

SUPPORTING STATEMENT

Suggested Documentation for Demonstrating Compliance with The Channels of Trade Provision

A. Justification

1. Circumstances that make the collection of information necessary:

On August 3, 1996, the Food Quality and Protection Act (FQPA) was signed into law. This law, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. In accordance with the FQPA, the Environmental Protection Agency (EPA), the agency responsible for regulating the use of pesticides (under FIFRA) and establishing tolerances for residues of pesticide chemicals in food commodities (under the FFDCA), is in the process of reassessing the pesticide tolerances and exemptions that were in effect when the law was signed.

As part of the tolerance reassessment process mandated by the FQPA, in a cancellation order published in the **Federal Register** of October 27, 1999 (64 FR 57877), EPA cancelled, effective on the same date, several registered food uses for the pesticide methyl parathion. This action was precipitated by EPA's determination that the dietary risks from exposure to methyl parathion exceeded the safety standard under the FFDCA. Under the terms of the cancellation, application of the pesticide on the crops specified became unlawful after December 31, 1999.

Under section 408 (1) (2) of the FFDCA (21 U.S.C. 346a (1) (2)), (Attachment 1) when the registration for a pesticide is canceled or modified due in whole or in part to dietary risks posed by residues of that pesticide chemical on food, the effective date for the revocation of such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

Since the registration for certain uses was canceled on October 27, 1999 and December 31, 1999 was the last date application of the pesticide on the crops specified was lawful, the tolerance is mandated by law (§408 (1) (2) of the FFDCA) to be revoked within 180 days of the latter date—December 31, 1999. FDA enforcement of the revoked tolerance must also begin at that time, since FDA is charged with enforcing the pesticide tolerances set by EPA for food commodities.

However, due to the residue dissipation rates of methyl parathion and the impact of food processing and storage, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the tolerance revocation takes effect. For example, methyl parathion residues are expected to remain in foods stored at ambient temperature for up to nine months after

the last pesticide application. Residues are expected to remain in foods stored under refrigerated conditions for up to a year, and in frozen foods indefinitely.

FDA would normally deem a food found to contain a pesticide residue in excess of its set tolerance to be in violation of the law by virtue of it bearing an illegal pesticide residue, and the food would be subject to FDA enforcement action as an “adulterated” food. However, the channels of trade provision of the FQPA addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA (§408 (1) (5) of the FFDCFA).

The information collection proposed in the draft guidance is necessary for FDA to determine whether or not food commodities found to contain methyl parathion after the tolerance for the pesticide in those particular commodities has been revoked, are in compliance with the channels of trade provision.

Examples of the information collected may include documentation associated with packing codes, batch records, and inventory records.

2. How, by whom, and for what purpose the information is to be used:

The information collected will be used to determine whether or not commodities found to contain methyl parathion after the tolerance for the pesticide in those particular commodities has been revoked, are in compliance with the channels of trade provision ((§408 (1) (5) of the FFDCFA). Such information will be collected by field personnel during the course of or in follow-up to inspections, investigations, and/or sample collections.

3. Use of technological techniques or other forms of information technology:

The collection of information does not involve the additional use of automated, electronic, mechanical, other technological collection techniques, or other forms of information technology. A route of electronic submission of this information has not been determined, but would be considered if proposed.

4. Efforts to identify duplication:

The information need only be collected should a potential violation be identified (i.e., a sample is found to contain an illegal pesticide residue). The documentation suggested in the draft guidance for demonstrating compliance with the channels of trade provision serves as another option provided to industry with regard to what type of information may be submitted to FDA should a potentially-violative sample be identified.

5. Impact on small businesses or other small entities:

The information collection does not have a significant economic impact on small businesses or other small entities.

6. Consequences if the collection is not conducted or is conducted less frequently:

If the collection is not conducted or is conducted less frequently, FDA will not be fulfilling its statutorily-mandated requirement (§408 (l) (5) of the FFDCA) to provide firms whose food product(s) are found to contain illegal pesticide residues an opportunity to demonstrate compliance of the product(s) with the channels of trade provision.

7. Special circumstances:

If, for some reason, samples are collected from a firm on a more-than-quarterly basis and these samples are found to be potentially violative, the firm may wish to report information with regard to demonstrating compliance of such commodities with the channels of trade provision. This would result in a firm reporting on more than a quarterly basis.

In addition, since methyl parathion residues are expected to remain in frozen food commodities indefinitely, and frozen foods are expected to remain in the channels of trade for up to four years after harvesting, firms dealing with frozen foods which may be found to contain methyl parathion residues after the tolerance has been revoked, may wish to maintain records relating to the information collection for at least four years to ensure compliance with the provision may be demonstrated should a residue be identified.

8. Publication in the Federal Register:

A copy of the June 2, 2000 **Federal Register** notice (Attachment 2) announcing the availability of the draft guidance document proposing the channels of trade policy for commodities with methyl parathion residues is attached (65 FR 35376). No comments were received.

Efforts to consult with persons outside the agency include correspondence with other agencies within the federal government (e.g., EPA and USDA), state government representatives (e.g., Departments of Agriculture in AZ, CA, FL, NM, and TX), industry groups (e.g., National Food Processors Association (NFPA) and the American Frozen Food Institute (AFFI)), as well as representatives from individual food-processing firms.

9. Payment or gifts to respondents:

No decision has been made to provide any payment or gifts to respondents.

10. Assurance of confidentiality:

All information obtained by the agency will be reviewed in accordance with the guidelines set forth in the FDA Freedom of Information Regulations (21 CFR Part 20).

11. Questions of a sensitive nature:

This information collection does not contain questions of a sensitive nature (e.g., those regarding sexual behavior and attitudes, religious beliefs, etc).

12. Hour burden for the collection of information:

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 have been revoked.

Table 1—Estimated Annual Reporting Burden¹

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

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

Estimated annual reporting burden was determined 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 non-frozen 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 foods 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 non-frozen 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 the draft guidance, would be subject to the reporting requirement since it would be the burden of the responsible party to demonstrate that the food found to contain methyl parathion residues within the former tolerance was packed or processed on or before December 31, 2000.

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

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

In determining the Estimated Annual Recordkeeping Burden, both 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.

Because all residues are expected to have dissipated from non-frozen foods by the time FDA intends to ask for a showing under section 408 (l) (5) of the FFDCA (i.e., after December 31, 2000), FDA used the number of frozen food processors when determining the annual recordkeeping burden. As with the annual reporting burden estimate, although non-frozen 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 non-frozen commodities after December 31, 2000.

The Annual Recordkeeping Burden was originally determined to be 6,660 hours. However, due to revisions made to the draft guidance document, the proposed information collection was refined, and the Annual Recordkeeping Burden decreased to 1,328 hours. This is because “Category II Documentation”, which consisted of documentation relating to the institution of auditing programs and supplier verification, was removed from the draft guidance as suggested documentation to be provided to demonstrate compliance with the channels of trade provision.

Costs to Respondents

Annualized cost to respondents for the reporting burden determined (201 hours) was estimated to be \$2,010. This was determined using an average wage of \$10/hr for employees involved in reporting information used to demonstrate compliance with the channels of trade provision.

Annualized cost to respondents for the recordkeeping burden determined (1,328 hours) was estimated to be \$13,280. This was determined using an average wage of \$10/hr for employees involved in the recordkeeping aspect of information used to demonstrate compliance with the channels of trade provision.

13. Annual cost burden to respondents or recordkeepers:

For firms that do not maintain (or maintain access to) documentation such as batch records and inventory records as part of their normal manufacturing operations, it was estimated that with \$500 or less, the necessary software and/or hard copy filing systems could be obtained to implement a system.

14. Annualized cost to the federal government:

This information will be collected in response to potentially-violative samples of commodities found to contain methyl parathion residues. Firms responsible for such samples generally submit, or have an opportunity to submit, information in their defense to the agency. This information provides firms another option with regard to what type of information may be submitted should a potentially-violative sample be identified, and will therefore not require additional FDA personnel or funding to review.

15. Reasons for program changes and adjustments:

This is a new collection; there were therefore no program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

16. Plans for tabulation and publication of information whose results will be published:

The results of this information collection will not be published.

17. Reasons why display would be inappropriate if seeking not to display OMB-approval date:

Approval to not display the expiration date for OMB approval of the information collection is not being sought.

18. Reasoning for exceptions to the certification statement:

No exceptions to the certification statement were identified.

B. Collection of Information Employing Statistical Methods

The collection of information proposed in this draft guidance does not employ statistical methods.