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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 390

[FDMS Docket Number FSIS–2005–0028]

RIN 0583–AD10

Availability of Lists of Retail Consignees During Meat or Poultry Product Recalls

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to provide that the Agency will make available to the public the names and locations of the retail consignees of meat and poultry products that have been recalled by a federally-inspected meat or poultry establishment if the recalled product has been distributed to the retail level. This rule will apply only where there is a reasonable probability that the use of the recalled product will cause serious adverse health consequences or death (Class I recalls).

FSIS will routinely post this information on its Web site as it compiles the information during its recall verification activities. FSIS is taking this action to provide an additional mechanism for prompting consumers to examine products stored in their refrigerator, freezer, or cupboard when there is a reasonable probability that the product will cause adverse health consequences. The retail consignee information will complement the product identification information that FSIS already makes available and will provide additional opportunities for local media outlets and State and local health officials to transmit more

targeted information about the recall to consumers.

EFFECTIVE DATE: August 18, 2008.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FSIS is responsible for ensuring that meat and poultry products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). These two statutes require Federal inspection and provide for Federal regulation of meat and poultry products prepared for distribution in commerce for use as human food. When there is reason to believe that meat or poultry products in commerce are adulterated or misbranded, FSIS requests that the establishment 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 seize the products.

When an establishment recalls products, it is responsible for promptly notifying each of its affected consignees about the recall. In general, the recalling establishment conveys the following information to its affected consignees:

- That the product in question is subject to a recall;
- That further distribution or use of any remaining product should cease immediately;
- Where applicable and required as part of the recall strategy, that the direct consignee should in turn notify its consignees that received the product about the recall;
- Instructions regarding what to do with the product; and
- Contact information for questions (e.g., a name and toll-free number).

Affected consignees carry out instructions provided to them by the recalling establishment and, when necessary, extend the recall to their consignees.

FSIS also widely disseminates recall information. For Class I or II recalls, defined in FSIS Directive 8080.1,

Revision 4, Recall of Meat and Poultry Products, dated 5/24/04¹, as those situations where there is a reasonable (Class I) or remote (Class II) probability that the use of the product will cause serious adverse health consequences, FSIS typically issues a press release and distributes recall information to wire services and media outlets in the areas where the product was distributed. FSIS also alerts Congressional delegations and public health partners, such as the Association of Food and Drug Officials, and State departments of health and agriculture, concerning these recalls and posts the recall information on the FSIS Web site. For Class III recalls, defined as those situations where the use of the product will not cause adverse health consequences, FSIS usually does not issue a press release (except in cases of egregious economic adulteration). It distributes a Recall Notification Report (RNR) to the appropriate Federal, State, and local public health and food inspection agencies and posts it on FSIS' Web site.

Through press releases and RNRs, FSIS provides the public with pertinent information about the recalled products. To help consumers identify the product, FSIS provides a description of the food being recalled; any identifying codes, including lot numbers, when available; the reason for the recall; the name and official number of the producing establishment; the types of establishments and facilities to which the recall extends; the availability of product at the retail level; FSIS' classification of the recall; pictures of the product or label, when available; and the appropriate contact persons for FSIS and the recalling company. FSIS lists those States to which recalled product was shipped if fewer than 13 States were involved in the recall. If the recall extends to 13 or more States, it is considered a nationwide recall. To date, FSIS has not publicized the names or locations of the retail consignees that received recalled meat or poultry products, although FSIS has on occasion, identified a store or chain if it was the sole retail outlet for the recalled product.

During the recall process, FSIS obtains from the recalling establishment the names of the known consignees of the recalled product (based on its

¹ <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf>

records). These consignees may include distributors, warehouses, and retailers.² FSIS uses this information to contact all of recalling establishment's affected consignees in order to verify that the establishment has notified all of them of the recall, and that the consignees have removed the recalled products from the market and disposed of them as directed by the recalling establishment.

FSIS also compiles lists of all subsequent consignees to which the recalling establishment's direct consignees distributed the recalled product by contacting those consignees to ensure that they were also notified of the recall. The Agency traces the recalled product forward to the retail level. When there is concern that the original distribution information is not accurate or complete, e.g., a generic list of chain stores is missing a few known stores, FSIS will prepare a list identifying the consignees or distributors that may have received the recalled product but were not included in the distribution information provided by the firm.

Through this process, as well as that of verifying the effectiveness of the recalling establishment in conducting the recall, FSIS develops a list of consignees, down to and including the retail level, that have, or have had, the recalled products in their possession. FSIS begins its process of verifying the effectiveness of the recalling establishment in conducting the recall, which is described in FSIS Directive 8080.1, as soon as possible within three working days of the initiation of a Class I recall and substantially completes it within 10 working days of the initiation of the recall.

On March 7, 2006, FSIS published a proposed rule in the **Federal Register** (71 FR 11326) in which the Agency proposed to post on its Web site the names and locations of the retail consignees of recalled meat and poultry products. FSIS proposed to post this information as the Agency obtained it during its recall verification activities described above. The proposal was developed by FSIS after its evaluation of requests from consumer groups and some State officials, who advocated the public release of information on where recalled meat and poultry products have been shipped or distributed. The State officials requested that this information be provided to them without the limitations imposed by FSIS' regulations,³ believing that they would

be better able to protect the public health with this information. Similarly, some consumer groups asserted that the public could use this information to identify more easily and effectively the product being recalled. These State officials and consumer groups believe that making the retail distribution information available will materially improve the effectiveness of recalls.

FSIS solicited comments on the proposal for thirty days. In addition, on April 24, 2006, FSIS held a public meeting to solicit comments on the proposal. A transcript of that meeting can be found at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2006-0009_Transcript.pdf. Following requests made during the public meeting and written requests submitted during the comment period, FSIS reopened the comment period on May 10, 2007, and solicited comments for an additional 30 days. (71 FR 27211).

In response to the proposed rule and public meeting, FSIS received almost 6,000 comments from consumers, consumer advocacy organizations, industry representatives, Federal and State agencies, and professional organizations. This number includes several comments made by individuals at the public meeting and taken from the transcript of that event. There was strong support for the rule from consumers, consumer advocacy organizations, Federal and State agencies, and professional organizations. Collectively, these individuals and groups filed 26 comments supporting the rule. The remainder of the comments supporting the rule were form letters. FSIS received nine comments from industry representatives opposed to the proposed rule. These comments expressed generally similar objections to the rule.

After carefully evaluating the comments, FSIS has decided to adopt the proposed rule with modifications. Specifically, the Agency has decided to limit the application of this final rule to Class I recalls, that is, recalls where the Agency has determined that there is a reasonable probability that the use of the product will cause serious adverse health consequences or death. FSIS proposed applying the rule to all classes of recalls. However, after evaluating the comments, including those that suggested that it is not necessary to make publicly available retail consignee

confidential distribution lists from public disclosure and a written commitment not to disclose any information provided by FSIS without the written permission of the submitter of the information or the written confirmation by FSIS that the information no longer has confidential status.

lists in situations where food safety concerns are minimal, FSIS has concluded that it is prudent to modify the rule to apply only to those recalls involving products where there is a reasonable probability that the use of the recalled product will cause serious adverse health consequences or death.

In addition, this final rule makes clear that FSIS will make available the names and locations of all retail consignees of recalled meat or poultry products that the Agency compiles in connection with a Class I recall. The list will not be limited to those consignees that are actually the subject of FSIS recall effectiveness checks, which was how some commenters interpreted the proposed rule. Finally, FSIS simplified and removed unnecessary text from the codified language.

II. Response to Comments

Some commenters asserted that knowing the names of retail consignees would help members of the public make better informed decisions in responding to recalls. Other commenters stated that providing retailer names and locations would enhance the usefulness to consumers of the information that FSIS already provides, such as the States in which product was distributed, because consumers would be more likely to check the meat and poultry products in their possession if they regularly shop at a store that sold the product involved in a recall. Therefore, these commenters believed that the overall effectiveness of recalls would be increased. Some commenters stated that the information currently provided by FSIS may not be sufficient because consumers may not know where to look for product codes or establishment numbers; others stated that this rule change is a common sense solution that will help consumers to identify recalled products if they have them in their possession and thus better protect themselves from adulterated or misbranded products.

The Agency believes that its current recall system has been effective, but when there is a reasonable probability that the product will cause adverse consequences, it would be useful to provide an additional mechanism for prompting consumers to examine products stored in their refrigerator, freezer, or cupboard. The retail consignee information will complement the product identification information that FSIS already makes available and will provide additional opportunities for local media outlets and State and local health officials to transmit more targeted information about the recall to consumers.

² This final rule applies to FSIS-regulated meat and poultry products only.

³ 9 CFR 390.9(a)(1) requires a written statement establishing the State's authority to protect

If the name of a store where a consumer shops appears on the posted list of consignees, it will very likely prompt the consumer to use product-specific information to determine whether recalled product is one he or she may have purchased and stored. If the consumer in fact has the recalled product, he or she can take appropriate action to either dispose of the product or return it to the retailer and not consume it.

As noted by the commenters who supported this rule change, the retail consignee information should be particularly helpful in recalls involving products where the product identification information is limited, such as non-branded product and meat and poultry products that are packaged at the retail level. Products packaged at the retail store usually do not bear the establishment number of the official establishment that is recalling the product.

Some commenters favoring the rule suggested that FSIS list the retail consignees in the press release because some people may not own a computer or know how to find the information on the FSIS Web site.

In most cases, FSIS will not have information on retail consignees available at the time the press release is issued, which generally occurs before the recall verification activities begin. Of course, FSIS will continue to provide in its press release the same important information about the recalled products currently made available, including a description of the food being recalled; any identifying codes, including lot numbers, when available; the name and official number of the producing establishment; the types of establishments and facilities to which the recall extends; the availability of product at the retail level; FSIS' classification of the recall; pictures of the product or label, when available; and the appropriate contact persons for FSIS and the recalling company in the press release.

FSIS intends to release the information regarding retail consignees of products subject to a Class I recall as soon as possible during the course of the recall. Generally, for Class I recalls, this information should be available within three to 10 working days.

One commenter generally concurred with the proposal but suggested that FSIS clarify the rule to explain that the posted information is incomplete because only those retail locations selected by the Agency in conducting recall effectiveness checks would be identified.

The commenter misunderstood the Agency's proposal. FSIS intends to post the names and locations of all known retail consignees identified as having received meat or poultry products subject to a Class I recall, irrespective of whether the Agency conducted a recall effectiveness check at that location. FSIS has modified 9 CFR 390.10 to make this clear.

Several commenters supported the proposed rule but stated that it did not go far enough. In addition to identifying the retail consignees, they believe that FSIS should also make available the names of intermediate consignees, including hotels, restaurants, food service institutions, and intermediate distributors. Intermediate consignees may receive product directly from the manufacturer or from a distributor at the wholesale level. Intermediate consignees prepare their products for immediate, on-site consumption, not for delayed consumer preparation at home.

Several commenters supporting the rule believe that limiting distribution information to retail consignees will create an unnecessary hurdle for State or local public health agencies to overcome to obtain timely distribution information. One commenter stated that providing this information for food service establishments would "provide consumers greater protection from the risks associated with tainted meat or poultry," while another suggested that restaurants be included so that individuals are fully aware of the scope of recalls.

FSIS is making no changes based on these comments, which are outside the scope of this rulemaking. The Agency is taking this action to provide an additional mechanism for prompting consumers to examine products stored in their refrigerators, freezers, or cupboards when there is a reasonable probability that the product will cause adverse health consequences so that they can take appropriate action to either dispose of the product or return it to the retail store at which it was purchased. Making available the names of intermediate consignees will not advance the purposes of this rulemaking because there is no reason to believe that this information will help consumers to determine that they have the recalled products in their possession.

Further, FSIS does not agree that publicly identifying food service establishments would provide consumers greater protection from the risks associated with tainted meat or poultry. To ensure that Class I recalled products held by intermediate consignees do not reach consumers,

intermediate consignees that have recalled products in their possession are obligated to segregate them from all other non-recalled products and dispose of them as directed by the recalling establishment. This is also true of recalled products held by retail consignees. In addition, FSIS already has in place a process to share distribution information, including the names and addresses of intermediate consignees, with State and local public health agencies to ensure that intermediate consignees have disposed of the recalled product.⁴

Several commenters opposed to the rule stated that adoption of the proposal would hamper the currently effective recall procedures and adversely affect public health. These commenters stated that providing consumers with the names of retail consignees will hamper recall efficiency because this information may be inaccurate, leading to increased returns of product that has not been recalled. One commenter stated that the lists of retail consignees will be untimely and may lead to consumer apathy and failure to heed recall notices. A few commenters stated that consumers have all the information they need to identify recalled product, and that they do not require retail store information to identify implicated product.

FSIS disagrees that publishing the names of retail consignees will diminish the effectiveness of the Agency's recall procedures, hamper identification of recalled product, or result in the release of untimely or inaccurate information. As they currently do, the FSIS verification procedures will ensure that any inaccuracies in the retail consignee list are identified and corrected quickly. FSIS has determined that starting to post the names and locations of retail consignees within three working days of the initiation of a Class I recall will make its lists timely. FSIS does not believe consumers will ignore the product specific information that the Agency currently provides to assist them in accurately identifying the recalled product. Rather, retail consignee information will complement the product identification information that FSIS already makes available and will provide additional opportunities for local media outlets and State and local health officials to transmit more targeted information about the recall to consumers.

Further, FSIS notes that in some recalls, product specific information is limited. Some products do not bear product codes or establishment

⁴ See 9 CFR 390.9.

numbers. They are packaged at the retail level and thus have limited identification. In 2007, almost 9 percent of the recalled meat and poultry products sold at retail stores were non-branded. Providing the names and locations of retail consignees, in conjunction with the other information provided, in these cases, will be particularly important for prompt identification.

In addition, for a variety of reasons, consumers may remove product from the original packaging and store it in containers that lack the identification information. In these situations, publishing only the establishment number, product codes, and States where the product was distributed is of little use to the consumer. However, identifying the retail store at which the product was available for sale by name and location provides consumers with additional information that will trigger efforts on their part to determine whether they purchased the recalled product.

FSIS is providing this information on the retail consignees of a Class I recalled product so that consumers can use it in conjunction with the information the Agency already provides to identify the recalled products and to act appropriately with respect to those that have actually been recalled. Returning recalled products to the store at which they were purchased is just one option consumers have. Consumers may also dispose of such products at home. The objective of the rule is to provide an additional mechanism for prompting consumers to examine products stored in their refrigerator, freezer, or cupboard when there is a reasonable probability that the product will cause adverse health consequences. The retail consignee information will complement the product identification information that FSIS already makes available and will provide additional opportunities for local media outlets and State and local health officials to transmit more targeted information about the recall to consumers.

In response to commenters and to ensure that consumers do not misunderstand the retail consignee list, FSIS will provide the following explanatory statement that will accompany the list that will make it clear that the list is still under development:

FSIS has reason to believe that the following retail locations received [describe meat or poultry products that are subject of recall] that has been recalled by [name of company]. This list may be incomplete. Please use the product-specific identification information, which is available at [insert link

to specific recall] to check meat or poultry products in your possession to see if they have been recalled.

FSIS continues its investigation in conjunction with this recall and will update this list, as appropriate.

Significantly, the statement gives the Agency an opportunity to urge people to consult the identifying information about the product.

Some of the commenters opposed the rule because they believed that the provision of incomplete lists of retailers by FSIS could weaken public health protection by providing consumers a false sense of security. These commenters felt that incomplete lists, even if accompanied by an appropriate explanation, would not be helpful. Consumers might assume that product from unlisted stores was safe to eat, and they would not check the product information provided in the Agency's press release in addition to the store information. Other commenters believed that incomplete lists would force consumers to return repeatedly to FSIS' Web site. An explanatory statement, in itself, they stated, indicates that consumers should not place confidence in the list when deciding what to do about recalled products. On the other hand, commenters favoring the proposal said that some information is better than none, and that FSIS should post the retail consignee information, even if incomplete, along with an appropriate explanation stating that, for example, the posting consists of retail consignees known to date.

FSIS has concluded that the retail consignee information will effectively complement the product information currently made available and will be helpful to consumers in responding to the recall. While there is always some slight potential for misinterpretation of the retail consignee information, FSIS has also concluded that an appropriate explanatory statement will minimize any such potential. As discussed previously, FSIS will post an explanatory statement on its Web site, along with the retail consignee information.

The Agency also thinks that local media outlets, including television stations and newspapers, will publicize the names and locations of new retail consignees as they are posted on FSIS' Web site. FSIS will also notify relevant State officials if retail stores in their states are identified as having received recalled product.

One commenter suggested that, as an alternative to this rulemaking, the Agency might consider providing additional consumer education materials that would encourage

consumers to focus on available product identification information.

While FSIS agrees that improvements in consumer education might encourage consumers to focus on available product identification information, improving consumer education alone will not achieve the goals of this rule. As stated previously, the retail consignee information will complement the product identification information that FSIS already makes available and will provide additional opportunities for local media outlets and State and local health officials to transmit more targeted information about the recall to consumers. FSIS will certainly explore additional ways to improve communication and consumer education concerning recalls and hopes to work with industry, consumer groups, and other stakeholders to achieve this end.

FSIS' goal in a recall is to provide the important information that allows consumers to identify recalled product and to determine whether that product is in their possession as effectively and quickly as possible. FSIS has already taken several steps to assist consumers in identifying recalled product. FSIS agrees with the commenter, for example, that information about the frequent availability of photos of the recalled product labels on the FSIS Web site should be promoted. That is why each Agency press release or other information on the FSIS Web site already includes photographs of the recalled products' labels, if available. A fact sheet on recalls, which can be found on the Agency's Web site at http://www.fsis.usda.gov/Fact_Sheets/FSIS_Food_Recalls/index.asp, also informs readers that FSIS includes pictures of the recalled product as part of the online recall press release. Each press release or RNR also informs consumers that the label bears the establishment number inside the USDA seal of inspection and provides the timeframe during which the recalled product was produced, another piece of information that the commenter believes consumers would find useful.

Some industry commenters opposing the proposal stated that retail consignee information is protected from mandatory public disclosure by exemption 4 of the FOIA because it is confidential business or commercial information, and the potential value of this information would not outweigh the competitive harm that would be caused by its release. They pointed out that FSIS has traditionally treated a

company's distribution list as confidential business information.⁵

The FOIA generally requires that agencies disclose records unless the records fall within one of the FOIA exemptions from disclosure, such as the exemption for trade secrets and commercial or financial information found in 5 U.S.C. 552(b)(4). In this situation, an agency must analyze whether the information constitutes privileged or confidential commercial information within the meaning of 5 U.S.C. 552(b)(4).

FSIS, however, in considering the application of Exemption 4, has determined that the names and locations of retail consignees of recalled meat and poultry products compiled by the Agency do not constitute confidential commercial information because the disclosure of this information will not impair the Agency's ability to obtain necessary information in the future and will not cause substantial harm to the competitive position of any business.

As noted in the proposed rule in this proceeding, FSIS is not releasing a firm's distribution list to the public. The Agency is also not posting the names and locations of any of the intermediate consignees that received recalled product or that routinely receive product from that firm. Rather, FSIS is making public a list that FSIS personnel compile of only the retail consignees that received recalled product. This would be true even in those rare instances in which the list of retail consignees includes all of the recalling establishment's customers.

Because of the complex food distribution system in the United States, which can include multiple wholesalers or other intermediate distributors, it is quite possible, and perhaps likely, that the retail consignees that ultimately sell the product to the consumer are not customers of the federal establishment that produced the product. Therefore, only very rarely, if ever, will the names and locations of retail consignees expose a recalling establishment's entire customer or distribution list. Even in such circumstances, the establishment's customer list will not be identified as such. As a result, members of the public and industry will not be able to determine what significance the list has for the recalling establishment.

The disclosure of the names and locations of retail consignees of recalled meat and poultry products compiled by the Agency is not likely to impair FSIS's

ability to obtain the names of consignees that have received recalled product. Under the FMIA, PPIA, and the implementing regulations that FSIS has adopted under those Acts, persons engaged in the business of buying, selling, or transporting meat and poultry products are required to give representatives of FSIS access to their records.⁶ Among the records that are required to be kept are those that provide a description of the articles sold, including the net weight of the articles, the name and address of the buyer of the articles sold by the person, and the name and address of the consignee or receiver, if other than the buyer.⁷ Because retail consignees that have received recalled meat and poultry products are engaged in the business of buying (and selling) meat and poultry products, they must keep various required records associated with those products, and they must make them available to FSIS. As such, FSIS's disclosure of those retail consignee names is not likely to impair the Agency's ability to obtain the names of such consignees in the future.

FSIS has also determined that disclosing the names and locations of retail consignees that have received meat and poultry products that are the subject of a Class I recall will not cause substantial harm to any business. Companies have a general, affirmative interest in letting consumers know where product is available for purchase, and they make this information known in various ways, including company Web sites and advertising. Thus, where the product that is the subject of a Class I recall is branded, the company will suffer no substantial harm from the release of retail consignee names and locations.

Even when unbranded product is the subject of a Class I recall, there will not be substantial competitive harm from release of the consignee list. First, the fact that the company that produced the unbranded product is experiencing a recall is known. It is disclosed by the Agency's press release. Second, in this situation, the name of a supplier of unbranded product (e.g., ground beef) is of minimal to no commercial value. Furthermore, information as to the type of product sold in the store is readily available from its advertising or from visiting the store.

Finally, there is no reason to believe that the retailer would suffer substantial harm to its competitive position from the release of its name. Many retailers

post notices of recalls in their stores, and some take affirmative steps to notify consumers of recalls by, for example, contacting holders of customer loyalty cards who purchased the product. This behavior is simply inconsistent with a claim of harm.

For all of these reasons, the Agency has determined that the retail consignee information does not constitute confidential commercial information.

FSIS does not intend to change how it compiles its lists of the consignees to whom recalled products have been distributed as a result of this rule, nor does it anticipate that recalling establishments will do so either. FSIS routinely compiles consignee information when a recall occurs, and it expects that recalling firms will continue to make available to the Agency information on the firms to which it has shipped the recalled products, consistent with regulatory and statutory requirements.

Some commenters stated that the proposal may force firms recalling product out of business because those firms' competitors will take their retail customers during a vulnerable time period. These commenters also stated that the rule will damage the relationship between processors and their customers, allowing competitors to take advantage of the situation.

FSIS disagrees. The situation described by the commenters already arises whenever there is a meat or poultry recall. When there is a recall, retail consignees seek to replace the recalled product as quickly as possible. To do so, they may turn to their regular supplier's competitor for a similar product, or they may ask their supplier to replace the recalled product. Whether the processor-retail consignee relationship is impaired by a recall is a function of the nature, scope, and circumstances of the recall, not of the disclosure of the consignee list.

FSIS recognizes that a retail consignee may be solicited by a new supplier attempting to use a recall as a basis for gaining new customers, and that the supplier may identify the consignee from the posted list. No evidence has been presented in this rulemaking proceeding, however, that the availability of a list of recall consignees will significantly enhance the effect of those efforts. In fact, through the years, many retail stores have made clear that they sold product that was the subject of a recall through signs, placards, and contacts with holders of bonus or club cards. Through these steps, these retail stores have made clear to the public that they carried the recalled product and thus they made themselves readily

⁵ See "Sharing Recall Distribution Lists With State and Other Federal Government Agencies," (67 FR 20009; April 24, 2002).

⁶ 21 U.S.C. 642(a), 460(b) and 9 CFR 320.1(a), 320.4, 381.175(a), 381.178

⁷ 9 CFR 320.1(b), 381.175(b).

identifiable to competitors of the recalling firm. Accordingly, the Agency has concluded that there is no basis upon which to conclude that any substantial harm will result.

A few commenters expressed concern that public interest groups may use the retail consignee lists to encourage their members to harass or boycott businesses involved in a recall and not to improve consumer awareness of recalls. These commenters expressed concern that such use could result in damage to the reputation of an establishment or its customers.

As discussed above, many retail stores have notified their customers and the public when they have sold recalled meat and poultry products. Nonetheless, the commenters raising this concern did not cite specific occurrences of retailer harassment or boycotts due to the self-release of retailer names, nor is the Agency aware of any situation where this information has been misused in the way suggested by the commenters.

One commenter suggested that distributing the names and locations of retail consignees to the public is not necessary for the proper performance of the functions of the Agency and suggested that the proposed rule was inconsistent with the Paperwork Reduction Act.

FSIS disagrees. This rule imposes no new information collection requirements on the regulated industry. Under this final rule, FSIS will continue to compile the names and locations of retail consignees that have received recalled meat and poultry products. The only change is that FSIS will be making this list public.

As previously noted, FSIS already requires federally-inspected establishments and companies that engage in the business of buying or selling meat or poultry products to maintain records that will fully and correctly disclose all transactions involved in their businesses subject to the FMIA and PPIA.⁸ These entities must also allow representatives of the Secretary of Agriculture access to their places of business so that they can examine and copy all the records.⁹

FSIS routinely compiles information contained in these records in carrying out its existing recall procedures.¹⁰ FSIS is not requiring companies to submit any new or different information to the Agency as a result of this rule. The

burden remains on FSIS to compile and distribute the information.

Furthermore, sections 677 of the FMIA and 467d of the PPIA provide that section 9 of the Federal Trade Commission Act (FTCA) (15 U.S.C. 49) is applicable to the administration and enforcement of the FMIA and the PPIA. Under Section 9, duly authorized agents of the Secretary have, at all reasonable times, access to, for the purpose of examination, and the right to copy, any documentary evidence of any person, partnership, or corporation being investigated or proceeded against.

A few commenters stated that the proposal is not in conformity with the Data Quality Act (DQA) because the data will not be compiled by FSIS in a timely fashion and is not of sufficient quality because it could be inaccurate.

FSIS disagrees with these commenters and has determined that this rule fully complies with applicable requirements of the DQA and relevant guidelines issued thereunder. Under this rule, accurate, objective information will be disseminated to the public that will be useful in helping consumers to determine if they possess recalled meat and poultry products.

USDA's Information Quality Activities Regulatory Guidelines require that the information disseminated by USDA agencies and offices in conjunction with their rulemaking activities be reasonably reliable and reasonably timely. From direct contacts with the producer and distributors of the recalled product, FSIS compiles a list of retail consignees that have received recalled meat and poultry products, generally within 10 days of the initiation of the recall. It is from these contacts that the Agency will compile, and then post on its Web site, the listing of retail consignees that have received meat and poultry products subject to a Class I recall. Because the contacts with the producer and distributors are direct, FSIS has determined that the lists of retail consignees are reliable. FSIS is committed to posting the information in a timely fashion.

Executive Order 12866 and Regulatory Flexibility Act

This rule was reviewed by the Office of Management and Budget under Executive Order 12866 and was determined to be significant.

FSIS, after reviewing public comments to the proposed rule, concluded that further analysis of the costs and benefits of the rule, and a regulatory flexibility analysis was warranted. The Agency analyzed the potential impact of the final rule on

small meat and poultry establishments and small retail firms as part of this Final Regulatory Flexibility Analysis. The Final Regulatory Flexibility Analysis data is included in this final regulatory impact analysis (FRIA) and is presented below.

This FRIA differs from the preliminary regulatory impact analysis (PRIA) that was published for the proposed rule. First, the FRIA now focuses only on Class I recalls. Even though this does not significantly affect the impact analysis, FSIS has concluded that it is prudent to modify the rule to apply only to those recalls involving products that present the greatest risk to public health. Second, more of the analytic information is provided so that the public can better understand the number of recalling establishments and retailers that are affected.

A. Need for the Rule

FSIS is taking this action to provide an additional mechanism for prompting consumers to examine products stored in their refrigerator, freezer, or cupboard when there is reasonable probability that the product will cause adverse health consequences. The retail consignee information will complement the product identification information that FSIS already makes available and may provide additional opportunities for local media outlets and State and local health officials to transmit more targeted information about the recall to consumers.

B. Baseline

The baseline provides a set of conditions against which the costs and benefits of the rule can be measured. It is important to note that the baseline for this rulemaking takes into account that, in some cases, Class I recalled products have not reached the retail level at the time the recall is initiated.

1. Recall Procedures

Once an establishment agrees to recall adulterated or misbranded meat or poultry products, FSIS widely disseminates information about the recalled product to the public. For Class I recalls, FSIS issues a press release to media outlets. The press release lists the names of the states to which recalled product was shipped, if less than 13 states are affected. If the recall extends to 13 or more states, it is considered to be a nationwide recall, and FSIS does not list the names of the states to which the recalled product was shipped. FSIS sends recall information to wire services and media services in the areas where the product was distributed. In addition, FSIS sends recall information to several

⁸ 21 U.S.C. 642(a), 460(b) and 9 CFR 320.1, 381.175.

⁹ 21 U.S.C. 642(a), 460(b) and 9 CFR 320.4, 381.178.

¹⁰ OMB control number 0583-0015.

media and constituent list-servers. The Agency also informs or works with affected State and local public health officials to identify recalled products. These State and local public health officials then further publicize the information about the recalled products.

The only change in the recall process brought about by this rule is that FSIS

will make available to the public the names and locations of retail consignees of meat and poultry products subject to a Class I recall, as they are identified by FSIS inspection program personnel.

2. Total Number and Size of Recalls

The total number of Class I recalls and the amount of product for all classes

recalled for 2000–2007 are shown in Table 1. The last column shows that the majority of recalls are Class I recalls (ranging from 63.5% to 99.9% of total recalled products), although the number and the volume of Class 1 recalls varied from year to year.

TABLE 1.—NUMBER OF CLASS I RECALLS AND VOLUME OF CLASS I AND TOTAL RECALLS (IN POUNDS)

| Year of recalls | Number of class I recalls | Volume class I recalls | Total volume of all classes (I, II, and III) recalls | Class I as a percent of total recalls |
|-----------------|---------------------------|------------------------|--|---------------------------------------|
| 2000 | 65 | 21,099,672 | 22,743,092 | 92.8 |
| 2001 | 61 | 21,230,301 | 33,410,564 | 63.5 |
| 2002 | 81 | 56,415,558 | 58,911,071 | 95.8 |
| 2003 | 45 | 2,288,040 | 3,503,689 | 67.0 |
| 2004 | 40 | 2,454,558 | 2,882,018 | 85.4 |
| 2005 | 48 | 5,940,089 | 6,446,149 | 92.5 |
| 2006 | 26 | 4,785,669 | 5,947,933 | 80.5 |
| 2007 | 50 | 142,885,981 | 143,063,822 | 99.9 |

Source: FSIS, Recall Management Staff, March 2008. Historical recall information is available at: www.fsis.usda.gov.

3. Amount of Product Recovered

While the majority of recalls in the past eight years (2000–2007) were Class

I recalls, the recovery rate of Class I recalled products was relatively low in six out of the eight years. The average

annual percentage of product recovered from a Class I recall was only 27.7 percent (Table 2).

TABLE 2.—NUMBER OF FOOD PRODUCT CLASS I RECALLS: AMOUNT RECALLED, AND RECOVERED

| Year | Volume of recalls (in million lbs.) | Volume recovered (in million lbs.) | Percentage recovered |
|------------|-------------------------------------|------------------------------------|----------------------|
| 2000 | 21.1 | 3.37 | 16.0 |
| 2001 | 21.23 | 4.46 | 21.0 |
| 2002 | 56.42 | 9.20 | 16.3 |
| 2003 | 2.29 | 0.49 | 20.6 |
| 2004 | 2.45 | 1.43 | 58.4 |
| 2005 | 5.94 | 4.46 | 74.4 |
| 2006 | 4.79 | 0.66 | 13.8 |
| 2007 | 142.89 | 1.65 | 1.2 |

Source: FSIS, Recall Management Staff, March 2008.

4. Number of Retail Consignees

Retail consignees are defined as establishments that receive product directly from a federally-inspected meat or poultry establishment or through an intermediary, i.e., distributor or wholesaler, also called an intermediate consignee. A retail consignee sells product received in this manner to the

final consumer. Distributors or institutions that do not sell product directly to the general public are not retail consignees. Restaurants are not retail consignees.

The number and type of retail consignees potentially affected by the final rule are shown in Table 3. This is a total of about 73,215 retail firms. The

retail trade sector comprises facilities engaged in retailing merchandise, generally without transformation, and rendering services incidental to the sale of merchandise (U.S. Census Bureau, 2002 *Economic Census: Retail Trade*). Retailing is the final step in the distribution of merchandise.

TABLE 3.—RETAIL FIRMS HANDLING PRODUCT PRIMARILY SUBJECT TO RECALL

| NAICS code | Kind of business | Number of firms ¹ | Number of small firms ² |
|--------------------------|---|------------------------------|------------------------------------|
| 44511 | Supermarket and other grocery (except convenience) stores | 42,318 | 34,638 |
| 44512 | Convenience stores | 25,527 | 25,410 |
| 44521 | Meat markets | 5,354 | 5,024 |
| 45291 | Warehouses and Supercenters | 16 | 3 |
| Total ³ | | 73,215 | 65,075 |

¹ Source: U.S. Census Bureau, 2002 *Economic Census: Retail Trade*. Establishment and Firm Size EC02-4455-52. November 2005.

² Small Business Administration, Office of Advocacy. Comment to FSIS Docket Clerk, May 4, 2006 regarding Docket No. 04-006P. Firms comprised of supermarkets, convenience stores, and warehouse clubs are defined as small if annual sales are less than \$25 million; meat markets are small if sales are less than \$6.5 million.

³ This is an undercount of the number of retail firms that would be subject to recalls because there are firms that are primarily fueling stations or drug stores that sell relatively small quantities of milk, bread, convenience foods, and packaged lunch meat that are not counted by the U.S. Census Bureau.

The kinds of businesses identified as potentially subject to the final regulation are:

- 44511—Supermarkets and other grocery (except convenience) stores. These facilities sell a general line of food.
- 44512—Convenience stores. This industry comprises facilities known as convenience stores or food marts (except those with fuel pumps) primarily engaged in retailing a limited line of goods that generally includes milk, bread, convenience foods, soda, and snacks.
- 445210—Meat markets. These facilities are engaged in retailing fresh, frozen, or cured meats.
- 452910—Warehouse clubs and supercenters. This industry is comprised of facilities known as warehouse clubs, superstores, or supercenters primarily engaged in retailing a general line of groceries in combination with general lines of new merchandise, such as apparel, furniture, and appliances.
- In addition, there are a number of retail firms that would be subject to recalls because, while these firms primarily sell fuel or drug stores items, a small fraction of their sales represent milk, bread, convenience foods, and packaged lunch meat.

Most, if not all supermarkets, convenience stores, meat markets, and warehouse clubs sell product from federally-inspected establishments and derive a significant share of revenue from those products. While fueling stations and drug stores sell product from federally-inspected establishments, they derive an insignificant share of revenue from those products. If Class I recalled products from federally-inspected establishments were to be sold by these fueling stations and drug stores, then their names and locations would be made publicly available by FSIS during the relevant recall investigation since they would be

considered retail consignees that have received Class I recalled meat and poultry products.

C. Description of Alternatives

FSIS considered several options, including amending its regulations to include local health departments as entities that could receive recall distribution lists or making the lists available only in response to Freedom of Information requests and to State agencies with agreements under 9 CFR 390.9. In addition, FSIS considered further education of consumers, but FSIS already has education programs and information on its Web site to inform consumers about how to identify recalled meat and poultry products. FSIS also considered making available to the public the names and locations of retail consignees of both Class I and Class II recalls. However, FSIS chose to limit the requirements of the final rule to Class I meat and poultry recalls because Class I recalls are reasonably likely to affect the public health, while Class II recalls are only remotely likely to affect the public health. Furthermore, most (64 to 99.9 percent) of the recalled products were Class I recalls (see Table 1). FSIS has adopted an approach that will alert individual consumers, State and local authorities, and other Federal agencies of the names of retail stores in which the Class I recalled products may be found in as expeditious a manner as possible.

D. Analysis of Cost

For this rule, the cost impacts for meat and poultry processors and retail consignees are expected to be minimal.

1. Impact on Meat and Poultry Processors

This action will not impose additional significant monetary cost on processing establishments conducting a Class I recall. FSIS acknowledges that some products might be incorrectly returned

because they are similar to what is being recalled and are sold by the listed retailer. However, the Agency is aware that consumers already return products incorrectly (i.e., products not subject to recall) without knowing the retailers associated with the recalled products. Whether the incorrectly returned products would increase or decrease with the implementation of this rule is an empirical question. The Agency does anticipate that the volume of correctly returned products will increase as this rule is intended to enhance the effectiveness of recalls.

2. Impacts on Retail Outlets

The effects of this rule on the product and financial markets for retail facilities that receive Class I recalled product are likely to be even less pronounced than those for the processing firms that produce the adulterated or mislabeled product. Already, some retail facilities, such as Wegman's, notify customers about Class I recalled meat and poultry products. Some costs may accrue for retail consignees as a result of increased product handling and disposal. As mentioned before, it is not certain whether the incorrectly returned products and the associated costs will increase or decrease as a result of this rule.

E. Analysis of Benefits

If consumers use retail consignee information and are prompted to identify and return Class I recalled meat and poultry products, the recall process will be more timely and effective. Nonetheless, the Agency acknowledges that it is difficult, if not impossible to quantify, ex ante, the potential benefits, as one cannot predict what kind and how many recalls will take place in the future.

1. Increased Opportunity to Target Information to Consumers

Information about the safety of food will cause consumers to respond if there is a clear and relevant message, actions are advocated that consumers can understand and accomplish, and there are continued reminders. If consumers have access to recall information that is meaningful, recall recovery rates can be expected to increase for Class I recalls, given the level of risk.¹¹

The current recall system will be augmented by providing targeted information to consumers about the retail destinations of products subject to a Class I recall.

The potential value of the Class I recall information depends on the consumer's ability to remember recent purchases of meat and poultry products and the ability of the information to trigger in the consumer the behavior to check whether he or she purchased the recalled product.

Consumers may be prompted to take action if they are informed that the product was sold at the retail location where they purchase groceries for themselves and their families. The retail consignee information will effectively complement the product identification information that FSIS already makes available and will provide additional opportunities for local media outlets and State and local health officials to transmit more targeted information about the recall to consumers.

2. Effectiveness of Recalls

The amount of product recovered during a recall depends on many factors. Among these factors are the amount of time taken to alert the public after the adulterated product has been identified, the time required by FSIS to perform recall verification activities, the type of product being recalled (some products are consumed within days of distribution), the amount of time the product is in distribution and retail channels, the efficiency of recalling establishment's recall management system, the depth into the distribution system the recall management system operates, the number of distributors through which the recalled product has moved, and the responsiveness of consumers to Class I recall information.

As mentioned above, the objective of this rule is to improve the current recall system by providing targeted

information to consumers about the retail destinations of products subject to a Class I recall. FSIS believes this rule will have an impact on recall effectiveness primarily through consumer responsiveness. FSIS also believes that making information concerning retail destinations available to the public may also influence the firms' efforts to recall their products; however, it is difficult to predict all of the variables that could be affected, given the differences among the various distribution channels for meat and poultry products.

Because this rule provides an additional mechanism for prompting consumers to examine products, FSIS has determined that posting the list of retail consignees will enhance the effectiveness of Class I recalls.

F. Net Benefits

There is no evidence to suggest that the impacts on retail establishments would be significant because Class I recalled products are typically credited to the affected retail establishment by the processing establishment that manufactured the product.

The potential benefits of the rule hinge on the consumer being able to use the retail consignee information in combination with the information currently provided to identify product more quickly and effectively than he or she does currently, so that more illnesses and deaths can be avoided.

Based on these factors, the Agency has determined that the expected benefits of the proposal exceed potential costs.

Final Regulatory Flexibility Analysis

The Agency analyzed the potential impact of the final rule on small entity meat and poultry establishments and small entity retail firms that receive product subject to a Class I recall.

The Agency's analysis of the adverse impacts of the rule on small retail firms focuses on the increased amount of product returns retail stores would receive in response to a Class I recall, even product that is not subject to the recall. The number and type of small entity retail consignees potentially affected by the final rule is shown in Table 3. This is a total of about 65,075 small retail firms. Some costs may accrue as a result of increased product handling and disposal. But as mentioned above, it is not certain whether incorrectly returned products and their associated costs will increase or decrease as a result of this rule.

Based on the above analysis, the Agency has concluded that the rule will not have a significant economic impact

on a substantial number of small entities.

References

1. Buzby, Jean, Paul D. Frenzen, and Barbara Rasco. 2001. "Product Liability and Microbial Foodborne Illnesses," AER-799, USDA, Economic Research Service, Washington, DC.
2. RTI, International. June 2005. *Survey of Meat and Poultry Slaughter and Processing Plants. Final Report.* RTI Project Number 08893.007. Research Triangle Park, NC 27709.
3. RTI, International. April 2006. *Survey of Meat and Poultry Processing Only Plants. Final Report.* RTI Project Number 0208893.016. Research Triangle Park, NC 27709.
4. U.S. Census Bureau. 1997 Economic Census, Retail Trade. EC97R455-SM. Issued January 2001. <http://www.census.gov/prod/ec97/97r44-sm.pdf>.

Paperwork Requirements

No new paperwork requirements are associated with this final rule. FSIS is making available to the public on its Web site the names and locations of the retail consignees of recalled meat or poultry products that the Agency compiles in connection with its recall verification activities.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. When this final rule is adopted: (1) All state and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

E-Government Act Compliance

The Food Safety and Inspection Service is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at http://www.fsis.usda.gov/regulations/2008_Final_Rules_Index/. FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to

¹¹ The rate of recovery of recalled product could be affected by other factors, however. The share of products affected by Class I recalls that are raw or ground is likely higher than that for other recall classes. Consequently, the product may move quickly through distribution and retail channels than processed or RTE products.

provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an e-mail subscription service that provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/news_and_events/email_subscription/. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 390

Public information.

■ For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III, Subchapter D, as follows:

PART 390—FREEDOM OF INFORMATION AND PUBLIC INFORMATION

■ 1. The authority citation for part 390 is revised to read as follows:

Authority: 5 U.S.C. 301, 552; 21 U.S.C. 451–471, 601–695; 7 CFR 1.3, 2.7.

■ 2. A new § 390.10 is added to read as follows:

§ 390.10 Availability of Lists of Retail Consignees during Meat or Poultry Product Recalls.

The Administrator of the Food Safety and Inspection Service will make publicly available the names and locations of retail consignees of recalled meat or poultry products that the Agency compiles in connection with a recall where there is a reasonable probability that the use of the product could cause serious adverse health consequences or death.

Done in Washington, DC, July 11, 2008.

Alfred V. Almanza,
Administrator.

[FR Doc. E8–16221 Filed 7–16–08; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0639; Directorate Identifier 2007–NM–003–AD; Amendment 39–15564; AD 2008–13–01]

RIN 2120-AA64

Airworthiness Directives; Fokker Model F27 Mark 050 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During scheduled X-ray inspections of Fokker 50 (F27 Mark 050) engine mounting frames, welding defects were discovered. In two forward frames and one aft frame, defects were found in a total of 4 weld locations. Investigation showed that during manufacture of the frames, when the tubes were welded to the end fittings, unintentional sideways movement of the electric arc resulted in some welds running beside the borderline for a part of the tube circumference. Where a weld runs beside the borderline, there is no connection between tube and end fitting for that part of the circumference, directly affecting the structural integrity of the engine mounting frame connections. The defective welding process appears to have happened at some of the welds in an unknown number of engine mounting frames. This condition, if not corrected, could lead to failure of the engine mounting frame in cases where multiple welds are severely affected, potentially resulting in in-flight loss of an engine. * * *

This AD requires actions that are intended to address the unsafe condition described in the MCAI.

DATES: This AD becomes effective August 1, 2008.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of August 1, 2008.

We must receive comments on this AD by August 18, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The Civil Aviation Authority—The Netherlands (CAA-NL), which is the aviation authority for the Netherlands, has issued Dutch Airworthiness Directive NL–2005–015, dated November 30, 2005 (referred to after this as “the MCAI”), to correct an unsafe condition for the specified products. The MCAI states:

During scheduled X-ray inspections of Fokker 50 (F27 Mark 050) engine mounting frames, welding defects were discovered. In two forward frames and one aft frame, defects were found in a total of 4 weld locations. Investigation showed that during manufacture of the frames, when the tubes were welded to the end fittings, unintentional sideways movement of the electric arc resulted in some welds running beside the borderline for a part of the tube circumference. Where a weld runs beside the borderline, there is no connection between tube and end fitting for that part of the circumference, directly affecting the structural integrity of the engine mounting frame connections. The defective welding process appears to have happened at some of the welds in an unknown number of engine mounting frames. This condition, if not corrected, could lead to failure of the engine mounting frame in cases where multiple welds are severely affected, potentially resulting in in-flight loss of an engine. Since