the required data, conducting the new risk assessment and completing the registration review.

- Section 155.57, *Registration review decision*: A registration review decision is EPA's determination whether a pesticide meets the standard for registration in FIFRA.
- Section 155.58, *Procedures for issuing a decision on a registration review case*: EPA will announce in the *Federal Register* the availability of a proposed registration review decision or a proposed interim registration review decision, and at that time, EPA will place its proposed registration review decision and the bases for the decision in the pesticide's registration review docket. EPA's proposed decision will identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements; state whether additional data are needed; and specify proposed labeling changes. After considering any comments on the proposed decision, EPA will issue a registration review decision or interim registration review decision, which will include an explanation of any changes to the proposed decision and EPA's response to significant comments.

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We hope this information is helpful. As always, please call if you have any questions.