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MEMORANDUM

Via E-Mail

DATE: August 4, 2006
TO: Firm Clients and Friends
FROM: Bergeson & Campbell, P.C.
RE: EPA Signs Final Registration Review Rule

On August 1, 2006, U.S. Environmental Protection Agency (EPA) Administrator Stephen L. Johnson signed the final rule establishing the procedural regulations for the pesticide registration review program mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The rule has not yet been published in the *Federal Register*.

Using the procedures set forth in the final rule, EPA intends to meet the statutory goal of reviewing existing pesticide registrations every 15 years to determine whether they continue to meet the statutory standard for registration. EPA expects to begin the registration review program in **Fall 2006**. According to EPA, the final rule is scheduled to be published the week of **August 7, 2006**. The final rule will be effective 60 days after publication in the *Federal Register*. More information and the prepublication text are available on the Internet at http://www.epa.gov/oppsrrd1/registration_review/index.htm. Our July 28, 2005, memorandum on the proposed rule is available at <http://www.lawbc.com/updates/072805-fifra.pdf>.

The final rule provides for the establishment of pesticide cases for review, the scheduling of reviews, the initiation, completion and documentation of reviews, and associated public participation procedures. According to the final rule, EPA intends the registration review program “to ensure that all pesticide registrations are systematically reviewed in a manner that is based on sound science and provides for public participation, transparency and efficiency to protect public health and the environment.”

For each pesticide, EPA will consider what has changed since the chemical’s last assessment; the significance of the changes; and what value would be added from more data or a new risk assessment. EPA will require additional data and conduct new risk or risk/benefit assessments “whenever they are needed to determine whether a pesticide continues to meet the statutory standard.” To meet the goal of reviewing each pesticide every 15 years, EPA states that it plans to make decisions on 45 or more registration review cases -- or about 70 pesticide active



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ingredients -- each year. EPA intends to issue a schedule for pesticide registration review within one month of publication of the final rule.

OVERVIEW OF COMMENTS

EPA received 23 comments on its July 13, 2005, proposed rule, as follows: one individual; two consultants; one public interest group; four registrants; one state pesticide safety coordinator; three state lead agencies for pesticides; five California water sanitation agencies; and six trade associations. EPA organized the comments into three broad topic areas: requests for changes in the procedural regulations (EPA summarizes these comments and its responses in the preamble); operation and implementation of the registration review program (EPA summarizes these comments and its responses in the preamble); and issues concerning the licensing of pesticides in general (EPA addresses these in the response to comments document placed in the docket for the rulemaking). EPA states that, in general, comments on the proposed rule resulted in minimal revisions in the final rule. EPA will continue to discuss early implementation with the Pesticide Program Dialogue Committee. EPA may issue additional guidance on the registration review program “as it gains experience with these procedures.”

COMMENTS ON THE PROCEDURAL REGULATIONS

Section 155.42 -- Baseline Dates for Registration Review Cases

An industry comment suggested that, to avoid duplication of effort, EPA amend Section 155.42 to use the date of approval of significant new uses as the baseline date for the registration review case. EPA responds that it intended the baseline date “to be the date of the last *comprehensive* review.” According to EPA, a review of a new use may not be comprehensive because previously approved uses may not be included in the evaluation of the new use. Another commenter asserted that baseline dates should be either the initial registration of a pesticide or the completion of the reregistration eligibility decision (RED). The commenter stated that the interim reregistration eligibility decision (IREED) should not be used because it does not include an assessment of cumulative risk that is required for pesticides that have a common mechanism of toxicity with other substances. EPA “agrees that the RED would update the comprehensive IRED regarding cumulative risk or other issues,” but notes that “the RED itself may not be a comprehensive review.” In cases where there is both an IRED and a RED, EPA needs the flexibility to decide which document represents a comprehensive review, and thus the final rule allows EPA to use the date of either document as the baseline date.



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Section 155.44 -- Establishing and Announcing Schedules for Registration Review

Chronological vs. Risk-Based Criteria as Basis for Establishing Schedules for Registration Review

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

Considerations That Could Change the Registration Review Schedule

At any time, EPA could receive new information suggesting that it should reevaluate a previous decision to register a pesticide. After the registration review program begins, EPA will continue to address emerging risk concerns. If a pesticide presents an urgent potential risk of concern, EPA may opt to review all other aspects of the pesticide’s registration at that time, rather than only looking at the risk of concern.

Three-Year Schedules

Although the preamble of the proposed rule contemplated maintaining a three-year schedule, the proposed rule did not specify a timeframe. In response to comments requesting this change, EPA modified Section 155.44 to specify that the schedules would cover the current year and at least two subsequent years.

Section 155.48 -- Data Call-In (DCI)

DCI Procedures

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



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Data Compensation for “Voluntarily” Submitted Data

In the final rule, EPA “acknowledges the importance of this issue and agrees that this concern should be addressed in the conduct of the registration review program.” To the extent EPA requires any data for registration review, such data are eligible for the data protections provided by FIFRA. EPA states that if a company submits data to the docket voluntarily (as opposed to providing the data in response to a DCI), “such data are not ‘required’ data eligible for protection under the statute.” EPA may evaluate these data and find that it must rely on the data to support the continued registration of pesticide products, however. If EPA makes such a finding in the course of a pesticide’s registration review, the final rule states: “[T]his finding would be a determination that the voluntarily submitted data or information are now required. This would be a ‘compensable event’ and would trigger the requirement for compensation to be addressed.” Competitors of the original submitter would be required to submit their own data or offer data compensation to the data submitter for use of the study. The final rule states that a “compensable event” would also arise should EPA issue a DCI Notice for the same data as were previously submitted voluntarily, “but a [DCI] Notice is not necessary to trigger compensability should the Agency determine and announce as part of its registration review decision that the particular data were required to support the registrations in question.” EPA’s registration review decision document may identify such data, and the registration review decision document may establish a deadline for registrants whose registrations depend on such data to offer compensation to the owners of the data or submit their own data. According to the final rule, EPA “may cancel the product registration of registrants who fail to adequately support a registration.”

Section 155.52 -- Stakeholder Engagement

The final rule establishes procedures that provide the public with the opportunity to participate in the review process and to review materials that EPA uses as the basis of proposed registration review decisions. EPA states that it generally does not announce in the *Federal Register* meetings with registrants or other stakeholders “because it needs the flexibility to hold such meetings when the need arises,” and EPA may meet privately with industry to discuss proprietary or other confidential business information (CBI). Under Section 155.52(a) and (b), EPA will place in the docket minutes of meetings with registrants or other stakeholders. EPA’s protection of information claimed to be CBI is governed by FIFRA Section 10 and 40 C.F.R. Part 2.



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Section 155.53 -- Conduct of a Pesticide's Registration Review

Public participation procedures

Several commenters noted that, under EPA's procedures for public participation in the reregistration and tolerance reassessment programs, EPA may announce the availability of a revised risk assessment and invite the public to suggest approaches for mitigating the risks identified in the revised risk assessment. The proposed rule for registration review did not provide this opportunity. In response to comments, EPA revised Section 155.53(c) to provide the public an opportunity to comment on possible risk mitigation when a revised risk assessment shows risks of concern.

Section 155.57 -- Registration Review Decision

FIFRA Standard for Registration

According to the final rule, comments from industry strongly opposed EPA's intention to consider a pesticide's benefits during registration review. The final rule states that the comments referred to a discussion in the preamble of the proposed rule where EPA explained that it would evaluate information about the benefits of a pesticide with known high risks during registration review if a new and safer alternative to a pesticide has become available. The comments asserted that it is inappropriate for EPA to base continued registration of a pesticide on a comparative benefits assessment with other pesticides.

EPA says that it believes the commenter "misapprehends" the nature of FIFRA's risk-benefit balancing standard. Determination that a pesticide meets the registration standard under FIFRA at one time does not necessarily mean that the same pesticide will meet the standard at all times in the future, even if the science associated with the risks posed by the pesticide does not change. Significant changes in the benefits picture, such as the development of pest resistance or new alternatives, can also affect whether a pesticide continues to meet the FIFRA registration standard. EPA states that it does not intend to compare benefits of two or more pesticides that do not pose risks of concern. As the commenters noted, "EPA may not make a determination of essentiality when two pesticides meet the FIFRA requirements for registration." When there are risks of concern for a pesticide, EPA notes, FIFRA requires EPA to weigh those risks against the benefits of that pesticide to determine whether the risks are unreasonable. EPA continues:



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Benefits are the advantages that accrue to the pesticide users or society in general, such as increased production, decreased production costs, pest-free homes, or disease-vector control. The magnitude of those benefits often depends on the availability of alternative pest control measures, whether chemical, biological or cultural. Benefits are, in general, expected to be higher when there are no viable alternatives.

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

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

COMMENTS ON THE OPERATION OF THE REGISTRATION REVIEW PROGRAM

Scope of the Registration Review Program

Assessing Risks of Substitute Pesticides

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



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commenters expressed concern that EPA would consider using the registration review program to address reviews that might be the outgrowth of cancellation proceedings. In the final rule, EPA states that it “generally” would assess risks of substitute pesticides as part of the cancellation process under FIFRA Section 6. According to EPA: “In the rare event that it is necessary to perform a comprehensive review of a substitute pesticide, such a review might be tantamount to conducting the registration review of that pesticide. In such cases, EPA might find that it would be more efficient to conduct the registration review of the pesticide at the same time.”

Review of Inert Ingredients

In the preamble of the proposed rule, EPA explained that it would handle inert ingredients in a process that is separate from registration review. EPA “recognizes that there may be interactions among the various chemicals in pesticide products.” Currently, EPA requires acute toxicity data for end-use products. These studies address, albeit to a limited extent, potential synergistic effects of mixtures of active and inert ingredients in a pesticide product. EPA states that to test and review all of the potential combinations of ingredients would require significant resources, however. Instead, EPA will consider new scientific methodologies to identify potential interactions among chemicals, “should they become available.”

Work-Sharing

The preamble of the proposed rule described EPA’s intention to develop work-sharing agreements with its partners in the Organization for Economic Cooperation and Development (OECD) and the North American Free Trade Agreement (NAFTA). In comments on the proposed rule, industry trade associations expressed concern that conducting reviews jointly with EPA’s NAFTA or OECD partners might cause delays. In the final rule, EPA states that it “continues to believe that harmonization and work-sharing will result in process efficiencies and superior decisions.” EPA and its Canadian counterpart have begun discussions for work-sharing during registration review with the expectation that they will develop a work-sharing plan by the **December 2006** meeting of the NAFTA Technical Working Group on Pesticides. EPA intends to continue encouraging the OECD community to participate in work-sharing efforts. EPA states that it “may adjust its schedule slightly to take advantage of these potential opportunities for work-sharing.”



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Achieving Label Improvement through the Registration Review Program

According to the final rule, several commenters see the registration review program as an opportunity to improve the quality of labels on individual pesticide products. One aspect of label improvement would be to minimize the number of different labels for the same product. According to comments, this situation arises because many states require state registration and impose their own labeling requirements. In the final rule, EPA affirms its commitment to improving the consistency of labels. EPA notes that FIFRA Section 24(b) prohibits states from establishing or maintaining labeling requirements.

IMPLEMENTATION ISSUES

Transition from Reregistration to Registration Review

Industry comments asserted that EPA must clarify when the registration review program will begin and that EPA should address how it will handle the work of registration actions, reregistration actions, and other mandated regulatory actions before it commits to initiating the registration review program. EPA responds that it “has announced that the registration review program officially begins when these regulations go into effect.” EPA’s first actions under the new program will be to issue schedules and to begin to open registration review case dockets. EPA recognizes that, to avoid confusion during the transition between the reregistration and registration review programs, “it must clearly communicate” whether action on an existing pesticide is taken under reregistration (FIFRA Section 4) or registration review (FIFRA Section 3(g)).

PROGRAM COSTS

Impacts on Small Businesses

EPA has determined that this rule will not have a significant adverse impact on a substantial number of small businesses. Nonetheless, EPA states that it “recognizes that, from the perspective of a small business whose product is undergoing registration review, the costs of data generation in registration review could be significant.” Accordingly, EPA “is willing to work on a case-by-case basis with a small business for whom the requirements for data generation in registration review are burdensome.” EPA notes that DCI Notices issued under FIFRA Section 3(c)(2)(B) allow a registrant to request a data waiver based on economic factors. In lieu of a new study, EPA “is generally willing to consider whether substitute data or bridging data would be adequate.”



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Cost of Product-Specific Data

At public meetings on the proposed rule, EPA said that it would require new product efficacy tests for public health pesticides. During the registration review of a public health pesticide, EPA would determine whether to continue to base the product's registration on existing product efficacy data. According to the final rule, EPA may ask for new product efficacy data if the product's composition has changed so that existing data no longer support the current composition of the product, or the test method is no longer valid, or there is information suggesting that the formulation might not be efficacious as claimed. EPA states that it believes that the costs of replacing product efficacy data for a few products in a registration review case "will be much lower than the costs of generating new generic data to support the active ingredient(s) in a registration review case."

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