SUPPORTING STATEMENT JUSTIFICATION FOR MODERNIZATION OF SWINE SLAUGHTER INSPECTION

1. Circumstances Making Collection of Information Necessary:

This is a request for a new information collection related to the proposed rule for Modernization of Swine Slaughter Inspection.

The Food Safety and Inspection Service (FSIS) 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.). This statute mandates that FSIS protect the public by ensuring that meat products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS is proposing to amend the Federal meat inspection regulations to establish a new inspection system for market hog slaughter establishments that has been demonstrated to provide equivalent or greater public health protection than the existing inspection system. The Agency is also proposing several changes to the regulations that would affect all establishments that slaughter any swine, regardless of the inspection system under which they operate or the age, size, or class of swine. These proposed changes would allow all swine slaughter establishments to develop sampling plans that are more tailored to their specific operations, and thus be more effective in monitoring their specific process control. These proposed changes also would ensure that before the start of slaughter operations, food-contact surfaces are sanitary and free of enteric pathogens.

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 is proposing that all swine slaughter establishments develop sampling plans that are more tailored to their specific operations. All establishments operating under the New Swine Slaughter Inspection System (NSIS) would have to monitor their systems through microbial testing and recordkeeping. For each sample on which a microbiological test is conducted, there are two "responses" for the establishment: one response for the actual collecting of the sample and sending it to the laboratory for analysis, and the other for recording the sample result. Under the proposed rule, large establishments would test and record microbiological results for enteric pathogens, at both pre-evisceration and post-chill, 13 times a day; small high-volume establishments, one-time a day; and small low-volume and very small establishments, 13 times a year. FSIS estimates that large establishments would test and record microbial results for the pre-operational environment weekly; small establishments, biweekly; small low-volume and very small establishments, monthly. Furthermore, all swine slaughter establishments operating would have to maintain records that document that the products resulting from its slaughter operations meet the definition of RTC pork products.

FSIS is also proposing that each establishment operating under the NSIS submit on an annual basis an attestation to the management member of the local FSIS circuit safety committee stating that it maintains a program to monitor and document any work-related conditions of establishment workers.

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 enteric pathogens in official swine slaughter establishments. 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 582 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 <u>Federal Register</u> on February 1, 2018, 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 reporting and recordkeeping requirements associated with this information collection is 57,077 hours.

FSIS estimates that a total of 610 establishments would conduct a micro test 226,083 times annually for a total of 9,420 hours.

MICROBIAL TESTING (9 CFR 310.25)

(0.011,020120)						
Type of Establish- Ment	No. of Respon- dents	No. of Responses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours	
Large	28	6,846	191,688	2.5	7,987	
Small (high vol)	49	430	21,070	2. 5	878	
Small (low vol)	54	25	1,350	2.5	56	
V. Small	479	25	11,975	2.5	499	
Total	610	7326	226,083		9,420	

FSIS estimates that a total of 610 establishments would record the results of a micro test 226,083 times annually for a total of 47,656 hours.

MICROBIAL TESTING DATA RECORDKEEPING (9 CFR 310.25)

Type of Establish- Ment	No. of Respon- dents	No. of Responses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Large	28	6,846	191,688	12.5	39,935
Small (high vol)	49	430	21,070	12.5	4,390
Small (low vol)	54	25	1,350	15	338
V. Small	479	25	11,975	15	2,994
Total	610	7,326	226,083		47,656

FSIS estimates that a total of 41 respondents would provide attestations on work-related conditions 41 times annually for a total of 1.37 hours.

ATTESTATION OF WORK-RELATED CONDITIONS

	Estimated No. of Respon- dents	No. of Responses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Large	28	1	28	2	.93
Small (high	13	1	13	2	.43

	Estimated No. of Respon- dents	No. of Responses per Responden	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
vol)					
Total	41		41		1.37

The cost to the respondents is estimated at \$2,226,003 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 57,077 hours and \$2,226,003. 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:

The cost to the Federal Government for these information collection requirements is \$850,000 annually.

15. Reasons for Changes in Burden:

This is a new information collection with an estimated 610 respondents, 452,207 responses, and 57,077 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.