

**SUPPORTING STATEMENT JUSTIFICATION FOR  
EGG PRODUCTS HACCP AND SANITATION STANDARD OPERATING PROCEDURES**

**1. Circumstances Making Collection of Information Necessary:**

This is a request to renew the information collection related to Egg Products Inspection Regulations.

The Food Safety and Inspection Service (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.). FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged.

FSIS requires that official plants that process egg products develop and implement Hazard Analysis and Critical Control Points (HACCP) systems and Sanitation Standard Operating Procedures (Sanitation SOPs), in accordance with the regulations in 9 CFR parts 416 and 417, and to meet other sanitation requirements consistent with FSIS's meat and poultry regulations. The Agency has eliminated those regulations that are incompatible with the regulations for HACCP and Sanitation SOPs and converted prescriptive, command-and-control requirements to general sanitation standards.

**2. How, By Whom and Purpose For Which Information is to be Used:**

The following is a discussion of the required information collection and recordkeeping activities.

FSIS requires official plants to develop and maintain HACCP and Sanitation SOP records and plans, as well as various transaction records. The egg products industry's documentation of its processes, first in a plan and thereafter in a continuous record of process performance, is a more effective food safety approach than the sporadic generating of information by inspection program personnel. This documentation gives inspection program personnel a much broader picture of production than they can generate and provides them additional time to perform higher priority tasks. At the same time, it gives plant managers a better view of their own process and more opportunity to adjust it to prevent safety defects.

Sanitation SOPs: To meet the proposed regulation's sanitation requirements, each processor develops and maintains a Sanitation SOP. The Sanitation SOP specifies the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. As part of the Sanitation SOP, a plant employee records results of daily sanitation checks at the frequencies stated in the Sanitation SOP.

The burden of documenting the adherence to Sanitation SOPs is based on three factors: recording, reviewing, and storage.

Recording encompasses conducting and inscribing the finding from an observation and filing the document produced.

HACCP: The requirements for the implementation of HACCP in official plants are the same as those being met by meat and poultry products establishments operating under HACCP. The plant maintains on file the name and a brief resume of the HACCP-trained individuals who participate in the hazard analysis and subsequent development of the HACCP plans. Plants develop written HACCP plans that include: Identification of hazards reasonably likely to occur in the production process; identification and description of the CCP for each identified hazard; specification of the critical limit which may not be exceeded at the CCP, and, if appropriate, a target limit; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records which would be generated and maintained regarding this CCP; and description of the facility verification activities and the frequency at which they are to be conducted. Critical limits that are currently a part of FSIS regulations must be included. The adequacy of a plant's HACCP plan must be reassessed at least annually and whenever changes occur that could affect the hazard analysis or alter the HACCP plan.

The HACCP records are reviewed by a plant employee other than the one whom produced the record, before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be the reviewer. The reviewer signs the records. Lastly, HACCP records generated by the processor are retained on site for at least 1 year.

### **3. Use of Improved Information Technology:**

Under the E-Gov Act, firms may keep records electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data.

### **4. Efforts to Identify Duplication:**

No other Government agency requires information regarding Egg Products HACCP and Sanitation SOPs. There is no available information that can be used or modified.

### **5. Methods to Minimize Burden on Small Business Entities:**

Data collected from small businesses are the same as for large ones. The information collections must apply to all official egg products plants. FSIS estimates that 73 small establishments will be subject to this information collection.

### **6. Consequences If Information Were Collected Less Frequently:**

To conduct the information collections less frequently will reduce the effectiveness of the egg products inspection program.

## **7. Circumstances that Would Cause the Information Collection to be Conducted in a Manner:**

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

Establishments are required to collect and record data more frequently than quarterly. There are no other circumstances that would cause the guidelines above not to be met by this information collection.

## **8. Consultation with Persons Outside the Agency:**

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the Federal Register, on September 27, 2023, (88 FR 66372). The Agency received one public comment that was not relevant to the information collection. FSIS contacted Senior Vice President Food Safety Regulatory Affairs, United Egg Producers, 770-360-9220; Operations Manager, Osky Foods, [hangle@oskyfoods.com](mailto:hangle@oskyfoods.com); and Director of Regulatory Affairs and International Compliance, Michael Foods, Inc. 952-258-4052. Based on their input, the Agency is making no change to the burden estimates.

## **9. Payment or Gifts to Respondents:**

Respondents will not receive any gifts or payments.

**10. Confidentiality Provided to Respondents:**

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

**11. Questions of a Sensitive Nature:**

The applicants are not asked to furnish any information of a sensitive nature.

**12. Estimate of Burden**

The total burden estimate for the recordkeeping requirements associated with this information collection is 76,280 hours.

HACCP development	35,360
HACCP reassessment	16,500
HACCP recordkeeping	2,860
<u>HACCP records review</u>	<u>1,144</u>
Total HACCP	55,864
SSOP plan development	396
SSOP recordkeeping	17,160
<u>SSOP records review</u>	<u>2,860</u>
Total SSOP	20,416
Total HACCP and SSOP	76,280

FSIS estimates that 6 egg products plants will develop a total of 26 HACCP plans. A plant can have multiple plans depending on the products and processes in the plant. This results in a total of 260 annual responses. Each response is estimated to take 8,160

minutes for a total of 35,360 hours annually.

**HACCP Plan Development  
(9 CFR 417.2)**

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg products plants	6 plants and 26 HACCP plans	43.33	260	8,160	35,360

FSIS estimates that 81 egg products plants with 132 HACCP plans will conduct HACCP plan reassessments annually for a total of 660 responses and a total of 16,500 hours.

**HACCP Plan Reassessment  
(9 CFR 417.4)**

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg products plants	81 plants (with 132 plans)	8.15	660	1,500	16,500

FSIS estimates that 81 egg products plants with 132 HACCP plans will perform HACCP recordkeeping activities for a total of 34,320 responses and a total of 2,860 hours.

**HACCP Plan Recordkeeping  
(9 CFR 417.5)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg products plants	81 plants (with 132 plans)	423.7	34,320	5	2,860

FSIS estimates that 81 egg products plants with 132 HACCP plans will conduct a HACCP records review for a total of 34,320 responses and a total of 1,144 hours.

**HACCP Plan Records Review  
(9 CFR 417.2)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg products plants	81 plants (with 132 plans)	423.7	34,320	2	1,144

FSIS estimates that 81 egg products plants will develop SSOP plans for a total of 396 responses. Each response is estimated to take 60 minutes for a total of 396 hours annually.

**SSOP Plan Development  
(9 CFR 416.12)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg	81 plants	4.89	396	60	396

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
products plants	(with 132 plans)				

FSIS estimates that 81 egg products plants with 132 SSOP plans will perform SSOP recordkeeping activities annually for a total of 34,320 responses and a total of 17,160 hours.

**SSOP Recordkeeping  
(9 CFR 416.16)**

	Estimated No. of Respon- dents	No. of Res- ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg products plants	81 plants (with 132 plans)	423.7	34,320	30	17,160

FSIS estimates that 81 egg products plants with 132 SSOP plans will conduct a SSOP records review annually per plan for a total of 34,320 responses and a total of 2,708 hours.

**SSOP Records Review  
(9 CFR 416.14 and 416.15)**

	Estimated No. of Respon- dents	No. of Res- ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg products	81 plants (with 132 plans)	423.7	34,320	5	2,860

	Estimated No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
plants	plans)				

The cost to the respondents is estimated at \$3,611,858 annually. The Agency estimates that it will cost respondents \$47.35 an hour, including fringe benefits, in fulfilling these reporting and recordkeeping requirements. Respondents will spend an annual total of 76,280 hours and \$3,611,858. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2022.

**13. Capital and Start-up Cost and Subsequent Maintenance**

There are no capital and start-up costs and subsequent maintenance burdens.

**14. Annual Cost to Federal Government and Respondents:**

There is no cost to the Federal Government for these information collection requirements.

**15. Reasons for Changes in Burden:**

There is no change in burden.

**16. Tabulation, Analyses and Publication Plans:**

There are no plans to publish the data for statistical use.

**17. OMB Approval Number Display:**

FSIS will display the OMB approval number on any instructions it publishes relating to recordkeeping activities.

**18. Exceptions to the Certification:**

There are no exceptions to the certification. This information collection accords with the certification in item 19 of the OMB 83-1.



