

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 2003D-0263]

### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

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

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (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.

**Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency**

Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the Food Quality Protection Act of 1996 (FQPA), EPA is expected to revoke, suspend, or modify tolerances for the pesticide chemicals on various food commodities. Section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 346a) includes a provision, referred to as the “channels of trade provision,” that addresses the circumstances under which a food will not be deemed unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.

In general, FDA anticipates that the party responsible for food found to contain the previously mentioned pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, e.g., packed or processed, during the acceptable timeframes cited in the draft guidance by providing appropriate documentation to the agency as discussed in the draft guidance document. FDA is not suggesting that firms maintain an inflexible set 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 handled during the acceptable timeframes.

Examples of documentation which FDA anticipates will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate 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 that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

In the **Federal Register** of July 23, 2003 (68 FR 43535), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received that did not pertain to this information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
652	1	652	3	1,956

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

FDA does not know which pesticide chemicals will have their 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 positive findings 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. First, the positive residue test may be below the new tolerance. Second, tolerances may not be altered for all products. If the tolerance was altered for only vegetables but not fruit, then the number of affected establishments would be smaller. 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 total number of pesticide tolerances that are revoked, suspended, or modified by EPA to increase.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Capital Costs
65	1	65	16	1,042	\$32,571

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

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. 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.

Dated: October 9, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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