

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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the proposed rule or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket ID 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.

F. What Can I Do if I Wish the Agency to Maintain a Tolerance that the Agency Proposes to Revoke?

This proposed rule provides a comment period of 60 days for any person to state an interest in retaining a tolerance proposed for revocation. If EPA receives a comment within the 60-day period to that effect, EPA will not proceed to revoke the tolerance immediately. However, EPA will take steps to ensure the submission of any needed supporting data and will issue an order in the **Federal Register** under FFDCA section 408(f) if needed. The order would specify data needed and the time frames for its submission, and would require that within 90 days some person or persons notify EPA that they

will submit the data. If the data are not submitted as required in the order, EPA will take appropriate action under FFDCA.

EPA issues a final rule after considering comments that are submitted in response to this proposed rule. In addition to submitting comments in response to this proposal, you may also submit an objection at the time of the final rule. If you fail to file an objection to the final rule within the time period specified, you will have waived the right to raise any issues resolved in the final rule. After the specified time, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

II. Background

A. What Action is the Agency Taking?

EPA is proposing to exempt methoprene from the requirement of a tolerance, and therefore to revoke the existing tolerances for methoprene. The other actions involve maintaining exemptions from the requirement of a tolerance for specific pesticides, while removing redundant portions of 40 CFR part 180 relating to those tolerance exemptions.

1. *Methoprene.* EPA is proposing to revoke the tolerances in 40 CFR 180.359 for residues in or on specific food commodities for control of hornflies because review of methoprene toxicity data indicate that these tolerances are not necessary to protect human health or the environment. An EPA Decision Document on Tolerance Reassessment for Methoprene, prepared by EPA's Inert Ingredient Focus Group (IIFG) and finalized in August 2002, finds that methoprene is of low toxicity.

More specifically, the document finds that methoprene is not acutely toxic, and is neither irritating to skin or eyes, nor is it a dermal sensitizer. Developmental toxicity was not observed in studies with rabbits and mice. Methoprene is not carcinogenic in studies in rats and mice, and is not mutagenic in the Ames assay or in the dominant lethal assay. No adverse effects were seen in rats in a 2-year study. Metabolism studies in rats, mice, guinea pigs, and cows indicate rapid biodegradation of methoprene and its metabolites in mammals and that its metabolites are incorporated into natural body constituents (primarily fatty acids). The decision document concludes:

i. *Determination of safety.* Based on its review and evaluation of the available information, EPA concludes that there is a reasonable certainty that no harm will result to the general

population, and to infants and children from aggregate exposure to residues of methoprene.

ii. *IIFG inert ingredient focus group recommendation/deferral to BPPD management.* At this time, 40 CFR 180.1033 specifies that methoprene is exempt from the requirement of a tolerance in or on all raw agricultural commodities when used to control mosquito larvae. There are also numerical tolerances for specific commodities in 40 CFR 180.359.

The methoprene risk assessment in the IIFG decision document used conservative assumptions that assumed the existence of a broad-based tolerance exemption. A broad-based tolerance exemption assumes that methoprene can be used on all crop commodities and that these crop commodities can be used as feed. The safety finding supports the tolerance exemption approach.

Based on the IIFG report, EPA is proposing to revoke the tolerances in 40 CFR 180.359 by removing that section from the CFR. EPA is also proposing to exempt methoprene from the requirement of a tolerance in or on all food commodities when methoprene is used as an insect larvicide. (A copy of the IIFG report will be made available in the docket for this proposed rule.)

2. *Two virus coat proteins and the genetic material necessary to produce the coat proteins in squash.* EPA is proposing to revoke the tolerance exemptions in 40 CFR 180.1132 for watermelon mosaic virus-2 coat protein, and zucchini yellow mosaic virus coat protein and specific portions of the viral genetic material when used as plant-incorporated protectants in squash because the tolerance exemptions are duplicated in the more recent, broader 40 CFR 180.1184. The exemption in 40 CFR 180.1184 includes all food commodities, rather than being limited to squash. Therefore, 40 CFR 180.1132 is not needed to protect human health and the environment.

B. What is the Agency's Authority for Taking these Actions

A "tolerance" represents the maximum level for residues of pesticide chemicals legally allowed in or on raw agricultural commodities and processed foods. Section 408 of FFDCA, 21 U.S.C. 301 *et seq.*, as amended by the FQPA of 1996, Public Law 104-170, authorizes the establishment of tolerances, exemptions from tolerance requirements, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods (21 U.S.C. 346(a)).