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Paul Kiecker,  
Administrator.

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS-2021-0008]

#### Notice of Request To Revise an Approved Information Collection (Requirements To Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments)

**AGENCY:** Food Safety and Inspection Service (FSIS), USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and the Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to revise the approved information collection regarding requirements for official establishments to notify FSIS of adulterated or misbranded product, prepare and maintain written recall procedures, and document certain HACCP plan reassessments. The approval for this information collection will expire on September 30, 2021. FSIS has decreased the burden estimate for this collection by 37,515 hours due to more recent, updated information. The public may comment on either the entire information collection or on one of its three parts.

**DATES:** Submit comments on or before June 14, 2021.

**ADDRESSES:** FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700.

- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Washington, DC 20250-3700.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2021-0008. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

*Docket:* For access to background documents or comments received, call (202)205-0495 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250-3700.

**FOR FURTHER INFORMATION CONTACT:** Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250-3700; (202) 720-5627.

#### SUPPLEMENTARY INFORMATION:

*Title:* Requirements To Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments.

*OMB Number:* 0583-0144.

*Expiration Date of Approval:* 9/30/2021.

*Type of Request:* Renewal of an approved information collection.

*Abstract:* FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS is requesting revision of the approved information collection regarding requirements for official establishments to notify FSIS of adulterated or misbranded product, prepare and maintain written recall procedures, and document certain HACCP plan reassessments. FSIS has decreased the burden estimate for this collection by 37,515 hours due to more recent, updated information.

The regulations at 9 CFR 418.2, 418.3 and 417.4(a)(3) require establishments to notify FSIS that they have shipped or received adulterated or misbranded product in commerce, prepare and maintain written recall procedures, and

document certain HACCP plan reassessments. Accordingly, FSIS requires three information collection activities under these regulations.

First, FSIS requires that official establishments notify the appropriate District Office that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened. Industry representatives of official establishments may now use FSIS Form 5720-16, *Industry Report of Adulteration*, to notify FSIS that an adulterated or misbranded meat, meat food, poultry, or poultry product was received from or shipped to commerce by the official establishment. The form is available as a paper form and digitally in PHIS.

Second, FSIS requires that establishments prepare and maintain written procedures for the recall of meat and poultry products produced and shipped by the establishment for use should it become necessary for the establishment to remove product from commerce. These written recall procedures have to specify how the establishment will decide whether to conduct a product recall, and how the establishment will effect the recall should it decide that one is necessary.

Finally, FSIS requires that establishments document each reassessment of the establishment's HACCP plans. FSIS requires establishments to reassess their HACCP plans annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary.

FSIS has made the following estimates as part of an information collection assessment.

*Estimate of burden:* The public reporting burden for this collection of information is estimated to average .232 hours per response.

*Respondents:* Official meat and poultry products establishments.

*Estimated annual Number of Respondents:* 6,300.

*Estimated average number of responses per respondent:* 6.8.

*Estimated annual number of responses:* 42,900.

*Estimated total annual burden on respondents:* 9,960.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection

assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250-3700; (202) 720-5627.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

Responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

#### Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to this **Federal Register** publication through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS can provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the

option to password protect their accounts.

#### USDA Non-Discrimination Statement

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Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720-2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD-3027, found online (<https://www.usda.gov/sites/default/files/documents/usda-program-discrimination-complaint-form.pdf>) and at any USDA office or write a letter addressed to USDA and provide in the letter all of the information requested in the form. To request a copy of the complaint form, call (866) 632-9992. Submit your completed form or letter to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) fax: (202) 690-7442; or (3) email: [program.intake@usda.gov](mailto:program.intake@usda.gov). USDA is an equal opportunity provider, employer, and lender.

**Paul Kiecker,**  
Administrator.

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. FSIS-2021-0009]

#### Notice of Request for Revision of an Approved Information Collection (Public Health Information System)

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995 and the Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to revise the approved information collection regarding its Public Health Information System (PHIS). The Agency has increased the burden estimate by 433 hours due to the addition of the FSIS Form 9060-5EP, *Egg Products Export Certificate of Wholesomeness*. FSIS is currently issuing FSIS Form 9060-5 (meat and poultry) and 9060-5S (Siluriformes) export certificates for 38 countries and territories through the PHIS export component (i.e., providing an electronic export certificate application for exporters and the FSIS Form 9060-5/5S printed on security paper). At this time, FSIS is seeking OMB approval to collect information for the existing paper FSIS Form 9060-5EP. FSIS will request additional approval for the electronic collection of information when egg products are added into the PHIS export component. FSIS will announce its plans to add egg products to the PHIS export component through a subsequent notice to the public, likely through the Agency's *Constituent Update*. The approval for this information collection will expire on August 31, 2022.

**DATES:** Submit comments on or before June 14, 2021.

**ADDRESSES:** FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700.