

follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0121. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to: opp-docket@epa.gov, Attention: Docket ID Number OPP-2003-0121. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2003-0121.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP-2003-0121. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI To the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be

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 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. What is the Agency's Authority for Taking this Action?

This proposed rule is issued under FFDCA section 408, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), and ARTCA (Public Law 105-324).

Section 408 of FFDCA authorizes the establishment of tolerances, exemptions from the requirement of a tolerance, modifications in tolerances, and revocation of tolerances for residues of pesticide chemicals in or on raw agricultural commodities and processed foods. Section 408(j)(2) of FFDCA provides that all regulations issued by FDA under FFDCA section 409 that stated conditions for safe use of substances that are now, post-FQPA, considered pesticide chemical residues

in or on processed food or that otherwise stated the conditions under which such pesticide chemicals could be safely used, shall be deemed to be regulations issued under FFDCA section 408.

Due to the FQPA and ARTCA amendments to FFDCA, those chemical substances originally regulated by FDA under FFDCA section 409 as food-contact surface sanitizing solutions are now the responsibility of EPA. These pesticide chemical regulations are now subject to modification or revocation at EPA's initiative under FFDCA section 408(e). The Agency is proposing to duplicate the substance of FDA's food additive regulations for those chemical substances found in 21 CFR 178.1010 which are now pesticide tolerance exemptions in a format consistent with EPA's authority under section 408 in a new section, 40 CFR 180.940.

EPA's rulemaking activity will have no effect on any of the FDA regulated FFDCA section 409 food additive regulations in 21 CFR 178.1010.

III. Summary of this Action

A. Why is There an Overlap of EPA's and FDA's Regulatory Authorities?

Since EPA was created in 1970, EPA and FDA have shared authority under FFDCA over pesticide chemical residues in food. Enactment of FQPA in 1996 amended FFDCA, and shifted to EPA regulatory authority over certain pesticide residues which were previously subject to FDA authority. Prior to 1996, products used to sanitize or disinfect permanent or semi-permanent food-contact surfaces were regulated by FDA as indirect food additives under FFDCA section 409. Under the FQPA and ARTCA amendments to FFDCA, antimicrobial formulations used on permanent or semi-permanent food-contact surfaces other than food packaging are now considered "pesticide chemicals" and are regulated by EPA under FFDCA section 408.

FQPA added a provision to FFDCA to assure an orderly transition to the new regulatory system. Section 408(j)(2) of FFDCA provides that all food additive regulations issued under FFDCA section 409 prior to the enactment of FQPA for antimicrobial uses that became pesticide chemical uses subsequent to FQPA and that were not affected by ARTCA shall be deemed to be regulations issued under FFDCA section 408. Thus, FQPA converted existing food additive regulations issued by FDA under FFDCA section 409, for chemical substances that post-FQPA became pesticide chemicals, into FFDCA section