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**SUBMITTED VIA ELECTRONIC MAIL**

Docket Clerk  
USDA Food Safety and Inspection Service  
1400 Independence Avenue SW  
South Agricultural Building, Room 2534  
Washington, DC 20250-3700

**Re: Docket No. FSIS-2009-0016  
Comments on FSIS New Information Collection Concerning the  
Responses by Official Establishment to Noncompliance Records**

To All Whom It May Concern:

This letter offers comments on the recently announced intent of the USDA Food Safety and Inspection Service (FSIS or Agency) to collect new information concerning responses by official establishments and plants to noncompliance records. FSIS Notice, 74 Fed. Reg. 31909 (July 6, 2009). Specifically, FSIS has announced an intent to collect written responses from official establishments to noncompliance records, and to do so by "using the noncompliance record form." I strongly support the Agency's routine collection of this new information,<sup>1</sup> and offer the following comments by way of explanation.

- (a) The Proposed Collection of Information is Necessary For the Proper Performance of FSIS's Functions, and Will Have Significant Practical Utility.

As stated in its announcement seeking public comment, "FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and properly labeled and packaged." (74 FR 31909). The Agency also explained that:

The noncompliance record, FSIS Form 5400-4, serves as FSIS's official record of noncompliance with one or more regulatory requirements.

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<sup>1</sup> In addition to being an expression of personal support, my support and comments are also offered on behalf of Marler Clark, LLP, a law firm dedicated to food safety advocacy and the representation of all persons injured as a result of foodborne illness outbreaks, including those related to adulterated meat.

Inspection program personnel use the form to document their findings and provide written notification of the official establishment's or plant's failure to comply with regulatory requirements.

*Id.* This documentation is important for a number of reasons, including the fact that the noncompliance records (NR) are the only means for the public to view the track-record of a given official establishment with regard to regulatory compliance. It is thus no accident that public attention is often focused on the history of NR's at a meat plant when illnesses are linked meat processed there. One need only look at the media coverage that outbreaks and recalls generate, and notice how often reporters write stories that detail the inspection records at a given plant, as evidenced by NR's and Comprehensive Assessments.

Over the last seventeen years, I have reviewed thousands of NR's involving many dozens of official establishments.<sup>2</sup> Although NR's can and do provide useful information about plant operations, experience has taught me that a response to an NR will tell you more than the NR itself about plant management, its approach to regulatory compliance, and its relationship with FSIS and inspection personnel. For example, there can be plants with near-identical instances of noncompliance, but responses can be as different as they are revealing. Indeed, responses are what provide the context needed to understand how and why the noncompliance occurred in the first place. Thus, anyone wanting to get an accurate understanding about a meat plant's management and operation will require the opportunity to review not only the NR's, but also the responses.

By having a more accurate and complete record of regulatory compliance at every official establishment, the Agency and all stakeholders benefit. Increased transparency is a *per se* benefit because it allows for increased accountability. The Agency will also be in a better position to make future decisions and rule-making if NR's have a corresponding written response. For example, FSIS will be able to search responses for information that can be used to offer improved guidance to other plants.

Finally, for those interested in coming to a fuller understanding of how FSIS does its job, that cannot be done without seeing the kinds of responses that FSIS accepts or not in response to an NR. By way of illustration, it would be similarly impossible to know the quality and effectiveness of traffic enforcement in a city if you knew that officers issued 150 infraction-notices per month, but did not know that infractions were dismissed upon a promise that drivers would try harder in the future, and try not to change lanes without signaling again. It is therefore necessary and important that written responses to all NR's are collected as part of the Agency's regulatory compliance function.

(c)<sup>3</sup> FSIS Should Enhance the Quality, Utility, and Clarity of the New Information By Making All NR's and NR-related Records Available Online As Soon As Possible.

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<sup>2</sup> To be accurate, prior to the adoption and implementation of the HACCP regulations, it was not NR's, but Process Deficiency Records that I reviewed.

<sup>3</sup> No comments are offered with regard to "(b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used."

Except for proprietary information that NR's and related materials might contain, these documents are public records that must be made available for inspection as a matter of law. Currently though, it takes months—and often more than a year—to obtain copies of such public records. And there is simply no excuse for that. In the vast majority of the cities and counties across the United States, one can view restaurant inspection reports as easily as going online or, at minimum, by obtaining photocopies in a few days from at the local health department. In contrast, FSIS discloses inspection record only in response to a FOIA request, and at a pace so slow that records are irrelevant by the time obtained.

What is particularly indefensible about the failure to make sure inspection records are available on a timely basis, is that increased transparency is one of the more effective tools that FSIS has to incentivize regulatory compliance, and thus product safety. If the public could go online, enter an Establishment Number, and so obtain inspection records for that plant in seconds (instead of months), that plant will have an increased incentive to take all of the needed steps to ensure compliance with all regulatory requirements. But so long as plants can rest easily knowing that its NR's, and its responses to NR's (including repeated appeals), will not be seen by the public, at least not easily or quickly, then there is no real downside to failing to comply, or to resisting Agency efforts, and in forestalling corrective action. I know from repeated personal experience that not even an NOIE Letter gets the attention of some official establishment's—*e.g.*, Nebraska Beef Ltd. That might change, however, if not only the public, but also Kroger and WalMart, could check online to see both NR's and responses. In short, by increasing the transparency of the inspection and enforcement process, FSIS will increase the accountability of both itself and the official establishments it inspects.

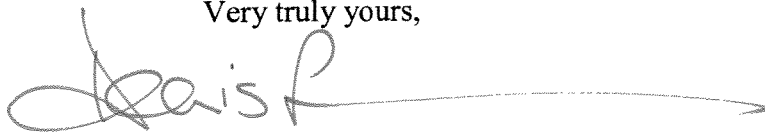
(d) FSIS Can Minimize the Burden of the Collection of the Information By Building Redaction of Proprietary Information Into the Initial Collection Process.

The FSIS inspection process is now largely computer-based, and the information is mostly stored electronically. The NR's currently being disclosed pursuant to FOIA are redacted as PDF documents, compared to the manual redaction that occurred not too long ago. Given the current relative sophistication of the information collection process, it will not be too difficult to automate the redaction process so that it occurs at the time that the NR and responses are generated. For example, the official establishment could be asked to propose the redactions as part of the response. If this was to happen, every NR and its response could be made available for public inspection, in near real-time.

In conclusion, let me emphasize that the FSIS plays a vital function in “protecting the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and properly labeled and packaged.” (74 FR 31909). What FSIS inspectors do inside official establishments, they do on behalf of the public and its safety. As such, the public has a right to a view of the inspection process, including knowing how it is that a given meat plant responds to a particular NR. More importantly, the public has a right to view the NR's and all related inspection and enforcement records as quickly and easily as possible. Currently, the only way to view these public records is pursuant to a FOIA request that will likely not result in the disclosure of documents for months, if not years.

This is not how it should be, and it must change. I thus respectfully submit that FSIS is correct in seeking to collect new information about NR-responses, but that it should also go further in making sure that all information so collected is made available to the public online as soon as possible.

Very truly yours,

A handwritten signature in dark ink, appearing to read "Denis W. Stearns", followed by a long horizontal line extending to the right.

Denis W. Stearns

cc: File