

Pesticide Registration (PR) Notice 2003-3

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

- ATTENTION:** Persons Interested in Pesticide Policy Development and Persons Responsible for Registration of Pesticide Products
- SUBJECT:** Procedural Guidance for EPA's Office of Pesticide Programs Procedures Concerning the Development, Modification, and Implementation of Policy Guidance Documents

EPA's Office of Pesticide Programs (OPP) will use the following procedures for developing, modifying, and implementing its pesticide program policy guidance documents. These procedures have two goals. The first is to facilitate public participation in the development, modification, and implementation of OPP policy guidance documents; the second is 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.

For several years OPP has provided an opportunity for the public to comment on proposed and/or draft policy guidance documents and related substantive revisions. This practice reflects OPP's general preference for public and stakeholder participation in the development of most significant policy approaches. OPP believes that routinely providing an opportunity for public review and comment has not only helped stakeholders interact with OPP more effectively but also has improved the quality of the resulting policy guidance documents. Accordingly, OPP believes that it makes sense to adopt procedural guidelines for its staff indicating when providing an opportunity for public comment on draft policy guidance 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.

OPP believes that procedural guidance on policy development and refinement should also help policy writers develop useful guidance documents that do not cross the line between non-binding policy statements and legally binding regulations. 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). See, e.g., General Electric, Co. v. EPA, 290 F.3d 377, 384 (D.C. Cir. 2002); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1023 (D.C. Cir. 2000). The challenge is to provide guidance to staff to help insure consistent agency decision-making, while at the same time not constraining agency discretion or appearing to discourage affected parties from seeking alternatives to agency policy approaches. Accordingly, this policy guidance document provides procedural guidance for OPP's drafters of policy guidance documents that will help them balance the sometimes conflicting objectives of

consistency and flexibility.

I. EFFECT OF THIS PROCEDURAL GUIDANCE DOCUMENT

This document sets forth procedures on developing policy guidance documents. In addition, it explains how staff should use policy guidance documents in agency decision-making. These procedures are not binding on EPA and any affected party may urge EPA to follow a different approach to policy development.

II. GENERAL STATEMENT OF OPP'S POLICY UNDERLYING THESE PROCEDURES

OPP thinks that public involvement in the development of all types of policy guidance documents is useful. Therefore, 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.

All policy guidance documents should clearly explain that, while they are intended to aid consistent decision-making by OPP, they are not binding either on OPP or on affected parties. In other words, policy guidance documents define a framework and starting point for OPP decision-making, but each regulatory action considered by OPP presents the opportunity to reassess both the policy itself and its application to the particular circumstances.

III. 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 (including orders issued under FIFRA section 3(c)(2)(B), whether issued to a registrant of an individual pesticide or multiple registrants of a group of pesticides), internal OPP administrative procedures, reports, speeches, press materials, or letters or other correspondence with individuals, organizations, or companies. This document describes two subgroups of policy guidance documents: “significant policy guidance documents” and “non-significant policy guidance documents.”

“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.

For example, each of these factors suggests that OPP's policy implementing the FQPA provision for an additional safety factor to protect infants and children would qualify as significant. OPP believes that its guidelines for performing pesticide testing would also be significant in most instances. Further, many Pesticide Registration Notices would meet these criteria for significance.

“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, Pesticide Registration Notices that simply convey information, such as where to send application materials, would also be considered non-significant policy guidance.

IV. PROCEDURES FOR SIGNIFICANT POLICY GUIDANCE DOCUMENTS

A. Procedures For significant policy guidance documents or significant modifications of such policy documents, notice of a draft policy and a comment opportunity should be provided in a manner likely to insure it comes to the attention of interested stakeholders. At a minimum, this should include a clear notice on the Agency's website (e.g., OPP's or the Science Advisory Panel's (SAP) website) and the publication of a notice in the Federal Register. In some cases, it may also be appropriate to provide individual notice to affected parties. When OPP or the SAP announces the opportunity to comment on a significant policy guidance document in the Federal Register, it will also follow applicable procedures for establishing and maintaining a public docket (including procedures for ensuring that confidential business information is not inadvertently released), utilizing EPA's online docket and comment system, EDOCKET at <http://www.epa.gov/edocket>. The period for public comment should be long enough to allow meaningful comment, taking into account any needs of OPP to act quickly.

B. Timing of Comment Opportunity 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. 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. When a policy guidance document makes a significant break with prior OPP practice, pre-implementation notice and comment is more appropriate; however, it is still important to take into account such factors as any need for OPP to act quickly to protect the public health and the environment or other goals of importance. If pre-implementation notice and comment is not provided, a prompt post-implementation notice and comment period should be held.

C. Response to Comment When OPP provides a comment opportunity on a significant policy guidance document, a document responding to all significant comments should generally be prepared. This document 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 evaluated public comments. To ensure easy and direct public access, this document will be placed in the public docket established for the draft policy guidance document. In circumstances where commenters voice a significant disagreement with a draft policy guidance document, release of a response to comments document prior to revision of the draft policy guidance document should be considered if such further interaction with stakeholders might substantially aid implementation of the guidance document.

V. PROCEDURES FOR NON-SIGNIFICANT POLICY GUIDANCE DOCUMENTS

A. Procedures. 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. Documents likely to fall into this category are certain OPP Standard Operating Procedures and minor modifications to significant policy guidance documents. As part of placing the document on the website, the document should identify a contact person within OPP and the public docket established in EDOCKET to which comments on the document may be sent.

B. Timing. Placement of such policy guidance documents on the website should occur as soon as practical after the document is issued. Staff should plan time, before posting the documents on the EPA website, to review the document for the presence of trade secret and Confidential Business Information (CBI) and for the preparation of the document to comply with requirements for accessibility by people with disabilities (29 U.S.C §794d).

C. Response to Comments. Non-frivolous, substantive comments received on non-significant policy guidance documents placed on OPP's website should be acknowledged and addressed appropriately, either individually or by preparing a generic response document. Comments received and OPP's responses will be placed in the public docket.

VI. PROCEDURES TO CLARIFY THE NON-BINDING NATURE OF POLICY GUIDANCE DOCUMENTS

Policy guidance documents do not bind either outside parties (regulated entities, advocacy groups, or the public) or OPP. Under general principles of administrative law, a document of general applicability including binding requirements is not a policy but a regulation, and thus must comply with the statutory requirements for promulgating regulations, i.e., the APA or other applicable statutory authority.

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 – in whole or in part – to a given situation, or to urge a totally different policy approach on OPP. A model statement is included in the Appendix.

VII. PROCEDURES TO AID IN CONSISTENT DECISION-MAKING UNDER POLICY GUIDANCE DOCUMENTS

Each policy guidance document should also emphasize the importance of consistent application of policy guidance documents by OPP staff. 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. 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 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. A model statement explaining these points is included in the Appendix.

After release of a policy guidance document, decisions made with regard to the policy guidance document should be periodically examined to determine if the policy guidance document has, in fact, aided in consistent decision-making. This evaluation process may be helpful in deciding whether the policy guidance document should be retained, revised, or eliminated.

Appendix – Model Language to Include in OPP Policy Guidance Documents

Non-binding Nature of This Policy Guidance Document

This document describes a current policy position of OPP, but it is not a legally binding regulation. It binds no one—not the regulated community, not advocacy groups, not the public, and not OPP. In any decision before OPP, any stakeholder may urge OPP to: (1) conclude that this policy guidance document is inapplicable; (2) consider factors other than those described in this policy guidance document; (3) make an exception to the policy guidance document as written; or (4) amend or abandon the policy in its entirety. Even if no such arguments are made to OPP, OPP may decide on its own initiative that the circumstances warrant the Agency to act at variance from this policy guidance document. Thus affected parties should not assume that carefully following this policy guidance document will guarantee a specific decision or action by OPP. If OPP does decide to vary from this policy guidance document, OPP would explicitly state how it varies from the policy and provide a written explanation for this variance in the context of that decision.

Consistent Application of This Policy Guidance Document

Although OPP's policy guidance documents, including this one, are non-binding, they reflect the current thinking of OPP, and therefore OPP staff are expected to use them as guides for decision-making unless there is a good reason for adopting an alternative approach. Accordingly, this policy guidance documents should serve as a reference and starting point for OPP staff for analyzing the issues as they arise in individual pesticide matters. Importantly, it should be remembered, however, that this policy guidance document does not provide authority for reaching specific results—each individual decision must be based on sound factual, scientific, and legal conclusions. Further, if OPP staff believe, based upon their own analysis or upon comments of any stakeholder, that an alternative decision-making approach to the one outlined in this policy guidance document is warranted, that approach would be presented to OPP decision-makers for their consideration. Any decision by OPP to vary from this policy guidance document should be accompanied by a written explanation provided in the context of that decision specifically addressing the reason for the variance.