

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Introduction

The purpose of this evaluation is to assess two recent changes made by the Food Safety and Inspection Service (FSIS) in its recall policy and procedures. A recall is a firm's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA).

In January 2000, FSIS announced two new recall actions in response to an August 1998 inhouse report on improving recalls.¹ Recommendations contained in this report led the Agency to change components of its public notification recall policy and develop guidance materials to help industry fulfill their role in recalls. The following changes were announced in January 2000:

- *Public Notification.* FSIS began issuing a press release for all meat and poultry recalls. Also, each press release reflects the level of health risk presented by the product being recalled and whether the product is identifiable to consumers.
- *Industry Guidance.* FSIS issued "Product Recall Guidelines for Establishments" to assist establishments in carrying out their responsibilities during a recall. The guidelines state that a plant should prepare and maintain a written recall plan. Also included are recommended actions that a plant should take in anticipation of a recall.

Main Findings

Public Notification

- Stakeholders are divided in their support of the policy change.
- Risk communication literature supports public notification when a health risk exists.
- Risk communication literature advocates clear, concise, targeted messages.

Industry Guidance

- Overall findings support the need for these guidelines.
- Product recall guidelines provided to industry by FSIS are comprehensive and effective in helping industry to understand and comply with its recall responsibilities.

Background

In regard to public notification of recalls, FSIS prepares and distributes two public documents for each recall – a recall notification report and a press release (see Attachment 1A and 2A). Prior to the policy change, a recall press release was issued primarily for class I recalls, while recall notification reports were issued for all recalls. Now, both documents are issued for all recalls.

Recall notification reports are distributed via facsimile and electronic mail, while recall press releases are distributed via facsimile only. Both are also available via the FSIS web site.

Recall notification reports are sent to food safety and public health officials throughout the country at federal, state, and local levels by the Recall Management Division (formerly known as Emergency Response Division). This notification provides the health community with important data to use in following up on reported illnesses that may be associated with a recalled product.

¹ FSIS Recall Policy Working Group, "Improving Recalls at the Food Safety and Inspection Service", August 1998.

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

All recall press releases are distributed by the Congressional and Public Affairs Office. Recall press releases are initially sent to 100 major media organizations throughout the country using a pre-programmed distribution list.

A computer-generated local media list is also created for each state impacted by the recall. Press releases are manually faxed to each organization on the local media list, which typically includes 20-70 organizations. Additionally, recall press releases are faxed each week to constituents across the nation, including trade associations and consumer groups.

Methodology

FSIS published recall policy changes in January 2000. The Agency committed to reassessing the policy changes later in the year. While it is too early to assess the impact of these policy changes, input was obtained from key stakeholder groups and literature reviews to assess the level of support.

The evaluation was conducted in cooperation with the Product Recall Research Group at the University of New Mexico. Three data collection activities were undertaken to obtain information from key stakeholder groups² and to learn from other research done in the field. Each survey and interview respondent represents a larger constituency, and their statements or responses should be viewed accordingly:

- Surveys administered by telephone or in person: media, consumer groups, trade associations, and retailers. Thirty-nine surveys were completed; seven media, nine consumer groups, nine trade associations, 14 retailers.
- Interviews were conducted by telephone or in person with various regulatory agencies. Ten interviews were completed: four with Food Safety and Inspection Service (FSIS), two with National Highway Traffic Safety Administration, and one each from the Consumer Product Safety Commission, Coast Guard, Environmental Protection Agency, and Department of Housing and Urban Development.
- Interviews were conducted by telephone or in person with FSIS staff in the Congressional and Public Affairs Office and Recall Management Division.
- Literature review: recall policies and practices, and risk communication.

Report Plan

This report includes a summary of the findings applicable to FSIS public notification of recalls and recall guidance provided to industry. Findings are reported in two main categories: public notification and industry guidance. For a broader view of recall policy and procedures related to regulatory agencies and industry, refer to the full report by the Product Recall Research Group.³

² Due to time and resource limitations, it was not possible to obtain input from consumers.

³ Dirk C. Gibson, "A Review of Recall Policies at the Food Safety and Inspection Service, United States Department of Agriculture", (The Product Recall Research Group), June 2000. Copies of the report are available from the Evaluation and Analysis Division.

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Findings

Findings are based on a synthesis of the information obtained from surveys, interviews, and literature reviews. Findings are discussed in two categories - public notification and industry guidance.

Public Notification

Public notification findings are presented in the following categories: Press Release for all Recalls, Distribution of Recall Public Notification Documents, Content of Recall Public Notification Documents, Format of Recall Public Notification Documents, and Recall Information on FSIS Web Site.

Press Release for all Recalls

As mentioned earlier, FSIS changed its policy regarding issuance of recall press releases. FSIS now issues a press release for all classifications of meat and poultry recalls, whereas press releases used to be issued primarily for class I recalls.⁴ Data were gathered from the six regulatory agencies, three stakeholder groups (media, consumer groups and trade associations), and literature review.

- Survey feedback received from the media, consumer groups, and trade associations indicates these stakeholder groups are divided in their opinion of the policy change. While the majority of media organizations disagreed with the policy, all media responses seemed to be based on their *need* for receiving press releases for all recalls. Five media organizations (three television networks, a national magazine, a local newspaper, and a trade press) indicated they don't need to receive all recall press releases because they only publicize high risk, large volume recalls. Two media organizations, a national wire service and national radio organization, stated they publicize all recalls and want a copy of each press release.

Consumer groups support the consumers right to know and agree with the policy. Additionally, one consumer group encouraged FSIS to take the policy to the next step and identify retailers where the recalled product is sold – “Not identifying the retailers undermines the efforts of protecting public safety.” However, many consumer groups also indicated they only publicize large volume, high risk recalls.

Trade associations disagree with the policy change. According to one trade association, “Recalls reflect badly upon our members and we don't want to publicize a recall any more than it already has been.” Another trade association criticized the issuance of a recent recall press release they received for a small quantity of meat only distributed in Hawaii – “the meat never left the island, yet a nationwide press release was issued.”

Constituent Opinion on FSIS Policy to Issue A Press Release for All Recalls

Stakeholder Group	Agree	Disagree
Media	2	5
Consumer Groups	8	1
Trade Associations	0	9

⁴ There are three recall classifications. Class I recalls are defined as situations where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Class II recalls are defined as situations where there is a remote probability of adverse health consequences from the use of the product. Class III recalls are defined as situations where the use of the product will not cause adverse health consequences.

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Media and trade associations who disagreed with the policy suggested the following alternatives: only issue press releases for class I recalls, issue press releases for all class I recalls and those class II recalls that have a health risk, issue press releases for all class I and II recalls (not class III), and issue press releases only for products that consumers can identify regardless of recall class number.

- Four trade associations and two consumer groups, some of whom agreed with the new policy, expressed concern that the new policy will result in information overload for consumers and cause them to either over-react or disregard recall messages. One consumer group stated “if people get too much information, they tend not to pay close attention and miss the serious ones.” Another consumer group who agreed with the policy change was also concerned that it may cause the “public to become paranoid and think no food is safe.” One trade association stated, “we don’t want anyone to become complacent about recalls.”

Findings from consumer focus groups conducted by Research Triangle Institute as part of the PR/HACCP Final Rule Evaluation reveal that consumers use the following sources to obtain food safety information: television, family/friends, grocery stores, magazines, newspapers, radio, and the internet. Data gathered from media surveys and the literature review indicate that media organizations serve as gatekeepers for FSIS recall information reaching consumers. Major media organizations typically only publicize large volume/high risk recalls and local media typically only publicize recalls impacting consumers in their geographic area. Therefore, information overload for the consumer due to FSIS issuing a press release for all recalls is likely not a valid concern.

- The Congressional and Public Affairs (CPA) Office has received similar feedback from media, consumer groups and trade associations with regard to the new policy. Generally, media and consumer groups support the new policy, and trade associations don’t support the new policy. In a news article published in response to the announcement of the policy change, the Consumer Federation of America expressed its support for the new policy by stating “it will prevent many of the adulterations that happen now.”⁵ In similar articles, several trade associations stated that the new policy unfairly subjects companies to increased negative publicity and will overload consumers with non-essential information. According to CPA, media and consumers want FSIS to add more detailed distribution information to all FSIS recall press releases.
- In a risk communication manual designed for government⁶ the following guidelines help to support the policy change:
 - When investigating a potential risk that people aren’t aware of, an agency should seriously consider making known what it is doing and why.
 - When it seems likely that the media or someone else may release the information before you are ready, release it yourself.

⁵ Philip Brasher, “Processors say USDA is going too far in publicizing recalls”, Associated Press, January 15, 2000.

⁶ Peter M. Sandman, et al. “Improving Dialogue with Communities: A Risk Communication Manual for Government”, 1988.

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

- According to the National Academy of Sciences (NAS), poor risk communication practices can result in an organization spending a great deal of time and resources defending a risk management decision.⁷ This finding is applicable to the December 1998 recall of Sara Lee hot dogs and deli products. On December 22, 1998, Sara Lee officials initiated a recall and FSIS issued a recall notification report, FSIS chose **not** to issue a recall press release. While the Agency later decided to issue a press release (January 28, 1999), the decision not to issue a press release at the time Sara Lee officials announced the recall was intensely criticized by the media.
- The risk communication literature indicates that consumers are more concerned about risks *not* under their control (pathogens in food) than those under their control (driving a car).⁸ FSIS can reduce consumer concerns by issuing press releases for all recalls. When a press release is issued, consumers have the opportunity to be informed and therefore can control their exposure to the risk associated with the recall, even when the product cannot be identified (i.e., they can decide not to purchase the product at retail or consume the product when eating at a restaurant).

An agency is faced with the challenge of developing policy that both satisfies stakeholders and is supported by research. Based on information obtained from FSIS stakeholders, expectations and needs vary regarding notification of all recalls. While these expectations and needs are considered in FSIS policy decisions, due to the variance, it isn't possible to have a policy that will satisfy all stakeholders. Aside from stakeholder input, the risk communication literature supports public notification when a health risk exists. Is there a health risk associated with every recall? If yes, then the policy should remain unchanged. If no, then FSIS should question if a press release should be issued for every recall. Based on the current FSIS definitions of a class III recall, one could assume that these recalls don't pose a health risk, and don't generate interest of the media or public.

⁷ FSIS Backgrounder, "Risk Analysis in the Food Safety and Inspection Service", July 1993.

⁸ Dr. Douglas Powell, "Setting the Stage: Understanding Communication Issues With Foodborne Pathogens", (May 4, 1998); available from World Wide Web @ <http://www.oac.uoguelph.ca/riskcomm/rc-basics/oca-talk/oca-talk.htm>

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Distribution of Recall Public Notification Documents

Information was also obtained from the media, consumer groups, and trade associations with regard to receiving FSIS recall press releases. Findings from these stakeholder groups indicate that opportunities for improvement exist with regard to distributing recall public notification documents.

- Even though recall press releases are currently only distributed via facsimile, media, consumer groups, and trade associations were asked if they would prefer electronic mail delivery versus facsimile. Approximately half preferred electronic mail delivery, while the other half preferred facsimile.
- Recall notification reports are being distributed via facsimile and electronic mail. According to an FSIS official involved with the development and distribution of these reports, it would be easier to distribute these reports via electronic mail only, and they hope to accomplish this in the near future.
- Web site, direct mail, facsimile, and electronic mail were identified as the most used recall communication methods within the federal government by the five regulatory agency interviewees.
- Interviews with CPA staff revealed that preparing and distributing recall press releases is a time consuming task. Over the past couple of years, the Director of CPA and the Automated Information Systems Division have discussed the possibility of establishing a listserve/subscriber application for distributing recall press releases whereby stakeholders automatically receive recall press releases via electronic mail. However, according to the CPA Director, FSIS' current computer platform will not accommodate this application. The Department currently has this type of application on the USDA web site for USDA News Releases.

If the Agency were able to offer this application, it would considerably reduce the burden on Congressional and Public Affairs Office staff for distributing recall press releases. By designing this application with options, the Agency could also meet the varying needs expressed by our constituents for receiving all recall press releases. FSIS could establish three options for this application: option 1 could allow stakeholders to receive class I recall press releases, option 2 to receive class I and II recall press releases, and option 3 to receive all recall press releases. A similar application (options may not be appropriate) should be established to simplify distribution of recall notification reports by the Recall Management Division.

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Content of Recall Public Notification Documents

In addition to issuing a press release for all meat and poultry recalls, on each recall press release FSIS now defines the level of health risk associated with each recall and if the product is identifiable to consumers. Overall findings from the six regulatory agencies, three stakeholder groups (media, consumer groups, and trade associations) and literature review support these changes.

- All stakeholder groups were satisfied with the information contained in the new recall press releases. Several respondents strongly supported the recent content changes: addition of classification number, health risk level, and safe handling/preparation information (e.g., how to prepare ground beef for safe consumption and listeria precautions). Many respondents who further publicize a recall use the information contained in the FSIS press release, as well as information from the establishment and/or association.
- Research states that recall public notification messages must contain certain essential pieces of information. Included in this information is the level of risk posed to the consumer and method for consumer identification, which both are now included in recall press releases.⁹ Unfortunately, research guidance could not be found with regard to products that consumers cannot identify.
- Research also concludes that public notifications should describe actions to be taken by all people in the distribution cycle (distributors and consumers).¹⁰ Messages should also be specific and clear. Regulatory agency interviews also indicate that compliance instructions are one of the primary pieces of information to include in recall messages.

Currently, FSIS recall press releases do not specify instructions for businesses holding the recalled product. Based on the literature review and interview findings, FSIS should include messages for businesses holding recalled product in future recall press releases. These instructions should specify what to do with the product (i.e., return to establishment or destroy) or who to contact for further guidance or questions.

- Recall press releases and recall notification reports posted on the FSIS web site contain duplicate and sometimes confusing contact information. Consumer and media contact information are provided in multiple places on both documents (refer to Attachment 1A and 2A). Contact information should be consolidated into one location on each document. By eliminating duplicate contact information, the documents may be able to fit onto one page. Refer to Attachment 1B and Attachment 2B for report format options.

⁹ “Manual on Pre-Emergency Planning and Disaster Recovery”, National Food Processors Association, 1988.

¹⁰ American Society for Quality, The Product Recall Planning Guide (ASQ Quality Press, 1999), 84.

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Format of Recall Public Notification Documents

Information on the recall press release and recall notification report were reviewed and compared. Findings related to format are discussed below.

- Format is one of many factors that influence the extent to which stakeholders will understand and respond to the risk information being presented.¹¹ Information should be organized hierarchically so that people who only want answers to certain things can find them quickly.¹²

The recall classification, health risk category, and safe handling/preparation information are easily distinguishable on the top and side of each press release. However, the remaining recall information is organized in a narrative format without headings. FSIS could add a heading to the top of each press release to allow readers to quickly and easily identify the states affected by the recall (insert after recall classification and health risk information). (Refer to Attachment 2B – Proposed Recall Press Release.) To further ease the burden on the reader for finding their information of interest, FSIS could create bolded headings for each section (e.g., **Product, Distribution, Consumers, Illnesses, Pathogen**, etc) and state high interest information, such as illness information earlier.

Recall notification reports have relevant recall and product information dispersed throughout the report. For example, recall classification is in the middle of the report and recall case number is at the end of the report, and while most product related information is at the top of the report, the quantity recalled and product distribution appear later in the report, after the consumer/media contact information. The format for recall notification reports should be changed to allow related information to be grouped together – i.e., product, recall identification, contacts. Refer to Attachment 1B – Proposed Recall Notification Report.

- Spanish language options are being increasingly offered to consumers. FSIS should consider issuing recall press releases in both English and Spanish languages when recalls affect areas with large Spanish speaking communities.
- The recall press release and recall notification report each contain a small amount of unique information. However, the majority of the information contained in each document is the same (refer to Attachment 1A and 2A). If the Agency continues to issue a press release for all recalls, it should conduct a further study to determine if two public documents need to be issued for every recall. Internal procedures *may* be simplified if the information was consolidated into one document.

¹¹ Nancy A. Connelly and Barbara A. Knuth, “Evaluating Risk Communication: Examining Target Audience Perceptions About Four Presentation Formats for Fish Consumption Health Advisory Information”, *Risk Analysis*, Vol. 18, No. 5, 1998.

¹² Dr. Douglas Powell, “Setting the Stage: Understanding Communication Issues With Foodborne Pathogens”, (May 4, 1998); available from World Wide Web @ <http://www.oac.uoguelph.ca/riskcomm/rc-basics/oac-talk/oac-talk.htm>

EVALUATION REPORT – FSIS Recall Notification and Industry Guidance

Recall Information on FSIS Web Site

Comparisons were made between the information contained on the recall press releases and recall notification reports, with respect to other related recall information available on the FSIS web site. Findings are discussed below.

- Safe handling/preparation information now included on applicable recall press releases (e.g., how to prepare ground beef for safe consumption and listeria precautions) can only be found on the FSIS web site in recall press releases. Stakeholders should be able to find this information on the FSIS web site other than by accessing a recall press release. FSIS should add this information as a separate link on the FSIS web site (e.g., preparing ground beef for safe consumption, listeria precautions, etc). Possible options include: a link from the FSIS News and Information Web Page (<http://www.fsis.usda.gov/OA/newsinfo.htm>) and/or FSIS Consumer Education and Information Web Page (<http://www.fsis.usda.gov/OA/consedu.htm>).
- The “Food Recalls” information currently on the FSIS web site is incomplete (<http://www.fsis.usda.gov/OA/pubs/recallfocus.htm>):
 - Press releases are not defined for the public. Information on the web site states that FSIS notifies the public in two ways for every recall, through a press release and a recall notification report. A detailed definition of a recall notification report is provided, including the type of information included on the report as well as who receives the report. This information is not provided for a press release. To be consistent, the Agency should add a definition for the recall press release.
 - Health risk categories (high, moderate, or low) are not defined for the public. Both the class number and health risk category are currently located at the top left corner of each recall press release. Definitions for recall classifications appear on each press release as well as on the FSIS web site. Definitions for health risk categories do **not** appear on the press release or web site.
 - One health risk category can apply to more than one recall classification. A class I recall can receive either a high or moderate health risk categorization, and a class II recall can receive either a moderate or low health risk categorization. Given that health risk categories are not equal to recall classifications, the Agency should define these categories and include the information on the web site.

Industry Guidance

As mentioned earlier, FSIS issued “Product Recall Guidelines for Establishments” to assist establishments in carrying out their responsibilities during a recall. The guidelines state that an establishment should prepare and maintain a written recall plan and also outline actions that FSIS recommends a plant take in anticipation of a recall, including public notification. Findings from regulatory agencies, trade associations and literature review support the need for these guidelines.

- Almost all regulatory agencies and stakeholder groups agreed industry should have written recall plans. This finding is strongly supported by the literature review which emphasized not only the importance for industry to develop a written recall plan, but also the need to establish a recall committee and maintain sufficient distribution records to ensure recall success.
- Regulatory agencies identified unpreparedness by industry as the worst recall practice. Literature stated that despite the existence of guidance materials, most companies are not prepared to effectively initiate a product recall due to lack of a formal plan and/or incomplete distribution records.
- The 1985 NAS report, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program, advised of a need for: "A traceback and recall system from final sale to producer for all animals and products destined to enter the human food supply system" Proper maintenance of product distribution records by meat and poultry establishments facilitates tracebacks during a recall.
- Trade associations all stated they encourage members to have a written recall plan. Four trade associations stated they had used the FSIS guidelines and/or informed members to use the FSIS guidelines. The remaining trade associations refer members to existing in-house material or other industry materials as primary guidance in developing a recall plan. Since FSIS guidelines were published in January of this year, it is too early to fully assess their impact.
- Findings from literature reviews and trade associations revealed that an abundance of recall guidance materials have been published. However, when compared to other recall guidance materials, FSIS guidelines are more comprehensive in terms of outlining industry’s recall responsibilities. Additionally, the recall communication guidance provided by these guidelines allows industry to successfully fulfill its public notification recall responsibilities.
- Included in the guidelines was the “Emergency Response Division Recall Worksheet” (now known as Recall Management Division). This worksheet is sent to the recalling establishment for completion (previously FSIS used to complete the worksheet through information obtained from the establishment over the telephone). Overall, the Recall Management Division (RMD) Director has received positive feedback on the worksheet, it clearly outlines all of the information establishments need to supply to FSIS. However, the RMD Director did state that some establishments have expressed concern over the brief time period in which they are expected to complete the worksheet. Adding to the time period even more, some of the larger establishments have a corporate policy that requires their legal department to review the worksheet before sending it back to FSIS.
- The RMD Director expressed concern regarding awareness of the FSIS guidelines by some small and very small establishments. If a small or very small establishment is not a member of a trade association, it is doubtful they know the FSIS guidelines exist.