

United States Food and Drug Administration

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

OMB Control No. 0910-0562--Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) guidance. The Food Quality Protection Act of 1996 (FQPA), which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 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 responsible for regulating the use of pesticides (under FIFRA) and for establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FD&C Act). EPA may, for various reasons, *e.g.*, as part of a systematic review or in response to new information concerning the safety of a specific pesticide, reassess whether a tolerance for a pesticide residue continues to meet the safety standard in section 408 of the FD&C Act (21 U.S.C. 346a). When EPA determines that a pesticide's tolerance level does not meet the safety standard, the registration for the pesticide may be canceled under FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities.

Under section 408(l)(2) of the FD&C Act, when the registration for a pesticide is canceled or modified due to, in whole or in part, dietary risks to humans 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.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture has responsibility for monitoring residue levels and enforcing pesticide tolerances in meat, poultry, catfish, and certain egg products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. We would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an “adulterated” food. However, the channels of trade provision of the FD&C Act 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. The channels of trade provision (section 408(l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed “adulterated” by virtue of the residue, if the residue is within the former tolerance, and the responsible party can

demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner which were lawful under FIFRA.

To assist respondents with the information collection, we have developed the guidance document entitled, "*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 Pursuant to Dietary Risk Considerations*" (May 2005). The guidance represents the agency's current thinking on its planned enforcement approach to the channels of trade provision of the FD&C Act and how that provision relates to FDA-regulated products with residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified by EPA pursuant to dietary risk considerations. The guidance can be found at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-channels-trade-policy-commodities-residues-pesticide-chemicals>.

We anticipate that food bearing lawfully applied residues of pesticide chemicals that are the subject of future EPA action to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If we encounter food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, we intend to address the situation in accordance with provisions of the guidance. In general, we anticipate that the party responsible for food found to contain 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 guidance by providing appropriate documentation to the agency as discussed in the guidance document. We are not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, we are 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 we anticipate 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.

We therefore request extension of OMB approval of information collection provisions found in the guidance entitled, "*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 Pursuant to Dietary Risk Considerations*" as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Information will be collected by field personnel when firms want to demonstrate the residues of pesticide chemicals in their products are from lawful application, after the tolerances for the pesticide chemicals have been revoked, suspended, or modified. The information collected is used to determine whether commodities found to contain such pesticide residues are in compliance with the channels of trade provision of the FD&C Act.

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.

3. Use of Improved Information Technology and Burden Reduction

We do not specifically recommend the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology for use by respondents. In accordance with applicable regulations, the records must be made available upon FDA request. We estimate about 100% of the records will be maintained electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that 10% of respondents are small businesses who will use electronic means to fulfill the agency's requirement. However, we do not believe the information collection poses undue burden on these entities. We aid small businesses in complying with our requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via our Small Business Assistance webpage on the agency's website at <https://www.fda.gov/industry/small-business-assistance>.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule discussed in the guidance is consistent with section 408(l)(5) of the FD&C Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Special circumstances in the collection of information may occur when a firm's submission of appropriate documentation to the agency may contain trade secret and commercial confidential information. This information is protected by FDA as discussed below in Item 10. In addition, 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. Also, chemical pesticide residues may remain in processed foods (*e.g.*, frozen food commodities) for as long as they remain in channels of trade, which may be up to four years after harvesting. Firms dealing with processed foods may be asked to make a showing up to four years after the harvesting of the crop.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice requesting public comment in the *Federal Register* of August 2, 2023 (88 FR 50880). We received 2 comments, one of which was not PRA related and will not be addressed in this document. The other comment questioned the utility of pesticide application records used to demonstrate a pesticide was applied at an acceptable time and in a lawful manner for crops commingled with other commodities. The channels of trade provision (section 408(l)(5) of the FD&C Act) states that food containing a residue of such a pesticide shall not be deemed "adulterated" by virtue of the residue, if the residue is within the former tolerance, and the responsible party can demonstrate to FDA's satisfaction that the residue is present as the result of an application of the pesticide at a time and in a manner which were lawful under FIFRA. We leave it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes.

Pesticide spray records may be used as a documentation to demonstrate the residues in food are from an application of the pesticide at a time and in a manner which were lawful under FIFRA.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is point of contact name, business mailing address, business telephone number, and business email address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. Data will be kept private to the extent allowed by law.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of documentation	1	1	1	3	3

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

We expect the total number of pesticide tolerances that are revoked, suspended, or modified by EPA pursuant to dietary risk considerations in the next three years to remain at a low level, as there have been no changes to the safety standard for pesticide residues in food since 1996. Thus, we expect the number of submissions we receive under to the guidance document will also remain at a low level. However, to avoid counting this burden as zero,

we have estimated the burden at one respondent making one submission a year for a total of one annual submission.

Table 2.--Estimated Annual Recordkeeping Burden¹

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Record	Total Hours
Develop documentation process	1	1	1	16	16

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

12b. Annualized Cost Burden Estimate

Gathering the information requested in the guidance and providing it to the agency may be done by an administrative support employee familiar with batch records and inventory records. We estimate that the hourly wage for the employee would be \$28.18 per hour (corresponding to that of a Federal government employee at the GS-8, step 1 rate for the Washington-Baltimore locality pay area for the year 2023). Based on that, and on the total of the burden hours calculated above (16 + 3 = 19), the annual cost to respondents is \$535.42 (19 burden hours x \$28.18/hour). To account for overhead, this cost is increased by 100 percent, making the total estimated annualized cost to the respondents \$1,070.84 (\$535.42 x 2).

Table 3.--Estimated Annual Cost Burden

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Gathering information and providing to FDA	19	\$56.36	\$1,070.84

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We estimate that review and evaluation of records will be done by an employee at the GS-13, step 1 pay rate for the Washington-Baltimore locality pay area for the year 2023, which is \$53.67 per hour. Doubling that figure to account for overhead brings the cost to \$107.34/hour. We assume that review and evaluation of records take about 5 hours, which will bring annual costs to the Federal government to \$536.70 (\$107.34/hour x 5 hours).

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB

control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.