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

[Docket No. 04-006P] Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls; March 7, 2006; 71 *FR* 11326

Dear Sir or Madam:

The Food Products Association (FPA) is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

FPA appreciates the opportunity to comment on this proposed rulemaking that the Agency believes will improve efficiency of recalls and reduce the amount of non-implicated product that is typically returned during recalls. FPA supports effective policies and procedures that enable consumers to promptly identify and return, rather than consume, potentially hazardous product in their possession. Unfortunately, for a variety of reasons discussed herein, we do not believe the proposed regulation will improve the efficiency of product recalls. In fact, we are concerned that in some cases the posting of untimely or incomplete information could have quite the opposite effect by giving consumers a false impression that a product was not sold by their grocery store, when it actually was.

Highlights of FPA Comments

- FPA supports effective policies and procedures that provide timely information to the public that enables consumers to promptly identify and return or destroy implicated product in their possession.
- However, for a number of very important reasons, this proposal to post the name and location of retail consignees seems to be inadequately considered and highly unlikely to achieve its stated objectives.
- FSIS acknowledges that current recall procedures are effective. We concur, since in virtually all cases, all the information needed by consumers to identify and to properly dispose of recalled product in their possession is contained in the widely disseminated FSIS press release that announces a recall to the public and is posted on the FSIS website.
- Regardless of where inspected meat or poultry products might have been purchased, if a consumer has a product of the specified container size that bears the particular brand name, establishment number and production or lot code specified in an FSIS press release, he or she will know that this is the product being recalled and will be able to take appropriate actions immediately.
- Key problems with the proposal include the fact that the information on retail stores will not be timely and the lists will frequently include numerous consignees that did not receive the product being recalled.
- The proposal's most severe flaw is that an untimely or incomplete consignee list would be worse than no list at all if it causes or contributes to a consumer's failure to identify potentially hazardous product in his or her possession.
- Included in our comments are two alternatives to the FSIS proposal that we believe are worthy of consideration as enhancements to an already effective recall system. Neither would require a change in the current FSIS recall regulations.

Detailed FPA Comments

The Agency claims that posting the name and location of retail consignees will improve the efficiency of recalls by making consumers more likely to identify and return or dispose of meat and poultry products being recalled by an FSIS-inspected establishment. However, this proposal seems inadequately considered and the Agency provides little or no rationale for its beliefs.

When there is a need to recall potentially hazardous product from the marketplace, it is critical to provide consumers with timely information they need to identify any implicated product in their possession so that it will not be consumed. FPA supports effective policies and procedures that help accomplish this important goal. Unfortunately, the FSIS proposal would not enhance consumers' ability to identify and return recalled product in most instances. While it may seem intuitive that making more information available to consumers would be better, closer review of how this proposal would work strongly suggests otherwise.

Information consumers need to identify recalled product

FSIS acknowledges in the preamble to the proposal that current recall procedures are effective. We concur. In the vast majority of cases, all the information needed by consumers to identify and to properly dispose of recalled product in their possession is contained in the FSIS press release posted on the FSIS website at the start of a recall. This information (typically including the product name, container size, establishment number, and manufacturer's code) is available when a recall is announced and is very widely distributed on radio, TV and in the newspapers, as well as on the FSIS website, where photos of recalled product labels are being included more and more frequently. Regardless of where a consumer shops, no further information is required to readily identify potentially hazardous product in his or her possession.

If knowledge that FSIS will post a list of retail consignees on its website leads any consumer to wait until the list is posted before they check their pantry for products being recalled, this new Agency policy will send the wrong message to consumers and will be counterproductive. The message should continue to be for consumers to act promptly on the information provided in the initial press releases, not to wait for the posting of retail store information.

Lack of timeliness of retail consignee information

The consignee list to be posted would be compiled by FSIS staff from information provided to the Agency at the various steps in the distribution chain. Unfortunately in most cases, this information will not be timely. The Agency develops its list of consignees from information collected during verification activities associated with recall effectiveness checks. According to the current Agency document on Effectiveness Checks (Attachment 3 to FSIS Directive 8080.1, Revision 4, dated May 2, 2004), it is recommended that Agency personnel begin their verification activities within 3 working days of the initiation of a Class I recall. The document suggests that these verification activities "should be substantially completed" within 10 working days after that. At one point, we understood from communications with Agency personnel that the consignee lists would not be posted on the FSIS website until the lists were complete. Based on information provided at the recent public meeting, we realize this may no longer be the Agency intent. Nevertheless, using this FSIS document as our guide for a hypothetical Class I recall initiated, for example, on Friday, April 21, the recommendations would be satisfied if the verification activities were "substantially complete" by May 10. For a Class II recall, the satisfactory date for substantial completion would be May 17. Clearly, information posted weeks or even several days after a recall is initiated would not be timely. It is therefore of limited or no value relevant to prompt identification and disposition of potentially hazardous recalled product by consumers.

Incomplete or Inaccurate Lists and the Potential for Harm

For a variety of reasons, the posted consignee list is very likely to be incomplete or inaccurate at least on occasion. This could result from simple oversight resulting in a failure to include a specific store on an intermediary's distribution list. It could result from the inability of FSIS to visit and collect consignee information from all interim distributors in a massive recall situation. Other rarer, but equally real, circumstances by which stores selling product that is subsequently recalled would not appear on the FSIS consignee list include product purchased at a discount warehouse or club store for resale at a smaller retail outlet or product initially shipped to one store, but subsequently transferred to another store. This could also occur when product is routed through a salvage operation, a food bank, or as a result of product diversion.

In any event, a worst case scenario should this proposal be finalized is that a consumer who checks the incomplete or inaccurate retail consignee list posted on the Agency website could be misled into thinking a store omitted from the list in error did not carry the recalled product and therefore it would not be in his or her possession. The unfortunate result could be consumption of a potentially hazardous product and injury or illness for the consumer. The same result could occur if the family member that follows up on a recall announcement is unaware that another family member visited and purchased product now being recalled from a store that is on the list, because the family normally shops at a retail food store that does not appear on the list. In FPA's years of experience with recalls, consumers are frequently unable to recall the specific store where they purchased an individual product. This has never been more true than today with so many retail food outlets from which to choose and is yet another reason why posting consignee lists for product recalls could have unintended detrimental consequences.

It bears repeating that regardless of the accuracy of or the availability of a posted consignee list, in virtually all cases the press release provides consumers with the information they need to identify and dispose of recalled product regardless of its store of origin. When this information is available, the point of purchase is irrelevant!

Return of non-implicated product

The preamble to the proposed rule suggests that consumers armed with knowledge of the specific retail stores that sold recalled product would be less likely to return products not implicated in the recall. For a variety of reasons, we believe the proposal would actually lead to more non-implicated product being returned rather than less.

While the chance of omitting some stores from the posted consignee list is unacceptably high, the probability of including stores that did not receive the recalled product is even higher. This is because distributors generally track distribution by product, not by product code. Thus, in the absence of detailed knowledge about which consignees received the specific codes of product being recalled, distributors err on the side of caution and forward recall notices to any consignee that might have received the product. All such consignees are included on the distribution lists provided to FSIS during Agency effectiveness checks. In turn, the Agency proposes to compile

similar distribution lists from multiple sources into the consignee list to be posted. This means that, especially in larger scale recalls, many, perhaps very many, of the retail consignees posted on the FSIS website would not have actually received the product being recalled.

It seems likely that a consumer seeing his or her local store on the posted FSIS list will be more likely to return product not associated with the implicated code. Perceived knowledge that the recalled product was sold at their local grocery store is very likely to lead some consumers to ignore the product identification information provided in the press release and return different codes of the same product, similar products manufactured by other establishments, and even other totally different products in an industry segment. All these well documented and frequently occurring situations are more likely to be exacerbated than reduced should this proposal be finalized.

Disclaimer not a solution

At the public meeting on April 24, the following questions were posed by an Agency official:

- Does this possibility of incomplete lists undercut the usefulness of the list?
- Is there some type of disclaimer or other information that the Agency could provide with a list that explains the purpose of the list and makes clear that the list should not be consider definitive?

The mere fact that USDA is even considering the need for a disclaimer reinforces our position that the information will be both incomplete and inaccurate. We believe the answer to the first question is unequivocally "yes."

In regard to the second question, a disclaimer would definitely be required if the Agency decides to proceed with this ill-advised approach. However, it is our view that use of a disclaimer that fully acknowledges the problems we have identified above regarding incompleteness and lack of timeliness, as well as inclusion on the list of stores that did not carry the product being recalled, would accurately portray the list itself as unworthy of consumer confidence in making decisions about recalled product. Consequently, disclaimers are not a remedy for the incurable ailments afflicting the consignee list proposal.

Confidentiality of information

Finalization of this proposal would very likely result in the posting of confidential commercial business information. The Agency has provided no explanation why simply compiling multiple distribution lists into a single list would negate the confidential nature of the information. FSIS has always considered the names of retail consignees to be confidential commercial information, yet no explanation is provided in the proposed rule as to why this information is no longer considered as such. We believe the failure to provide an adequate explanation for this change is arbitrary and capricious.

Alternatives to this rulemaking

During initial discussions, some members expressed a desire for FPA to support this proposal, if it could enhance the recall process and better protect public health. Upon in-depth consideration of the proposal's elements, FPA members unanimously concluded that the proposal not only could not achieve its stated objectives, but quite likely would be detrimental to our currently effective recall system; and therefore should be opposed.

An effective and efficient recall system is in the best interest of all parties – consumers, industry and governmental entities. That is why we attempted to identify alternatives to the proposal that could improve, rather than compromise, the current recall system. Our conclusion is that there is no systemic problem with the current recall process that needs to be corrected so long as suitable product identification information for consumers is included in the initial FSIS press release announcing a voluntary meat or poultry product recall.

Consumer Education. To heighten awareness, one related action the Agency might consider undertaking is to provide additional consumer education materials that encourage consumers to focus on available product identification information and not on the point of purchase of the product. Inclusion of an informational piece on the FSIS recall website and as appropriate in certain recall press releases about the need to promptly check pantries and refrigerators and with details about how to identify product that is being recalled could be useful. Information about the frequent availability of photos of the recalled product labels on the FSIS website could also be promoted.

That piece could explain how the scope of a product recall is determined. It could review how the EST number identifies the specific establishment where the product was manufactured. It could explain that different container sizes of the same product are typically run on different production lines and for that reason other container sizes may not be implicated in the recall. It could emphasize the importance of other product coding, which at a minimum identifies the date on which product was manufactured and in some cases even permanently records the minute of production. In many cases, FSIS working with the company can pinpoint the timeframe during which a problem occurred. The FSIS press release will spell out the range of production codes that are being recalled. Typically, that range includes a margin of safety on either side of the identified problem. Consumers can rest assured that only those products with the specific codes in the press release are being recalled; other products bearing codes that are similar, but different, are not implicated and can be safely consumed.

The intent of such an educational piece would be to remind and to encourage consumers to promptly check for recalled product and to help give consumers confidence that they can readily distinguish product being recalled from similar looking product which is not subject to recall. It should also note that most food retailers are happy to answer consumer questions about whether or not product in their customer's possession is subject to recall.

Limited voluntary disclosure. Finally, in our consideration of possible enhancements to our already effective recall system, the one situation that might warrant further consideration is the relatively rare situation in which potentially hazardous product being recalled does not otherwise bear adequate information to allow its identification and proper disposition by consumers.

The recall linked to the first case of BSE identified in the US at the end of 2003 has been cited by some States and consumer groups as a prime example of why information on consignees should be made available to the public. Indeed, the FSIS press release issued, in an abundance of caution, on December 23, 2003 did not contain any information that would allow consumers to determine whether or not they had that product in their possession. Fortunately, there is no known BSE-related health risk associated with product from which specified risk materials have been removed and thus it is reasonable to question whether a recall was warranted in that case. Thus, in our opinion the lack of information for consumers in that specific recall in no way justifies the current FSIS proposal.

However, had that recall involved a significant public health threat, it would have been helpful if consumers could have been provided with some additional information to help them identify the potentially hazardous product. We conclude that this situation, which could result from a recall of beef that was ground at retail sue to the presence of *E. coli* O157:H7 or of chicken salad that was repackaged at retail for *Listeria monocytogenes*, for example, is one area worthy of further discussion by interested parties. Unlike the vast majority of meat and poultry recalls, recalled product that was prepared at retail bears no USDA establishment number and only a generic store label, distinguishable from similar product prepared at other stores in a chain only by the location of the store.

We do not believe that rulemaking would be required to address this particular issue. Even though industry maintains as a legal matter that distribution lists are confidential commercial information, recalling entities (for public health and for product liability considerations) would likely be willing to cede a limited waiver of their confidentiality privileges in order to voluntarily provide certain additional information, if that information is essential to consumer identification of product being recalled. We would be happy to work with the Agency to explore whether or not this possibility has merit for addressing this rare situation in which additional information may be needed by consumers to identify recalled product.

Summary

For the reasons presented, FPA strongly believes that this proposed rule would not only fail to achieve its stated objectives, but would also risk being harmfully counterproductive, if it misleads any consumer to believe he or she did not purchase recalled product due to the omission of their local store from the posted consignee list. Since we believe the serious problems with timeliness and omission are inherent and cannot be corrected, we urge the Agency to abandon this proposal.

We stand ready to work with the Agency on alternative means to further enhance the effectiveness of our recall system, such as by providing additional consumer education and/or by further discussion of a means for assuring that consumers have the means to identify recalled product in their possession, even in the rare event that it does not bear an establishment number and other production coding information that is already included in the vast majority of recall press releases.

We thank you for this opportunity to comment on this important issue.

Respectfully,

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and Chief Science Officer

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