

Docket Clerk
U.S. Department of Agriculture, Food Safety and Inspection Service
1400 Independence Ave., S.W.
Room 2543, South Agriculture Building
Washington, D.C., 20250-3700

Re: Docket number FSIS-2009-0016

We respectfully submit these comments in response to the July 6, 2009 *Federal Register* Notice entitled: "Notice of Request for a New Information Collection (Industry Responses to Noncompliance Records)," FSIS Docket 2009-0016.

We understand that the Food Safety and Inspection Service (FSIS) is obligated to issue this notice whenever it wishes to impose a new information collection on the private sector.

FSIS apparently intends to impose a new requirement that establishments must provide written responses to noncompliance records (NRs), FSIS Form 5400-4. We **oppose** such a new information collection for the reasons discussed below.

The Absence of Regulatory Authority

We respectfully question the existing regulatory authority under which FSIS is requiring an establishment to provide a written response to the NR. Existing HACCP and SSOP regulations (9 CFR §§ 416.16 and 417.5) mandate that an establishment take and document corrective actions. However, those regulations do not mandate such documentation be on an FSIS Form, such as the NR. For all other noncompliances, the establishment has responsibility to take corrective actions, however, there is not a regulatory requirement to document the actions taken, let alone a requirement to provide a written summary of the actions to FSIS.

Responses to Questions Posed in the Notice

The Notice contains a series of questions designed to assist FSIS and OMB in determining both the benefit and the burden of the new information collection. We believe that no benefit is achieved and that the burden has been significantly underestimated.

We respectfully submit that written responses to NRs is not necessary for the proper performance of FSIS duties. The inspection program personnel are to assess regulatory compliance, document instances of noncompliance and verify the establishment undertakes actions in response to a noncompliance. For certain noncompliances, the establishment is to document corrective actions. If the establishment has met this

obligation, it should not be necessary for the establishment to copy the documentation for entry onto an NR.

We have significant concerns regarding the time estimates presented by the Agency. We spend on average a minimum of two hours (120 minutes) responding to an NR. This includes reviewing the situation, documentation, and meeting with inspection personnel. This is at least four times more time than the 30 minutes per response estimated by FSIS.

Additionally, our company received an average of 12 NRs per establishment in 2008, compared to the 5 NRs annually per establishment estimated by FSIS. Moreover, the Agency's estimate of 5 NRs per plant is inconsistent with its own published data on the number of NRs issued on an annual basis. In the FSIS Quarterly Enforcement Report for 2008, the Agency issued 117,428 NRs in 2008. Given there are less than 6,000 establishments, the average number of NRs documented annually per establishment would be 20, not 5.

In closing, we strongly urge OMB and FSIS to re-consider the necessity of making the establishment response to the NR mandatory. FSIS personnel can continue to complete the form and the industry should continue to have the flexibility to determine the proper location to document its actions in response to a noncompliance.

Respectfully submitted,

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