

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals for
Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental
Protection Agency
Supporting Statement

A. Justification

1. Circumstances Necessitating Information Collection

On August 3, 1996, the Food Quality 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. The Environmental Protection Agency (EPA) is 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). In accordance with the FQPA, EPA 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, pesticide chemicals' tolerances may be revoked, suspended or modified.

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, suspension or modification 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.

However, due to the residue dissipation rates of pesticide chemicals 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, suspension, or modification takes effect. For example, many pesticide residues are expected to remain in frozen food 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 unsafe, i.e., 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 will not be deemed by FDA to be unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by the EPA.

The information collection described in the draft guidance is necessary for FDA to determine whether or not food commodities found to contain pesticide residues after the tolerance for the pesticide in those particular commodities has been revoked, suspended, or modified are in compliance with the channels of trade provision. The draft guidance is generic by design, and addresses circumstances that FDA anticipates may arise from most, if not all future tolerance actions i.e., revocations, suspensions or modifications by EPA. FDA states in the draft guidance that should a future EPA tolerance action result in circumstances that are not adequately addressed by this

generic guidance, FDA may elect to publish additional guidance in conjunction with the future EPA tolerance action.

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

2. How, By Whom, Purpose of Collection

The information collected will be used to determine whether or not commodities found to contain pesticide residues after the tolerances for the same pesticides in those particular commodities have been revoked, suspended, or modified are in compliance with the channels for trade provision ((408(1)(5) of the FFDCA). Such information will be collected by field personnel during the course of or in follow-up inspections, investigations, or sample collections.

3. Consideration Given to 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. Identification of Duplicative Information

The information need only be collected should a potential violation be identified (i.e. a sample is found to contain an apparent illegal pesticide chemical 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. Small Businesses

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

6. Less Frequent Information Collection

If the collection is not conducted or is conducted less frequently, FDA will not be fulfilling its statutorily-mandated duty (408(1)(5) of the FFDCFA) to provide firms whose food product(s) are found to contain apparently illegal pesticide residues an opportunity to demonstrate compliance of the products(s) with the channels of trade provision.

7. Information Collection 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 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, chemical pesticide residues may remain in processed e.g., frozen, food commodities indefinitely. Processed foods are expected to remain in the channels of trade for up to four years after harvesting. Firms dealing with processed e.g., frozen, foods may be asked to make a showing up to four years after the harvesting of the crop.

8. Publication in the Federal Register

A copy of the July 23, 2003 Federal Register notice (68 FR 43535-43538) announcing the availability of the draft guidance document describing the channels of

trade policy for commodities with revoked, suspended, or modified pesticide residues is attached as Attachment 2. No comments were received.

9. Payment or gifts to respondents

No decision has been made to provide any payments 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

Table 1: Estimated Annual Reporting Burden

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
652	1	652	3	1956

FDA does not know which pesticide chemicals will have tolerances revoked, suspended, or modified in the future. Instead of calculating the paperwork burden for any one pesticide, FDA calculated the cost for an “average” pesticide by looking at test results for 417 pesticide chemicals on domestic products and 450 pesticide chemicals on imported products. FDA then used the average percent of samples

found with residues as a substitute for the rate of residues found from a specific pesticide chemical.

The estimated annual reporting burden was determined using the average percent of samples found with residues for all pesticides for domestic and imported products. Using 1999 pesticide monitoring data, domestic products were tested for residues of 417 pesticide chemicals. On average, 1.02 percent of samples tested positive for a given pesticide chemical. For 450 pesticides tested for residues on imported products, on average 2.40 percent of samples contained a given pesticide chemical residue. This rate of finds for product samples was applied to the number of potentially affected establishments, 3,730 importers and 23,201 domestic businesses, giving an expected number of 326 potentially-affected businesses per revocation, suspension, or modification of a tolerance. FDA expects this number to be an overestimate of the number of affected businesses for two reasons. One, the positive residue test may be below the new tolerance. Second, tolerances may not be altered for all products. If the tolerance was altered only for vegetables but not fruits, then the number of affected establishments would be smaller. Finally, we assume two pesticide tolerances are altered per year, resulting in 652 businesses reporting per year. To date tolerances have been revoked for two pesticide chemicals. However, FDA expects the number of pesticide tolerances that are revoked, suspended, or modified by EPA to increase, due in part to the issuance of this guidance.

Table 2: Estimated Annual Recordkeeping Burden

No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Capital Costs
65	1	65	16	1042	\$32,571

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation such as packing codes, batch records, and inventory records as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not currently be maintaining this documentation to develop and maintain documentation, such as batch records and inventory records.

Cost to Respondents

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours	Labor Cost
652	1	652	3	1956	\$45,378

No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Labor costs
65	1	65	16	1042	\$24,202

Annualized cost to respondents for the reporting burden was estimated to be the hours spent on recordkeeping and reporting multiplied by the hourly wage rate for an administrative support employee, \$11.61, doubled to reflect overhead costs plus the capital costs. . The total of all costs is \$102,151.

13. Capital and operating and maintenance costs.

For firms that do not maintain 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 hardcopy filing systems could be obtained to implement a system. The total capital cost is \$500 multiplied by the 65 firms that do not maintain records, giving a total capital cost of \$32,571

14. Annual Cost to Government

This information will be collected in response to potentially-violative samples of commodities found to contain pesticide residues that do not comply with the pesticide tolerances. 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. Reason for Change

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. Statistical Reporting

The results of this information collection will not be published.

17. Display of OMB Approval Date

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions,” of OMB

Form 83I

No exceptions to the certification statement were identified.