

households. Specific data elements OCS is seeking to collect are detailed below.

In 2015, state LIHEAP grantees provided household-level data to identify LIHEAP recipients that participated in the 2015 RECS. ACF is requesting no changes in the type of data or the form of data collection for the 2020 reinstatement of the project. State LIHEAP grantees will be asked to furnish data for LIHEAP recipient households that reside in areas included in the RECS sample.

For each household, report the following:

- Name
- Address (including ZIP code)
- Gross Income
- Household Size

- Household or Client ID
- Heating assistance awarded
- Amount of heating assistance
- Date of heating assistance
- Cooling assistance awarded
- Amount of cooling assistance
- Date of cooling assistance
- Crisis assistance awarded
- Amount of crisis assistance
- Date of crisis assistance
- Other assistance awarded
- Amount of other assistance
- Date of other assistance
- Presence of children 5 or younger
- Presence of adult 60 or older
- Presence of disabled

The following are additional optional data items that grantees can provide if the data are available in your database:

- Tenancy (*i.e.*, own or rent)
- Type(s) of fuel used
- Heat included in rent

This data will help ACF to analyze specific information for the LIHEAP recipient population in accordance with 42 U.S.C. 8629(b)(2), including information related to benefits targeting, energy usage, and energy insecurity, and it will support analysis of LIHEAP data for the annual Report to Congress and the annual LIHEAP Home Energy Notebook. The collection of this data is authorized in 42 U.S.C. 8629(a).

*Respondents:* State Governments and the District of Columbia

#### ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Action Transmittal Reinstatement without Change of the FY 2020 RECS LIHEAP Administrative Data Matching ..	51	1	24	1,224	408

*Estimated Total Annual Burden Hours:* 408.

*As LIHEAP is a block grant, there is varying capacity to collect and report data among grantees. The estimated burden hours displayed above are for the average LIHEAP grantee. All LIHEAP grantees have existing data systems to collect, maintain, and analyze this data to complete annual reporting requirements.*

**Authority:** 42 U.S.C. 8629(a).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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**BILLING CODE 4184-80-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-2021]

#### Agency Information Collection Activities; Proposed Collection; 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 Pursuant to Dietary Risk Considerations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's guidance for industry 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."

**DATES:** Submit either electronic or written comments on the collection of information by July 13, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 13, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 13, 2020. Comments

received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-N-2021 for “Agency Information Collection Activities; Proposed Collection; 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 Pursuant to Dietary Risk Considerations.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### 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 Number 0910-0562—Extension

The Food Quality Protection Act of 1996, which amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (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 that 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 that were lawful under FIFRA.

In the **Federal Register** of May 18, 2005 (70 FR 28544), we announced the availability of a final 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 FDA’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 under dietary risk considerations. The guidance can be found at the following link: <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 FDA 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 that 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. Accordingly, under the PRA, we are requesting the extension of OMB approval for the information collection provisions in the guidance.

*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.

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

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of documentation .....	1	1	1	3	3

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

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

We expect the total number of pesticide tolerances that are revoked, suspended, or modified by EPA under dietary risk considerations in the next 3 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 the guidance document to 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.

We based our estimate of the hours per response on the assumption that the information requested in the 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 <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop documentation process .....	1	1	1	16	16

<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, we 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. We have retained our prior estimate of 16 hours per record for the recordkeeping burden. As shown in table 1 of this document, we estimate that one respondent will make one submission per year. Although we estimate that only 1 of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the 1 submission per year as 1/10th of a recordkeeper, we estimate that 1 recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

Dated: April 27, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-10272 Filed 5-12-20; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Questionnaire and Data Collection Testing, Evaluation, and Research for the Health Resources and Services Administration, OMB No. 0915-0379—Extension

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and

approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than June 12, 2020.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Questionnaire and Data Collection Testing, Evaluation, and Research for HRSA, OMB No. 0915-0379—Extension.

*Abstract:* The purpose of collections under this generic clearance is to obtain formative information from respondents to develop new questions, questionnaires and tools and to identify problems in instruments currently in use. This clearance request is limited to formative research activities emphasizing data collection, toolkit development, and estimation procedures and reports for internal decision-making and development purposes. This clearance request does not extend to the collection of data for public release or policy formation. It is anticipated that these studies will rely heavily on qualitative techniques to meet their objectives. In general, these activities are not designed to yield results that meet generally accepted standards of statistical rigor but are designed to obtain valuable formative information to develop more effective and efficient data collection tools that will yield more accurate results and decrease non-response.

A 60-day notice published in the **Federal Register** on March 2, 2020, vol. 85, No. 41, pp. 12307-09. There were no public comments.

*Need and Proposed Use of the Information:* HRSA conducts cognitive interviews, focus groups, usability tests, field tests/pilot interviews, and experimental research in laboratory and field settings, both for applied questionnaire development and evaluation as well as more basic research on response errors in surveys.

HRSA staff use various techniques to evaluate interviewer administered, self-administered, telephone, Computer Assisted Personal Interviewing (CAPI), Computer Assisted Self-Interviewing, Audio Computer-Assisted Self-Interviewing, and web-based questionnaires. Professionally recognized procedures are followed in each information collection activity to ensure high quality data. Examples of these procedures could include the following:

- Monitoring by supervisory staff of a certain percent of telephone interviews;
- Conducting cognitive interviewing techniques, including think-aloud techniques and debriefings;
- Data-entry from mail or paper-and-pencil surveys will be computerized through scannable forms or checked through double-key entry;
- Observers will monitor focus groups, and focus group proceedings will be recorded; and
- Data submitted through on-line surveys will be subjected to statistical validation techniques to ensure accuracy (such as disallowing out-of-range values).

Each request under this generic clearance will specify the procedures to be used. Participation will be fully voluntary, and non-participation will have not affect eligibility for, or receipt of, future HRSA health services research activities or grant awards, recruitment or participation. Specific testing and evaluation procedures will be described when we notify OMB about each new request. Appropriate consent procedures will be customized and used for each information collection activity and any collection of personal, privacy-protected information will be handled in accordance with all applicable requirements. If the encounter is to be recorded, the respondent's permission to record will be obtained before beginning the interview.

**Screening—**When screening is required (e.g., quota sampling), the screening will be as brief as possible and the screening questionnaire will be provided as part of the submission to OMB. **Collection methods—**The particular information collection methods used will vary, but may include the following

- Individual in-depth interviews—In-depth interviews will commonly be used to ensure that the meaning of a questionnaire or strategy is understood by the respondent. When in-depth interviewing is used, the interview guide will be provided to OMB for review.
- Focus groups—Focus groups will be used to obtain insights into beliefs and