



June 9, 2006

Docket No. 04-006P
FSIS Docket Clerk
U.S. Department of Agriculture,
Food Safety and Inspection Service
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, D.C. 20250

Re: Docket No. 04-006P – Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

Dear Sir/Madam:

The American Meat Institute (AMI or the Institute) submits the following comments regarding the above-referenced proposed rule. AMI represents the interests of packers and processors of beef, pork, lamb, veal, and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb, and veal products, and 70 percent of the turkey products in the United States. The Institute provides legislative, regulatory, public relations, technical, scientific, and educational services to the meat and poultry packing and processing industry.

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It is important that relevant information be communicated to consumers in the most effective manner possible in the event of a recall. The above-referenced proposal published by the Food Safety and Inspection Service (FSIS or the agency), however, will not accomplish that objective. Indeed, as the agency articulated less than four years ago when it last amended this regulation, the very type of disclosure contemplated in this proposed rule could have an adverse effect on recall efficacy, and concurrently on public health. For that reason alone, and for the other reasons articulated in the comments provided below, this proposal should be withdrawn. AMI, however, would be pleased to work with the agency to identify ways to enhance recall efficiencies.

Adoption of the Proposal will Hamper the Currently Effective Recall Procedures and Adversely Affect Public Health.

As the preamble to the proposed rule provides, and as agency officials acknowledged at the public meeting they held on this issue, current recall procedures provide all necessary product identifying characteristics to allow consumers to determine if they possess a meat or poultry product subject to recall, regardless of where the product was purchased.¹ Indeed, Phil Derfler, FSIS Assistant Administrator for the Office of Policy, Program and Employee Development said, “FSIS considers its recall process to be effective. The Agency believes that the measures it has put in place are effective in communicating to the public that a firm has decided to recall product.”² Existing agency procedures encourage consumers to do the single most important thing to avoid consuming a product subject to recall: check the product in their possession against the identifying characteristics to determine if that product is subject to recall.

¹ 71 *Fed. Reg.* 11327 (March 7, 2006)

² Philip Derfler, FSIS Assistant Administrator, OPPDE, April 24, 2006, Transcript of Public Meeting on Proposed Rule on the Availability of Lists of Retail Consignees During Meat and Poultry Recalls (Transcript), p. 22. In the same meeting Undersecretary for Food Safety Dr. Richard Raymond said “I think the current recall system that is in place at FSIS is a strong one.” Transcript at 5.

The very questions raised by this proposal were contemplated and rejected by the agency just a few years ago. In that regard, in 2002 FSIS amended the regulations at issue here and in doing so considered and rejected the concepts inherent in this proposed rule.³ Specifically, in the preamble to the final rule, FSIS concluded that dissemination of this information to the public would be harmful to the public health, saying:

Distribution information is confidential commercial information that is valuable to a firm and to its competitors. **FSIS recognized that if it made the information regularly available to the public, firms would be unwilling to voluntarily share this information with the Agency. The Agency's ability to verify that recalls were proceeding effectively would be significantly hampered as a result, and the public health would consequently suffer.**⁴

Significantly, nowhere in the current proposal does FSIS explain why it apparently has reversed its conclusion such that now disclosing this type of information will not significantly hamper the agency's "ability to verify recalls were proceeding effectively" nor, as it previously concluded that "the public health would consequently suffer."⁵

Rather than provide substantive reasons to support the proposal, the agency offers general comments in the preamble that some state officials have asserted that they could better protect public health by using retail consignee information, without the limitations imposed by the current regulations, 9 CFR 390.9(a)(1).⁶ Nowhere in the preamble or in the available administrative record is there anything to substantiate this assertion made by these anonymous state officials. Indeed, the agency does not provide a shred of information or any details to support these assertions (*e.g.*, number of states offering such a view, the rationale provided by the state officials to support their assertion that overcomes the earlier FSIS conclusion, measurements used to predict improvements in public health, examples illustrating the assertions, *etc.*).

³ See Final Rule, Sharing Recall Distribution Lists with State and Other Federal government Agencies, 67 *Fed. Reg.* 20009 (April 24, 2002).

⁴ *Id.* at 20010.

⁵ *Id.*

⁶ 71 *Fed. Reg.* 11327 (March 7, 2006).

The agency also states that “consumer groups believe that making the retail distribution information readily available will materially improve the effectiveness of recalls.”⁷ Again, neither in the preamble to the proposal nor in the publicly available docket does FSIS provide anything other than the opinion of these groups to substantiate these assertions. In that regard, there is no rationale articulated, nor is there any supporting data or examples of inefficiencies related to the absence of the retail data that support the conclusion that the proposed change would “materially improve” recall effectiveness. Adoption of the proposed changes in the absence of articulated reasons, with some form of support for those reasons, particularly given the agency’s previous conclusions, suggests that promulgating a final rule incorporating the proposed language would be arbitrary and capricious and in violation of the Administrative Procedure Act (APA).

The Proposed Rule Likely Would Mislead Consumers.

The proposal could adversely affect public health in another way, with dire consequences. The agency apparently has not considered the possible negative consequences of the proposed action. For example, current recall procedures provide the necessary product identifying characteristics so that consumers can check products, regardless of where a product was purchased. The agency suggests that if retail consignees are identified consumers would “focus on the products that are recalled.” However, it seems far more likely that the proposal will encourage people to check the product only if they remember visiting a retailer identified in the message.⁸

⁷ *Id.*

⁸ Unfortunately, the proposed rule does not appear to take into account the intricate nature of the food distribution system. For example, the proposal does not consider store-to-store transfers or other movement of products after they reach their initial retail destination.

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In that regard, adoption of the proposal could inadvertently provide consumers with a false sense of security, which could place them at greater risk. If the agency implements the proposal as FSIS has indicated, with an initial retail consignee list posted on a website and then amended and updated over time as more information is gathered by FSIS, such an approach presents the following very real possibility. A consumer becomes aware of a recall involving a product, checks the FSIS website on that day or perhaps the day after, does not find the store where he or she shopped because the list is not complete, and uses the product subject to recall relying on an incomplete posting.

FSIS officials asked during the public meeting if this problem can be resolved by incorporating a noticeable disclaimer on the website advising that the information is incomplete.⁹ Posting such a disclaimer will force consumers to check repeatedly the website to determine whether the store or stores at which they shop will ever be posted. Indeed, how will the consumer ever know, in a timely manner, if the store where they purchased the product will ever be posted, and what could be the impact if the consumer uses the product after checking the website once, twice, three times, or more, only to use it and have the store listed the next day?

In the alternative, if FSIS posts the list only after all retail stores are identified through the FSIS effectiveness checks, that process certainly will take a considerable period of time, often weeks according to FSIS Assistant Administrator Derfler. That model results in a list being posted well after the press release is issued and having no value.¹⁰

⁹ See Transcript at 25-26.

¹⁰ See Transcript at 20, 25.

Moreover, the agency's website posting can be accurate and complete only if FSIS officials visit every intermediate distribution entity at all levels between the producing company and the retail entities – a practice not currently followed by the agency. To extend those effectiveness checks to cover every entity would significantly increase the resources that FSIS must expend, an expenditure that seems to have at best very marginal, if any, benefits given the admitted efficacy of the current program. In short, failure by FSIS to fulfill those tasks will lead to an incomplete list, possibly leaving some consumers to believe, wrongly, that the product they purchased is not subject to recall. In any scenario, the proposed rule creates the possibility that consumers will be confused or misled, thereby adversely affecting the public health.

The Proposal Violates the Freedom of Information Act.

FSIS states in the preamble to the proposal that “it has authority to make available lists the Agency has compiled during recalls of the retail consignees of meat and poultry products that have been recalled.”¹¹ The proposal, however, provides no rationale for this conclusion nor is there any explanation in the preamble or the available administrative record regarding why FSIS reversed its longstanding legal position that this type of information is confidential commercial information.¹²

Indeed, the agency's assertion is a clear deviation from the longstanding and relatively recently affirmed agency position that such information is confidential commercial information, as defined by the Freedom of Information Act, and is exempt from disclosure under that Act.¹³ Indeed, at the April 24, 2006, public hearing regarding this proposal, Undersecretary for Food Safety Richard Raymond acknowledged that the very type of information the agency seeks to publish on the website is confidential commercial information.¹⁴

¹¹ 71 *Fed. Reg.* at 11327

¹² 67 *Fed. Reg.* at 20010.

¹³ *Id.*

¹⁴ Transcript at 7.

In addition, in the preamble to the 2002 final rule amending 9 CFR 390.9 FSIS stated that the new subsection “would enable FSIS to share with State agencies and other Federal agencies certain confidential commercial information, specifically, distribution lists from the firm recalling a meat or poultry product, which are protected from mandatory public disclosure by exemption 4 of the FOIA (5 U.S.C. 552(b)(4)).”¹⁵ In so saying the agency unequivocally acknowledged the confidential nature of this type of information and established a detailed process that states and other federal agencies would have to satisfy to be provided the information at issue.

That FSIS has considered the very type of information considered for release here to be confidential is evidenced again and again in agency correspondence. Indeed, the administrative record in this docket is replete with letters and other communication to consumers, members of Congress, and state officials emphasizing that distribution lists “are part of an establishments’ confidential commercial information.”¹⁶

The agency seeks to sidestep its longstanding position through its assertion that the list of retail consignees of recalled meat and poultry products and states is based on a list compiled by FSIS, with the agency’s subsequent conclusion that such information will not be “customer lists of any company.” Simply put, this position is a disingenuous fig leaf because the agency cannot glean the information it proposes to disseminate to the public from any source other than the recalling company and its customers.

In short, the legal shell game engaged in by the agency to try to justify publishing confidential commercial information violates the APA, which also requires FSIS to explain why it is deviating from long held agency policy. That the agency has such an obligation is even more pressing when, less than four years ago, the agency reiterated that such information is confidential commercial information when it amended the very regulation at issue here. In this case, however, the available administrative record and the preamble provide no such explanation or legal rationale.

¹⁵ 67 *Fed. Reg.* at 20010 (April 24, 2002).

¹⁶ Letter from Philip S. Derfler, Assistant Administrator, FSIS to Reverend Lloyd Cresci, December 17, 2004. See also, “FSIS has traditionally treated consignee identities and distribution lists obtained during recalls as confidential business information.” Letter from Philip S. Derfler to Jennifer M. Lyons, May 19, 2005; Letter from Philip S. Derfler to Dr. Michael Jacobsen, Enter for Science in the Public Interest (October 29, 2004); Letter for Philip S. Derfler to the Honorable Russell D. Feingold (July 21, 2005).

The Proposal Would Violate the Data Quality Act.

The Data Quality Act (DQA) requires that federal agencies promulgating regulations do so in a manner such that the quality of the data is not compromised, is timely, and is of sufficient quality.¹⁷ In this case the proposal achieves none of those objectives.

If the proposal becomes final, the agency could implement the rule in the two ways discussed above. Either the list of consignees could be published *en toto* when finally compiled or it could be published in an incomplete form when the first information becomes available to FSIS, and subsequently supplemented. Either approach is inconsistent with the DQA. In the first scenario, publishing the complete list would not be timely. As FSIS officials admitted at the public meeting, it can and likely will take weeks in most recalls for the agency to compile the list.¹⁸ No colorable argument can be put forth by FSIS contending that, in the case of recalls involving the public health, publication of the list weeks after the recall has been initiated by the relevant company would be timely has utility.¹⁹

On the other hand, the agency could follow an approach suggested at the public meeting, *i.e.*, that the list will be published with information gathered relatively soon after the recall is initiated and then supplemented as the agency conducts its effectiveness checks. In that circumstance FSIS officials acknowledged that the information initially posted and even supplemented thereafter likely will be incomplete, and again in violation of the DQA.²⁰ Following either approach, the agency cannot overcome the requirements imposed by the DQA with respect to this ill-conceived proposal.

The Proposal Would Result in More, not Less, Product Being Returned.

¹⁷ 44. U.S.C. 3504(d)(1) and 3516; Pub. L. No. 106-554, § 515 Appendix C, 114 Stat. 2763A-153 (2000)

¹⁸ See Transcript at 20, 25.

¹⁹ See USDA Quality of Information Guidelines “Use reasonably reliable and reasonably timely data and information (e.g., collected data such as from surveys, compiled information, and/or expert opinion). http://www.ocio.usda.gov/qi_guide/regulatory.html. (Visited June 6, 2006).

²⁰ See Transcript at 20, 25.

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Contrary to the preamble's assertion, publishing the list of retail consignees will almost certainly increase the likelihood that many products beyond the scope of the recall will be returned to retail establishments. The very mention of the retail venue stands to trump the product codes and will result in mass concern -- and mass return, particularly in light of the almost certain delay in time between the publication of the press release and the compilation of the complete retail consignee list.

Imagine, for example, a federal agency announcing a tire recall with the statement "Super Tough Radial Tires, code 555-XYZ sold at Sears, Midas and Costco stores are being recalled." Or imagine FDA recalling Acme Aspirin Tablets ABC-999 sold at CVS, Walgreens, and Rite Aid Drug Stores. The mention of the retail venue stands to trump the product codes and will result in mass concern -- and mass return.

When recalls become larger and needlessly involve consumers who do not own recalled product, consumers may become immune to recalls and tune out important information. Common sense says that information that can affect health should be specific, relevant, and meaningful, yet the agency is proposing a program that could shift consumer focus to less-specific considerations. This approach likely would result in circumstances in which consumers return a product to a store when the product has NOT been recalled.

Moreover, as with other elements in the proposal, the agency's conclusion is flawed in that it provides no rationale or information to explain how publishing retail consignee information will help make clear "that other, similar products are not being recalled," because the retail consignee list has nothing to do with the product, except where it was sold. Certainly, virtually all retailers will sell numerous meat and poultry products such that the retail name will not serve in any way to differentiate products, as asserted in the proposed rule. In short, to justify the proposed change, FSIS needs to provide a rational explanation supporting its conclusion rather simply making the self-serving conclusion that such a publication would help in product identification and recall efficacy.

No Federal Agency with Recall Authority Publishes Retail Information of the Nature Proposed.

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Finally, the agency seeks to break new ground with this proposal in that, although a number of other federal agencies either have mandatory recall authority or are involved in recalls of products, none of them follow the process suggested in the proposal. For example, the Consumer Product Safety Commission (CPSC), which has mandatory recall authority in at least some circumstances, does not list each retail entity that sold a product subject to recall.²¹ Nor does the Food and Drug Administration, the other federal agency with jurisdiction over food products.²² Indeed, none of the federal agencies involved in recalls, including CPSC, FDA, the Environmental Protection Agency, the National Highway Traffic Safety Administration, and the United States Coast Guard provide the type of retail consignee information that FSIS proposes to publish.

That all other agencies with an active role in the recall of defective products from the marketplace do not engage in the behavior proposed suggests that the publishing of retail consignees is a bad idea, because it is against the law, because it will harm consumers by providing inaccurate or incomplete information, or because it will adversely affect the efficacy of recalls, or for all three reasons. FSIS should not seek to lead the way in promoting suspect or bad public policy.

For the foregoing reasons this proposal should be withdrawn. AMI appreciates the opportunity to submit these comments and would be happy to

²¹ See <http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>

²² See <http://www.fda.gov/opacom/7alerts.html> and see www.fda.gov/opacom/Enforce.html (Visited June 6, 2006).

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work with FSIS to find ways that will improve the efficacy of recalls involving meat and poultry products.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'Mark Dopp', with a long horizontal flourish extending to the right.

Mark Dopp
Senior Vice President & General
Counsel
American Meat Institute

cc: J. Patrick Boyle
Skip Seward
Lynn Morrissette
Jim Hodges
Susan Backus