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

1. Circumstances Making Collection of Information Necessary:

This is a request for a new information collection related to the proposed rule for 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, not adulterated, and correctly labeled and packaged.

FSIS is proposing to amend the egg products inspection regulations (9 CFR part 590) to require 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 proposed sanitation requirements (proposed 9 CFR part 591). The Agency is proposing to eliminate those regulations that are incompatible with the regulations for HACCP and Sanitation SOPs and to convert prescriptive, command-and-control requirements to general sanitation standards.

The proposed rule will provide greater flexibility and incentives for innovation through reductions in paperwork and unnecessary approvals. In addition, plants voluntarily meeting HACCP requirements and also complying with current prescriptive regulations would reduce costs because they would be operating entirely under HACCP requirements.

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.

Under this proposed rule, FSIS is requiring 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, will be 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 will develop and maintain a Sanitation SOP. The Sanitation SOP would specify 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 will record 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 of the document produced.

HACCP: Under this proposal, the requirements for the implementation of HACCP in official plants will be the same as those being met by meat and poultry products establishments operating under HACCP. The plant will maintain 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 will 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 should be 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 would sign the records. Lastly, HACCP records generated by the processor would be 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 swine slaughter establishments. FSIS estimates that 31 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 swine slaughter 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 will be required to collect and record data more frequently that 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 embedded a 60-day notice in the proposed rule that published in the Federal Register on February 13, 2018, (83 FR 6314) requesting comments regarding this information collection.

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 71,389 hours.

HACCP development	32,640
HACCP reassessment	15,625
HACCP recordkeeping	2,708
HACCP records review	1,083
Total HACCP	52,056

SSOP plan development	375
SSOP recordkeeping	16,250
SSOP records review	2,708
Total SSOP	19,333

Total HACCP and SSOP	71,389

FSIS estimates that 24 plants will develop HACCP plans for 10 products for a total of 240 plans annually. Each plan is estimated to take 8,160 minutes for a total of 32,640 hours annually.

HACCP Plan Development
(9 CFR 417.2)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	24	10	240	8,160	32,640

FSIS estimates that 125 egg plants will conduct HACCP plans reassessments 5 times annually for a total of 625 responses and a total of 15,625 hours.

HACCP Plan Reassessment
(9 CFR 417.4)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	125	5	625	1,500	15,625

FSIS estimates that 125 egg plants will perform HACCP recordkeeping activities 260 times annually for a total of 32,500 responses and a total of 2,708 hours.

HACCP Plan Recordkeeping
(9 CFR 417.5)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	125	260	32,500	5	2,708

FSIS estimates that 125 plants will conduct a HACCP records review 260 times annually for a total of 32,500 responses and a total of 1,083 hours.

HACCP Plan Records Review
(9 CFR 417.2)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	125	260	32,500	2	1,083

FSIS estimates that 125 plants will develop SSOP plans 3 times annually for a total of 375 plans. Each plan is estimated to take 60 minutes for a total of 375 hours annually.

SSOP Plan Development
(9 CFR 416.12)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	125	3	375	60	375

FSIS estimates that 125 egg plants will perform SSOP recordkeeping activities 260 times annually for a total of 32,500 responses and a total of 16,250 hours.

SSOP Recordkeeping
(9 CFR 416.16)

	Estimated No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	125	260	32,500	30	16,250

FSIS estimates that 125 plants will conduct a SSOP records review 260 times annually for a total of 32,500 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 Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Egg plants	125	260	32,500	5	2,708

The cost to the respondents is estimated at $2,784,171 annually. The Agency estimates that it will cost respondents $39 an hour in fulfilling these reporting and recordkeeping requirements. Respondents will spend an annual total of 71,389 hours and $2,784,171. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2016.

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. There is annual estimated cost savings of $703,900.

15. Reasons for Changes in Burden:

This is a new information collection with an estimated 125 respondents, 131,240 responses, and 71,389 hours.

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-I.