

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1309]

DMPB

Display Date	10/5/00
Publication Date	10/6/00
Certifier	J. W. [Signature]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

oc00184

NI

Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

Description: Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the Food Quality Protection Act (FQPA), EPA has proposed to revoke the tolerances for the pesticide chemical methyl parathion on several food commodities. The FQPA includes a provision in section 408(1)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 346a(1)(5)), referred to as the “channels of trade provision,” that addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA. These circumstances are met if the party responsible for the food can demonstrate to FDA that the residue in the food resulted from application of the pesticide chemical to the food commodity at a time and in a manner that was lawful under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

In general, FDA anticipates that the party responsible for food found to contain methyl parathion residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, will be able to demonstrate that the residue resulted from a lawful application under FIFRA by providing appropriate documentation to the agency showing that such food was packed or processed on or prior to December 31, 2000, as discussed in the draft guidance that was announced in a notice that FDA published in the **Federal Register** of June 2, 2000 (65 FR 35376) (the June notice). FDA is not suggesting that firms maintain a certain set list of documents where anything less or different would likely be considered unacceptable. Rather, the agency is leaving it to each firm’s discretion to maintain appropriate documentation to demonstrate that the food was so packed or processed.

Examples of documentation that FDA anticipates will serve this purpose include but are not limited to packing codes, batch records, and inventory records; it is anticipated that most food processors routinely generate this documentation as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries who handle food products that may contain residues of methyl parathion after the tolerances for this pesticide chemical in those foods have been revoked.

In the June notice, the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
67	1	67	3	201

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs
83	1	83	16	1,328	\$500

¹There are no operating and maintenance costs associated with this collection of information.

Estimates for the annual reporting burden were determined by using the maximum number of samples collected throughout a year that FDA believes may be found to contain methyl parathion residues. Because all residues are expected to have dissipated from nonfrozen foods by the time FDA intends to question firms about when a food product was packed or processed (i.e., after December 31, 2000), FDA included only frozen food in its estimate (i.e., processors of foods stored under refrigerated and ambient conditions were excluded). Although residues within the former tolerance resulting from legal application of methyl parathion are not expected to be found in nonfrozen foods after December 31, 2000, under the channels of trade provision, firms will have an opportunity to make a showing that any such food was packed or processed on or before this date.

Considering the variation in and effects of food handling, particularly with regard to the time between pesticide application and freezing, FDA estimated that potentially half of all frozen food products sampled may contain methyl parathion residues, and therefore, the responsible party, under

the approach set forth in this guidance, would be subject to the reporting requirement since it would be the burden of the responsible party to demonstrate that food found to contain methyl parathion residues within the former tolerance was packed or processed on or before December 31, 2000.

When determining the annual recordkeeping burden, importers and domestic processors of frozen food commodities affected by the revocation of the pesticide chemical methyl parathion were considered. FDA estimated that most firms (at least 90 percent) maintain (or maintain access to) documentation such as packing codes, batch records, and inventory records as part of their basic food production and/or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms which may not currently be maintaining this documentation, to develop and maintain (or maintain access to) documentation such as batch records and inventory records. It was estimated that with \$500 or less, the necessary software and/or hard copy filing systems could be obtained to implement a system.

Because all residues are expected to have dissipated from nonfrozen foods by the time FDA intends to ask for a showing under section 408(l)(5) of the act (i.e., after December 31, 2000), FDA used the number of frozen food processors when determining the annual recordkeeping burden. In the June notice, this burden was originally determined to be 6,600 hours. However, due to revisions that FDA will include in the final guidance document, the proposed information collection was refined, and the annual recordkeeping burden decreased to 1,328 hours. The "Category II Documentation," which consisted of documentation relating to the institution of auditing programs and supplier verification, will be removed from the final guidance as suggested documentation to be provided to demonstrate compliance with the channels of trade provision.

As with the annual reporting burden estimate, although nonfrozen food processors are entitled to make a showing under the channels of trade provision, they were excluded from this estimate because based upon residue dissipation estimates provided by EPA, methyl parathion residues

within the former tolerance resulting from legal application are not expected to be found in nonfrozen commodities after December 31, 2000.

Dated: October 2, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

