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Docket Clerk
U.S. Department of Agriculture
Food Safety & Inspection Service
300 12th Street, SW
Room 102, Cotton Annex
Washington DC 20250

Re: Proposed Availability of Lists of Retail Consignees during Meat or Poultry Product Recalls (Docket No. 04-006P)

Dear Sir or Madam,

The Food Marketing Institute[1] (FMI) appreciates the opportunity to respond to the U.S. Department of Agriculture (USDA) Food Safety & Inspection Service's (FSIS's) proposal to post the names of retail consignees of meat and poultry products that have been voluntarily recalled on the Agency's website. 71 Fed. Reg. 11326 (March 7, 2006).

At the outset, we join with USDA in recognizing that the data demonstrate that the incidents of foodborne illness have declined dramatically in recent years as a result of improvements in our food safety systems. Moreover, we agree with USDA that, in those circumstances in which a recall is necessary, the current system is effective. With respect to consumers, our current system encourages them to do the single most important thing that they can to protect themselves: check their refrigerators and freezers for adulterated products and dispose of them immediately.

We are concerned, however, that the proposal under consideration would shift consumer focus away from the adulterated product itself. Indeed, instead of encouraging consumers to check products in their possession, consumers would be encouraged to check and re-check lists that the Agency intends to post on its website over the course of days or weeks after a recall has been initiated and which the Agency acknowledges will be incomplete. Accordingly, while FMI and its members support the goals of further improving

[1] Food Marketing Institute (FMI) conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

the recall system, we cannot support a proposal that USDA acknowledges will provide incomplete and untimely information to consumers, and may well endanger public health by discouraging consumers from checking the products in their possession, regardless of where they were purchased.

A. Background

Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, USDA is responsible for ensuring that meat and poultry products are safe, wholesome, and accurately labeled. If there is a reason to believe that meat or poultry products in commerce are adulterated or misbranded, FSIS will request that the firm that introduced the products into commerce recall them. If the establishment does not agree to recall the products, FSIS has the authority to detain and seek seizure of the products.

Under the current statutory scheme, it is the responsibility of the recalling firm to conduct the recall and to ensure that its actions have been sufficient to remove product from the marketplace. Toward this end, the recalling firm will notify the consignees of the product in question that they may have received meat or poultry products that may be adulterated. The recalling firm may do so by making phone calls or issuing letters, faxes, emails, and various other communications. Subsequent consignees are, in turn, expected to notify their consignees.

FSIS notifies the public by distributing a press release to wire services and media services in the areas where the product was distributed. The notice provides the public with information about the meat and poultry recall, including a description (and often a picture) of the food being recalled, any identifying codes, the reason for the recall, the name of the producing establishment, the level of product distribution, the recall classification, and contact persons at FSIS and the recalling company. On a case-by-case basis, the recalling firm may also notify the public via press release, public announcements, signs or other means.

After the recall is initiated, FSIS conducts recall effectiveness checks to verify that the recalling firm has been diligent and successful in notifying and advising the consignees of the need to retrieve and control recalled product and that the consignees have responded accordingly. FSIS Directive 8080.1, Rev. 4, Attachment 3. FSIS uses a statistical sampling plan to identify a sample of consignees to verify the effectiveness of the recall. The FSIS recall directive indicates the number of effectiveness checks that the Agency will conduct as a function of the number of consignees and the class of the recall. For example, for a class I recall, FSIS will conduct the following effectiveness checks:

Number of Consignees	Number of Effectiveness Checks	Percentage of Consignees Checked
1 – 200	100%	100%
201 – 10,000	200	100% - 2%
10,001 – 35,000	800	8% - 2%
35,001 – 500,000	800	2% - 0.16%
500,001 and over	1,250	<0.25%

In terms of timing, the Directive indicates that the verification checks should begin 3 working days after the onset of a class I recall and conclude 10 days later; longer periods are given for class II and III recalls.

During the recall effectiveness checks, FSIS obtains the names of the consignees of the recalling firm. As the Agency executes its statistical sampling plan, FSIS gathers from the consignees information on the identities of further consignees of the products. In the proposal under consideration, FSIS is considering releasing the retail consignee information obtained through the effectiveness checks conducted under the sampling plan set forth in the directive.

B. FMI Cannot Support a Proposal That Would Result in the Dissemination of Incomplete and/or Untimely Information to the Potential Detriment of Public Health

As discussed more fully below, we are concerned that, given the time lapse between the onset of a recall and the time in which the information is compiled by FSIS through its effectiveness check procedure and given the inherent incompleteness of the information obtained, the information that USDA proposes to release will not accomplish the goals of improving the recall system and will, in fact, mislead consumers. FMI cannot support a proposal that would result in the dissemination of incomplete and untimely information to the detriment of public health.

1. USDA Acknowledges, and FMI Agrees, That the Current System Is Effective.

The single most important characteristic of a recall system is for it to be effective at removing adulterated food products from the public domain. USDA and FMI both agree that the current system described more fully above is effective at achieving this goal. Indeed, FSIS Assistant Administrator for the Office of Policy, Program and Employee Development Mr. Philip Derfler noted USDA's conclusion at an April 24, 2006 public meeting to discuss the proposal:

> 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]

Nonetheless, FMI agrees that ways to improve the system should be sought and implemented when appropriate.

2. USDA Has Historically Held That Releasing This Information Would Endanger Public Health and Does Not Explain Here Why a Change Is Warranted

[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 (hereinafter "Transcript") at 22.

As recently as 2002, USDA reviewed the issue of releasing distribution list information to the public. 67 Fed. Reg. 20009 (April 24, 2002). At the time, the Agency concluded that if distribution list information was made publicly available, "the Agency's ability to verify that recalls were proceeding effectively would be significantly hampered . . ., *and the public health would consequently suffer*." Id. at 20010 (emphasis added). Indeed, the Agency concluded that, "[t]o enhance cooperation with State and other Federal government agencies, FSIS needs the ability, in some circumstances to disclose certain confidential commercial information to other agencies while still protecting the confidentiality of the information in all other respects." Id.

Given the well-articulated strength of its convictions on this matter in 2002, USDA must support the proposed change of course with a strong rationale and data to explain why the Agency was wrong in 2002 and correct today. However, such rationale is noticeably missing, not only from the preamble, but from the docket itself, which does not include a single fact in support of the Agency's proposal.

In the preamble to the current rule, the Agency vaguely refers to "consumer groups and some state officials" who "believe that making the retail distribution information readily available will materially improve the effectiveness of recalls." 71 Fed. Reg. at 11327. "Material improvement" is a high standard of change and if it could be accomplished it would certainly be welcome. However, neither USDA nor the consumer groups or state officials offer any data or supporting rationale in the preamble to indicate how the change in policy would impact consumer behavior or improve public health. USDA cannot rely on unsubstantiated claims as a basis for making a substantial change in policy. Indeed, a radical shift in regulations devoid of rationale might well be deemed arbitrary and capricious in violation of the floor set for agency rulemaking under the Administrative Procedures Act.

3. USDA Has an Obligation To Issue Data That Is Timely and Accurate, Particularly When Public Health Is at Stake

Under the statutory provision commonly known as the Data Quality Act (DQA), the Office of Management and Budget (OMB) issued "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies," which must be followed by all agencies in the executive branch.[3] In compliance with the OMB Guidelines, USDA issued its own Quality of Information guidelines that set forth the standard information quality criteria that the Agency will follow in developing and reviewing regulatory information and disseminating it to the public.

These standards apply to cost/benefit analyses prepared in support of rulemaking efforts, scientific analyses, and any other substantive analyses, document or procedures prepared in support of agency rulemaking activities or enforcement. Among others, the Agency is required to use data that are "reasonably reliable and reasonably timely." Indeed, throughout the Quality of Information guidelines that were developed at many of the agencies within USDA, the Department repeatedly reiterates that the information should be

[3] Congress directed OMB to issue these guidelines in Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554); section 515 is now commonly referred to as the Data Quality Act.

comprehensive, timely and reflect the most current information available. The guidelines apply to all information disseminated by USDA.

4. The Information USDA Proposes To Post Will Necessarily Be Incomplete and Untimely and USDA Has Acknowledged as Much

In this case, the data that USDA proposes to disseminate to the public will be both incomplete and untimely. As noted above, USDA proposes to post the information on retail consignees that the Agency obtains during its effectiveness checks. Those checks will occur over a period that is at least two weeks long if conducted within the time frame set forth in the recall directive (see above) and quite likely much longer. Indeed, Mr. Derfler stated at the April 24 public meeting that the recall effectiveness check process through which USDA intends to gather the information to be posted is time-consuming:

> The process of tracing the product forward to retail is, as I've said, very time consuming, often taking weeks to complete[4]….FSIS is not committing to a particular time frame for posting consignee lists. Under the proposal, the Agency will post them as soon as they are compiled, which, as I stated, could be weeks after the recall is announced.[5]

Given the length of time over which the retail consignee information will be compiled – *after the recall has already been initiated and consumers should already have checked the product in their possession* – the Agency will either be required to post the information in a piecemeal fashion, which will require consumers to check the website repeatedly to see if their retail location has been listed, or it will require the Agency to wait until all information is compiled before the information is posted. In the first case, the data certainly will not meet the standard that they be comprehensive or reliable. If the Agency chooses the second route, the information will be far from timely or serve any use to consumers who should have checked their kitchens for potentially adulterated product weeks earlier. Accordingly, the Agency's proposal fails to satisfy its obligations under the Data Quality Act.

Moreover, under USDA's current recall directive, USDA only checks a statistical sample of consignees, rather than all consignees. The percentage changes significantly given the size and class of the recall. Although the Agency will check all consignees in a class I recall if the number of consignees is 200 or less, that is the only circumstance under which USDA might achieve a complete list. Otherwise, as noted in the chart above, USDA will check no more than 8% and, in the largest recalls, less than 0.25% of consignees. As the Agency is only obtaining the retail consignee information that will be posted via recall effectiveness checks, the information will necessarily be incomplete.

At the April 24 public meeting, USDA suggested that the Agency might post a disclaimer with the information. Such a disclaimer is an inherent admission that the data are incomplete and unreliable. Any disclaimer would need to be sufficiently prominent and declarative to ensure that consumers understood the shortcomings of the USDA list and did not rely upon it to their detriment. *Any such notice should prominently remind consumers*

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[4] Transcript at 20.

[5] Transcript at 25.

that the most efficient way to determine whether they have adulterated product is to look for the product itself, regardless of whether any retailers at which they shop are posted on the website.

5. Changing USDA's Recall Effectiveness Check Process Would Have Significant Budgetary Impacts Without Any Concommitant Improvement in Public Health

As noted above, one of the significant shortcomings in the information that USDA intends to post derives from the fact that the Agency cannot possibly obtain complete information under its current recall effectiveness check system. Although the Agency does not articulate the system clearly in the preamble and raised more questions than answers at the public meeting, as we understand it, the Agency intends to post only the retail consignee information that is obtained during the recall effectiveness checks. Under FSIS's recall directive, the Agency only attempts to conduct effectiveness checks for all consignees in the smallest recalls – those with 200 or fewer consignees. All others are conducted on a statistical basis and in no case are more than 8% of retail consignees checked through recall effectiveness checks.

Changing USDA's policy to conduct recall effectiveness checks of all consignees for all recalls – which could be more than 500,000 consignees in some circumstances – would have enormous budgetary impacts. The benefit, if any, of such a change should surely be carefully evaluated before any such shift in policy is adopted.

6. Proposed Information Would Be Available Only to Those Consumers Who Have Sufficient Education and Means To Afford Internet Access and Who Have Learned of the Recall via Traditional Media Channels

USDA proposes only to post on its website information on retail locations that may or may not have received adulterated meat or poultry products. Therefore, the information will only reach those consumers who have enough savvy, sophistication, education, and income to own computers and understand how to search for this information on the internet. Accordingly, the proposal serves only a small percentage of the population.[6]

Moreover, only those consumers who are already aware of the recall as a result of press releases will even know to check the Agency's website to see if any additional information relevant to them is available. And, they will need to remember to check the website at least three days and perhaps several weeks after the press release has been issued to obtain the information. If the Agency decides on a piecemeal approach to posting the information, the consumer will need to check the website repeatedly over a period of days or weeks to determine whether any potentially useful information has been posted.

In contrast, under the present system, when the consumer receives notice of a recall from a press release, the consumer should get one message: check the product that is in your

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[6] Under its Quality of Information guidelines discussed above, USDA has an obligation to ensure that all consumers have access to information, including those who may have physical limitations.

refrigerator or freezer to see if it was recalled. This is the most useful message that the consumer can receive because, regardless of whether the consumer's store is listed on the website, the consumer may have the product in her possession. Only by looking at the product itself will the consumer know whether or not the product may pose a concern.

7. USDA's Cost-Benefit Analysis Does Not Support the Proposal

USDA, as all agencies, has a legal obligation to support the sufficiency of its regulatory amendments with an adequate cost-benefit analysis. In this case, the total analysis is as follows:

> Although the benefits of the proposed action are not quantified, it is reasonable to conclude that they are equal to or exceed the costs of the rule, because costs are expected to be minimal.

71 Fed. Reg. at 11327. The statement above is conclusory and offers no basis whatsoever for evaluating either the costs or the benefits of the Agency's action. Accordingly, the Agency has not met its obligation to perform a cost-benefit analysis. Indeed, given the potential public health concerns cited above that could result from the Agency's proposal, the Agency's simplistic statement is clearly inadequate.

8. USDA Has Not Adequately Addressed the Impact on Small Business Entities

Section 605(b) of the Regulatory Flexibility Act (RFA) requires federal agencies to evaluate the impact of their regulatory activities on small business entities. Indeed, the RFA requires agencies to perform a detailed initial regulatory flexibility analysis (IRFA) if the agency believes its actions will have a significant economic impact on small business entities or even if it is unsure of the impact.

In this case, USDA did not include an IRFA or even any factual basis for its certification that the proposed rule will not have a significant economic impact on a substantial number of small entities. The Agency only states its conclusion that the rule will not have a significant impact on a substantial number of small entities, but does not provide any rationale for its conclusion. 71 Fed. Reg. at 11327-28. Indeed, given the fact that the Agency determined that the rule is significant under Executive Order 12866, the Agency would seem to have a higher obligation to explain how it would not impact small business, despite the fact that it reaches the high standard of 'significance' established under E.O. 12866. In the grocery industry alone, there are more than 60,000 entities that meet the federal standard for small businesses.[7] The Agency has a duty to evaluate the impact of its proposed actions on these entities. USDA should conduct an IRFA to allow all affected parties the opportunity to understand and address the basis for the Agency's certification of no significant impact.

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[7] Nearly 35,000 supermarkets and 25,000 convenience stores meet the NAICS standards for small businesses.

9. USDA's Proposal Is a Significant Departure from Policy Followed by All Other Federal Agencies with Recall Oversight or Authority and Yet Is Superficial at Best in Its Analysis and Rationale

Under the current statutory system, numerous federal agencies are vested with the authority to initiate or oversee recalls of products that are suspected to violate the mandates of their statutory schemes. The Food and Drug Administration (FDA) has authority over adulterated or misbranded food products subject to its jurisdiction comparable to the authority given to USDA under its authorizing statutes. Indeed, while USDA regulates meat, poultry and some egg products, all other foods, as well as drugs, medical devices and cosmetics, are subject to FDA's jurisdiction. Other agencies with product recall authority or oversight include the Consumer Product Safety Commission, the Department of Transportation, and the Environmental Protection Agency.

Despite the broad number of agencies with recall authority, not a single one of these (including USDA at the present) believes that including the retail location at which the product may have been purchased is helpful enough to warrant a regulation requiring such disclosure. Rather, these agencies encourage consumers to focus on the product that is the subject of the recall, not the possible location of its purchase. Given the significant shift that USDA's proposal represents, a detailed analysis of its underpinnings and the benefits that the Agency expects to be derived should be included. In this case, no such analysis is included in the proposal or available at the docket.

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We appreciate the opportunity to provide the Agency with our comments on this proposal. We urge you to address the concerns expressed herein fully and on the record. If you have any questions, please do not hesitate to contact us.

Sincerely,

/S/

Deborah White
Vice President &
Associate General Counsel