Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

0910-0562

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

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, in accordance with the FQPA, is in the process of reassessing the pesticide tolerances and exemptions which were in effect when the FQPA was signed into law. When EPA determines that a pesticide's tolerance level does not meet the safety standard under section 408 of the FD&C Act (21 U.S.C. 346a), 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 in whole or in part to 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 (USDA) has responsibility for monitoring residue levels and enforcing pesticide tolerances in egg products and most meat and poultry products), to contain a residue of that pesticide that does not comply with the revoked or lowered tolerance. FDA 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.

In the Federal Register of May 18, 2005 (70 FR 28544), FDA announced the availability of a 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." 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 http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077918.htm.

FDA anticipates 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 FDA encounters food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, it intends to address the situation in accordance with provisions of the guidance.

In general, FDA anticipates 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. 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.

FDA is requesting OMB approval of the voluntary information collection provisions contained 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."

2. Purpose and Use of the Information Collection

Information will be collected by field personnel during the course of or in follow-up inspections, investigations, or sample collections. The information collected is 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 of trade provision of the FD&C Act.

Description of Respondents: The 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

The guidance does not specifically recommend the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology for use by firms. Companies are free to use whatever forms of information technology that may best assist them in retaining the appropriate records and making them available to regulatory officials.

The agency estimates that about twenty-five percent (25%) of the records will be maintained electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of information collection is likely because the information need only be collected once should a potential violation be identified (i.e., a sample is found to contain an apparent illegal pesticide chemical residue).

5. Impact on Small Businesses or Other Small Entities

FDA estimates that ten percent (10 %) of respondents are small businesses. Should a potentially violative sample be identified, providing the appropriate documentation to the agency is no more burdensome for small businesses than for large. There is no known way to minimize the burden on a small business wishing to demonstrate that the food was handled, e.g., packed or processed, during the acceptable timeframes cited in the guidance. FDA aids small businesses in complying with its requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. FDA has provided a Small Business Guide on the agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. 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 FD&C Act) 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. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The recommended information collection contained in the guidance generally does not involve: more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, or the use of statistical methods. However, 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 set out below in the response to question 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 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. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of March 9, 2011 (76 FR 12967). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Firms whose food product(s) are found to contain apparently illegal pesticide residues may provide records to FDA to demonstrate compliance of the products(s) with the channels of trade provision of the FD&C Act. Any records that the agency may copy or take possession of in such event would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Description of Respondents: The 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.

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

Table 1.--Estimated Annual Reporting Burden[1]

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

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

FDA expects the total number of pesticide tolerances that are revoked, suspended, or modified by EPA in the next three years to significantly decrease, as EPA concludes its review activity. Thus, the above estimates for respondents and numbers of responses are based on the submissions that the agency has received in the past three years and the expectation that the number of submissions will significantly decrease in the next three years. However, to avoid counting this burden as zero, FDA has estimated the burden at one respondent making one submission a year for a total of one annual submission.

The hours per response values were estimated as follows: First, we assumed that the information requested in this guidance is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission to FDA. The submitter will almost always merely need to copy existing documentation. We believe that this effort should take no longer than 3 hours per submission.

Table 2.—Estimated Annual Recordkeeping Burden[1]

Activity	No. of Record-keepers	No. of Records per Recordkeeping	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.

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 be currently maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. In previous information collection requests, this recordkeeping burden was estimated to be 16 hours per record. FDA has retained its prior estimate of 16 hours per record for the recordkeeping burden. As shown in Table 1, FDA estimates that one respondent will make one submission per year. Although FDA estimates that only one out of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the one submission per year as 1/10 of a recordkeeper, FDA estimates that one recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

12 b. 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. FDA estimates that the hourly wage for the employee would be $22.40 per hour (corresponding to a GS-8, step 1, 2011 federal government hourly salary). Based on that, and on the total of the burden hours calculated above (16 + 3 = 19), the annual cost to respondents is $425.60 (19 burden hours x $22.40 per hour). Overhead is estimated as being equal to salary. To account for overhead, this cost is increased by 100 percent, making the total estimated annualized cost to the respondents $851.20 ($425.60 x 2).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to Federal 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. The recommendations contained in the guidance clarify what information to submit. FDA estimates that its review of the submitted information would take five hours. FDA estimates the hourly cost for review and evaluation to be $42.66 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2011. To account for overhead, this cost is increased by 100 percent, making the total cost $85.32 per hour. Thus, in the event of a review, FDA estimates the cost to the Federal Government for the review of the submitted information would be $426.60 ($85.32/hour x 5 hours).

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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

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

There are no exceptions to the certification.