

SUPPORTING STATEMENT JUSTIFICATION FOR INDUSTRY RESPONSES TO NONCOMPLIANCE RECORDS

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a new information collection of burden hours for Industry Responses to Noncompliance Records

The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided 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 and poultry products are safe, wholesome, not adulterated, and properly labeled and packaged.

If FSIS in-plant personnel discover noncompliances with regulatory requirements they issue Noncompliance Records (NRs). Establishment management has the opportunity to respond in writing.

2. How, By Whom and Purpose Information Is To Be Used:

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

Responses to Noncompliance Records

The Noncompliance Record, FSIS Form 5400-4, serves as FSIS' official record of noncompliance with one or more regulatory requirements. Inspection program personnel use the form to document their findings and provide written notification of the establishment's failure to comply with regulatory requirement(s). The establishment management receives a copy of the form and has an opportunity to respond in writing using the Noncompliance Record form. Response by the establishment's management is voluntary.

There are a total of 136,000 burden hours for the information collection requests relating to establishment responses to receiving a Noncompliance Record.

3. Use Of Improved Information Technology:

FSIS fills out the FSIS 5400-4 and prints off a copy for the establishment. Currently, the establishment manually writes its response to the Noncompliance Record on the form. When FSIS gets the Public Health Information System (PHIS) up and running, establishments will have the option of responding to Noncompliance Records electronically.

4. Efforts To Identify Duplication:

FSIS has determined that these information collections will not duplicate any other information collections. The required records and reports are not available from other sources, either within government or from non-government sources. There is no similar 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.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently would reduce the effectiveness of the meat, poultry, and 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.

There are no special circumstances that require the collection of information to be inconsistent with 5 CFR 1320.6.

8. Consultation With Persons Outside The Agency:

FSIS published a 60 day notice in the Federal Register (74 FR 31909; July 6, 2009). The Agency received 9 responses.

One comment from industry said that a Noncompliance Record took 2 hours to complete, not 30 minutes and the average number of NRs was 20 a year, not 5. Another comment said that the responses to NRs should help the public to better understand the situation at the establishment and that these records should be made available to the public on a timely basis. One comment said that the time to complete a Noncompliance Record was underestimated and that the

number of NRs an establishment would respond to per year is underestimated. One comment said that FSIS does not do a good job of inspection.

One trade association said that 20 NRs per establishment was a better estimate. Another trade association said that FSIS had very much underestimated the time it takes to respond to a NR and the number of times an establishment would respond to a NR in a year. Moreover, it suggested that initial NR appeals be addressed to the Front Line Supervisor and not to the person who wrote the NR and suggested a completely electronic NR that would permit an electronic response by the establishment. And one trade association also said that the Agency underestimated the time it takes to respond to a Noncompliance Record.

One public interest group said that FSIS should require written Noncompliance Records and written responses for all humane handling violations. These records should be made for readily accessible to the public. In addition, FSIS should provide more guidance to industry on what information to include in its responses. The Agency should also provide more space on the form to allow for the establishments' responses and for FSIS inspectors' comments.

FSIS also contacted several industry people through a trade association (Lloyd Hontz; 202/639-5924). The comments said that the number of NRs that establishments respond to annually was underestimated—the number is closer to over 100,000 than 25,000. In addition, the commentors thought that it took between 1 to 2 hours to respond (on average) to a NR not the 30 minutes that the Agency had estimated.

Several of the comments mentioned that FSIS should not make the response to the NR mandatory.

In response to these comments, FSIS changed its estimate from 30 minutes to 60 minutes per response, from 5 to 20 NRs per establishment and a total of 136,000 hours.

9. Payment Or Gifts To Respondents:

Respondents do not receive gifts or payments.

10. Confidentiality Provided To Respondents:

No assurances other than routine protection provided under the Freedom of Information Act have been provided to respondents.

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 estimated burden for this information collection is 136,000 burden hours.

Responses to Noncompliance Reports

FSIS estimates that 6,800 establishments will 20 times a year take an average of 60 minutes to respond to a Noncompliance Record for a total of 136,000 responses and 136,000 hours.

**RESPONSES TO NONCOMPLIANCE RECORDS
(FSIS Form 5400-4)**

Type of Establish-Ment	No. of Respon-dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Ests./I-houses	6,800	20	136,000	60	136,000

The cost to the respondents is estimated at \$4,670,000 annually. The Agency estimates that it will cost respondents \$35 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total of 136,000 hours and \$4,670,000.

13. Capital, Start-up Cost, And Subsequent Maintenance

There are no capital or start-up costs related to this information collection activity.

14. Annual Cost To The Federal Government:

The cost to the Federal Government for this information collection is \$700,000 annually. The Agency estimates a cost of \$35 per hour for the time of its personnel.

15. Reasons For Changes In Burden:

This is a new information collection of 136,000 hours.

16. Tabulation, Analyses And Publication Plans:

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

17. OMB Approval Number Display:

The OMB approval number will appear on required FSIS forms. FSIS requests that it not be required to put the expiration date of the information collection of the form. Being required to put the expiration date on the form would place a burden of the Agency because 1) it would require FSIS to print new forms with the expiration date on them and would render the forms unusable in three years; 2) at the end of the approval period FSIS could not print up new forms until OMB gave a new expiration date causing unnecessary delay; and, 3) there is often a time lapse of several months between the date when the expiration expires and the time when OMB will finally give (usually) a three year approval to the extension or revision causing an almost impossible situation of attempting to having forms with the correct expiration date on them.

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.