



## MEMORANDUM

### Via E-Mail

DATE: November 26, 2003

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: OPP Procedural Guidance for the Development, Modification, and Implementation of Policy Guidance Documents

Today the U.S. Environmental Protection Agency (EPA) announced the availability of a paper discussing procedural guidance for policy development in the Office of Pesticide Programs (OPP). According to EPA, the procedural guidance has two goals: “[t]o increase public participation in the development, modification and implementation of OPP policy guidance documents; and to clarify that while such documents are non-binding policy statements and not legally binding rules, they nonetheless play an important role in helping to ensure a consistent starting point for OPP decision making.” EPA published the procedural guidance as Pesticide Registration (PR) Notice 2003-3 ([available online](#)).

According to the PR Notice, OPP believes allowing public comment on proposed and/or draft policy guidance documents and related substantive revisions “has improved the quality of the resulting policy guidance documents.” Accordingly, OPP believes that it “makes sense” to adopt procedural guidelines indicating when providing an opportunity for public comment “may be most valuable and should be used, and when doing so might provide little added value and merely delay the issuance or implementation of a policy or policy refinement.” The PR Notice notes that OPP also believes that procedural guidance on policy development and refinement should help policy writers develop “useful guidance documents that do not cross the line between nonbinding policy statements and legally binding regulations.” The PR Notice states: “EPA, as well as other federal agencies, have increasingly faced litigation claiming that policy documents are, in effect, thinly-disguised regulations and that they are invalid for failure to comply with the procedural requirements of the Administrative Procedures Act (APA) (5 U.S.C. § 553).”



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### **General Statement of OPP's Policy**

According to the PR Notice, OPP's general practice should be to provide notice and an opportunity for public comment "as early as practicable and appropriate in the development of all significant new pesticide policy guidance documents (defined below) or significant modifications to such policy guidance documents." Non-significant policy guidance documents (defined below) should be available to the public and a procedure should be described by which affected parties can communicate their views on such documents to OPP.

### **Definitions**

The PR Notice provides the following definitions:

- **Policy Guidance Document** -- A policy guidance document describes OPP policies of general applicability for the benefit of OPP staff, the regulated community, advocacy groups, and the general public. Policy guidance documents generally include the term "policy" or "guidance" in their titles. Policy guidance documents generally would not include pesticide-specific peer reviews or registration, reregistration, or tolerance decision documents, internal OPP administrative procedures, reports, speeches, press materials, or letters or other correspondence with individuals, organizations, or companies.
- **Significant Policy Guidance Document** -- The judgment that a policy guidance document is significant should take into account, among other things, the following factors:
  - (1) The potential impact of the policy on regulated entities and on the public health and the environment and whether some stakeholders are likely to regard the impact as significant;
  - (2) Whether the policy involves the initial implementation of statutory or regulatory changes;
  - (3) The complexity of the science or technical issues involved;
  - (4) The policy's potential for creating controversy; and
  - (5) The potential breadth of applicability of the document.



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- **Non-Significant Policy Guidance Document** -- Any policy guidance document that is not “significant” is considered a “non-significant policy guidance document.” Examples of documents which generally would not qualify as significant include Standard Operating Procedures for EPA review of studies or memoranda by any of OPP’s internal peer review committees, unless they contain significant new policy guidance. Additionally, PR Notices that simply convey information, such as where to send application materials, would also be considered nonsignificant policy guidance.

#### **Procedures for Significant Policy Guidance Documents**

Under the PR Notice, for significant policy guidance documents or significant modifications of such policy documents, OPP should provide notice of a draft policy and a comment opportunity “in a manner likely to insure it comes to the attention of interested stakeholders.” The PR Notice states that, at a minimum, this should include a clear notice on EPA’s website (*e.g.*, OPP’s or the Scientific Advisory Panel’s (SAP) website) and the publication of a notice in the *Federal Register*. In some cases, according to OPP, it may also be appropriate to provide individual notice to affected parties. The period for public comment should be long enough to allow meaningful comment, taking into account any needs of OPP to act quickly.

To the extent practical and appropriate, a notice and comment opportunity for a significant policy guidance document should be provided prior to the issuance of the document for implementation. The PR Notice states: “Frequently, however, policy positions are first implemented in individual pesticide registration or tolerance decisions, and only after accumulating experience through a case-by-case approach does OPP draft a policy guidance document for general applicability. Where such policy guidance documents principally systemize and extend the policies developed through earlier case-by-case decisions, the concept of pre-implementation notice and comment must be adapted to recognize the facts of the situation.” According to the PR Notice, if a policy guidance document makes a significant break with prior OPP practice, then pre-implementation notice and comment is more appropriate. If pre-implementation notice and comment is not provided, OPP should hold a “prompt” post-implementation notice and comment period.

Under the PR Notice, when OPP provides a comment opportunity on a significant policy guidance document, a document responding to all significant comments should “generally” be prepared, and it should “generally” be made available “in the same time frame as when the policy guidance document is issued and should be in a form that shows how EPA



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evaluated public comments.” The PR Notice notes that in circumstances where commenters voice a “significant disagreement” with a draft policy guidance document, OPP should consider release of the response to comments document prior to revision of the draft policy guidance document.

### **Procedures for Non-Significant Policy Guidance Documents**

According to the PR Notice, policy guidance documents that OPP does not regard as significant should be made available to the public on OPP’s website if they are of public interest. The document should identify a contact person within OPP and the public docket to which comments may be sent. Non-significant policy guidance documents should be posted on EPA’s website “as soon as practical” after the document is issued. The PR Notice states that non-frivolous, substantive comments should be acknowledged and addressed appropriately, either individually or by preparing a generic response document.

### **Procedures to Clarify the Non-Binding Nature of Policy Guidance Documents**

Under the procedures described in the PR Notice, policy guidance documents do not bind either outside parties (regulated entities, advocacy groups, or the public) or OPP. The PR Notice states: “Every OPP policy guidance document should clearly state that it is not binding on the public or OPP, and that OPP decision-makers and staff should not treat any policy guidance document as if it were a legally binding rule. Each policy guidance document should also explain that OPP staff should remain open to consideration of alternative approaches, and that affected parties remain free to assert that the policy should not apply B in whole or in part B to a given situation, or to urge a totally different policy approach on OPP.” The PR Notice includes a model statement.

### **Procedures to Aid in Consistent Decision-Making under Policy Guidance Documents**

According to the PR Notice, each policy guidance document should emphasize the importance of consistent application of policy guidance documents by OPP staff. The PR Notice continues: “Nonetheless, because policy guidance documents are not binding, they should also note that a decision cannot be justified simply by citing to the policy guidance document but must also contain the rationale for the decision. Further, the policy guidance document should specifically highlight the importance of explaining the rationale for any departure from existing policy guidance documents.” The PR Notice further states that, although OPP policy guidance documents are non-binding, “they reflect the current thinking of OPP, and therefore OPP staff are expected to apply them consistently unless there is a good reason for adopting an alternative approach.” If OPP staff believe an alternative approach is warranted, that



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approach and rationale should be presented to OPP decision-makers. Any decision by OPP to vary from a policy guidance document should explicitly state how it varies from existing guidance and provide a written explanation for the variation. The PR Notice includes a model statement explaining these points. The PR Notice states that after release of a policy guidance document, OPP should periodically examine decisions made with regard to the policy guidance document to determine if the policy guidance document has, in fact, aided in consistent decision-making.

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

[Attachment](#)