

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 390

[Docket No. 99-029P]

Sharing Recall Information With State and Other Federal Government Agencies

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) proposes to add regulations concerning sharing recall information with State and other Federal government agencies. This proposed rule would permit FSIS to disclose to officials of State governments certain proprietary information without being compelled to disclose the information to the public under the Freedom of Information Act (FOIA). Also, the proposed rule would advise the public that FSIS will share proprietary information with other Federal agencies. Specifically, this proposal addresses situations where, during a recall activity, it is beneficial for FSIS to share certain proprietary information from a firm with State and other Federal government agencies. This action is necessary to facilitate cooperation in regulatory activities and will contribute to improved public health protection.

DATES: Submit comments on or before November 20, 2000.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket Clerk, Docket #99-029P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250-3700. All comments submitted in response to this proposal will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Charles Gioglio, Director, Recall Management Division, Office of Public Health and Science, FSIS, U.S. Department of Agriculture. The mailing address is Maildrop 343, 3rd Floor—Room 333, 1400 Independence Avenue, SW., Washington, DC 20250. Telephone number (202) 690-6389.

SUPPLEMENTARY INFORMATION:

Background

Overview of Recalls of Meat and Poultry Products

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), which require Federal inspection and regulation of meat and poultry products prepared for distribution in commerce for use as human food. When meat or poultry products in commerce are found to present an actual or potential health hazard to consumers, or otherwise to violate the provisions of the FMIA or PPIA, FSIS will request that firms recall the suspect products.

Recalls are voluntary actions taken by manufacturers or distributors in cooperation with Federal and State agencies. A product is recalled when found to be adulterated or misbranded under provisions of the FMIA or PPIA. Although the product is marked, inspected and passed, FSIS may determine, based on information that has become available to the Agency, the product is no longer eligible to bear the mark of inspection.

FSIS does not have statutory authority to order recalls. Recall actions are initiated by a firm, either on its own initiative or at the request of FSIS. If a firm does not agree to initiate a recall, FSIS has authority to detain and seize the product once it is located. A recall may be undertaken by a firm that manufactures, wholesales, or distributes meat or poultry products. Retail establishments are exempt from inspection. However, when meat or poultry products are manufactured at retail establishments and found to be adulterated, FSIS expects the retail establishment to recall the product. FSIS will coordinate with State agencies to accomplish the recall. Firms can be large corporations, partnerships, or family owned businesses.

When firms conduct recalls, the Recall Management Division (RMD) of FSIS classifies the health risk associated with the recalled products. A Class I recall involves a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Class II recalls involve a potential health hazard situation where there is a remote probability of adverse health consequences from the use of the product. Class III recalls involve a situation where the use of the product will not cause adverse health consequences. RMD also recommends the scope (the amount and kind of product recalled) of the recall, distributes recall notification reports to public health officials, and assists FSIS' Office of Congressional and Public Affairs in notifying the public through press releases. Information on all recalls is posted on the FSIS web site, www.fsis.usda.gov. FSIS' Office of Field Operations, compliance personnel verify that firms conduct voluntary recalls and evaluate their effectiveness through checks performed in the field.

Changes in Recall Policy and New Recall Directive

Over the last few years, firms have initiated several major Class I recalls at FSIS' request, one of which involved over 25 million pounds of product believed to be contaminated with *E. coli* O157:H7. In November 1997, FSIS created a Recall Working Group to assess the adequacy of its current recall policies and practices. Based on a full review of issues presented to it, the Recall Working Group determined that the Agency's recall policies and procedures are basically sound; however, the Working Group believed that some improvements could be made in the recall process.

Based on its careful consideration of that report and the comments on it, and in consultation with the Secretary of Agriculture and the Under Secretary for Food Safety, FSIS issued on January 19, 2000 a new version of FSIS Directive 8080.1 (Revision 3), "Recall of Meat and Poultry Products" and issued a Guide (as an amendment to the new Directive), "Product Recall Guidelines for Establishments." The main purpose of the Directive is to update the Agency's procedures and to set out two new policies. First, FSIS has begun issuing

press releases for all meat and poultry recalls. The press releases are drafted to reflect the health risk presented by the product being recalled, and how the product is identifiable to consumers and users.

Second, the Directive defines the circumstances in which FSIS will consider a recall to be completed. The Agency states that it will consider a recall to be complete when the recalling firm has made all reasonable efforts to recover the product, and it either has disposed of the product or has it under control. FSIS addressed this concern in response to complaints that some recalls remained open for months and even years.

The Guide outlines the actions that a firm should take in anticipation of a recall and in the event that the plant decides to recall product. The Guide states that a firm should prepare and maintain a detailed, written recall plan. It further states that this plan should describe, on a step-by-step basis, the procedure that the firm will follow when recalling a product.

Changes in Recall Policy and Sharing Recall Information With State and Federal Agencies

This proposed rule is intended to facilitate the sharing of certain proprietary (non-public) information (e.g., distribution lists) with State and other Federal government agencies in order to enhance cooperation in recall activities, contribute to improved public health protection, and maintain effective communication with these agencies. FSIS has modeled this proposed rule, in part, on two Food and Drug Administration (FDA) regulations, 21 CFR 20.85 and 20.88, that permit FDA to disclose certain proprietary information to State governments and other Federal officials without requiring FDA to make the information or documents available to the public.

Historically, FSIS' communications with State agencies generally had the same status as communication with any member of the public. In accordance with 5 U.S.C. 552(a)(3)(A), any record of the Agency that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public.

There are times when public disclosure of information will undermine legitimate private rights and government responsibilities. In drafting the FOIA (5 U.S.C. 552), Congress recognized the need for the Federal government to be able to withhold certain categories of information from public disclosure. Examples of such

categories of records relevant to FSIS include:

1. Trade secret and confidential commercial information (5 U.S.C. 552 (b)(4));
2. Predecisional documents to protect the deliberative process (5 U.S.C. 552 (b)(5)); and
3. Information the disclosure of which may invade personal privacy (5 U.S.C. 552 (b)(6)).

FSIS works closely with Federal and State agencies in situations involving outbreaks of foodborne illness and the recall of meat and poultry products to protect the public health. To enhance cooperation with State and other Federal government agencies, FSIS needs the ability, in certain circumstances, to disclose confidential commercial information to other agencies.

Therefore, FSIS is proposing to amend 9 CFR part 390 by adding a new section that will enable FSIS to share with other State agencies non-public information that is protected from mandatory public disclosure by exemption 4 of the FOIA (5 U.S.C. 552(b)(4)). Exemption 4 covers two broad categories of information in Federal agency records—trade secret information and information that is: (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential ("confidential commercial information"). The new section also addresses sharing of information with other Federal agencies which is not limited by FOIA, but is included in the proposed rule to clearly advise persons that information will be shared with other Federal agencies.

The Agency is proposing to provide that the Administrator or designee may disclose confidential commercial information submitted to FSIS to State and other Federal government agencies as part of a cooperative effort between agencies, provided that:

The State government officials have provided a written statement establishing authority to protect confidential commercial information from public disclosure and a written commitment not to disclose such information without the submitter's written permission or written confirmation from FSIS that the information is no longer confidential. Federal agencies must provide a written commitment not to disclose the information, but to refer the confidential commercial information to FSIS in order for FSIS to respond to the request for information.

FSIS intends that the disclosure of information to other agencies will be for the purpose of recalls of meat and poultry products. The regulatory text of

this proposed rule limits the sharing of information to recalls.

The proposed amendment to 9 CFR part 390 would establish that the above government officials are not members of the public for purposes of disclosure of confidential commercial information submitted to FSIS, and that such disclosures would not invoke the requirements in 9 CFR part 390 of uniform access to records. Disclosure of confidential commercial information to government agencies as specified in the proposed amendment would be an "authorized" disclosure.

FSIS believes this proposed rule will do nothing to diminish current public access to Agency records. The purpose of this proposed rule is not to reduce the number or types of records that will be available to the public from FSIS but to enhance the Agency's ability to engage in information exchanges.

Also, this proposed regulation is related to a Memorandum of Understanding (MOU) between FSIS and the Food and Drug Administration (FDA) signed in February 1999 that facilitates sharing of information. This MOU is limited in effect by FSIS' inability to provide proprietary information on recalls to FDA or other affected authorities. This regulation would remedy this limitation of the MOU.

Compliance With Executive Order 12866 and the Regulatory Flexibility Act of 1996

This rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

The Administrator, FSIS, has determined that this action will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601) because this rule promotes cooperation among FSIS, other Federal and State agencies.

Economic Impact

Impacts/Net Benefits Associated With the Proposed Action

This proposed action is new. No significant changes in recall activities are expected as a result of this action.

1. Net benefits are likely to be increased public health protection.
2. Net benefits are likely to be enhanced communications and cooperation between FSIS and State and other Federal agencies.

Expected Benefits

During a meat or poultry recall, FSIS will be able to share sensitive,

confidential proprietary information with State agencies and other Federal agencies without having to disclose this information to the general public or media under the Freedom of Information Act. This will enable FSIS staff to verify that adulterated, un-healthy, or misbranded products are removed from consumer channels quickly and efficiently and to protect the public health.

Because of the proposed rule, the sharing of recall information will help all the government agencies work aggressively together to find solutions that will enhance public health and provide consumer protection from foodborne illnesses. The State agencies will provide a written agreement not to disclose such information without the submitter's written permission or written confirmation from FSIS. Federal agencies must agree not to release the information but to refer the information to FSIS for a response to the requestor. This will ensure that the other government agencies do not inadvertently share this information with the public. Increased consumer protection and public health, and efficiency in government are the basic benefits of this proposed rule.

Expected Costs

There are minimal costs associated with sharing recall information with State and other Federal agencies. Costs will consist of the labor it takes to draft and agree to Memorandum of Understandings, and the labor it takes to share the information with these agencies, but these costs are already absorbed by the labor cost of these officials. There are no costs to industry.

Expected Effects on Small Entities

No disproportionate significant economic impact will be experienced by small entities. FSIS will share with States and other Federal officials confidential and proprietary information of both large and small entities, if the recall warrants it.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this proposed rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at

<http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/ stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

Executive Order 12898

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," FSIS has considered potential impacts of this proposed rule on environmental and health conditions in low-income and minority communities.

Sharing recall information with other agencies will benefit FSIS, the regulated industry and consumers. Thus, this proposed regulation does not adversely affect the public health or environment in low-income and minority communities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 390.7 must be exhausted prior to any judicial challenge of the application of the provisions of this proposed rule, if the challenge involves any decision of an FSIS employee relating to a denial of access of information.

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

List of Subjects in 9 CFR Part 390

Confidential business information, Freedom of information, Government employees.

For the reasons set forth in the preamble, FSIS proposes to amend 9 CFR part 390 as follows:

1. The heading of 9 CFR part 390 is revised to read as follows:

PART 390—FREEDOM OF INFORMATION AND PUBLIC INFORMATION

2. The authority citation for part 390 continues to read as follows:

Authority: 5 U.S.C. 301, 552; 7 CFR 1.3, 2.7.

3. Section 390.9 is added to read as follows:

§ 390.9 Communications with State and other Federal government agencies.

(a) The Administrator of the Food Safety and Inspection Service (FSIS) or designee, may authorize the disclosure of confidential commercial information submitted to FSIS, or incorporated into agency-prepared records, to State and other Federal government agencies as part of a recall of meat or poultry products, provided that:

(1) The State agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided by FSIS without the written permission of the submitter of the information or written confirmation by FSIS that the information no longer has confidential status. Federal government agencies must provide a written commitment not to disclose the information, but to refer the confidential commercial information to FSIS in order for FSIS to respond to the request for information; and

(2) The Administrator of FSIS or designee determines that disclosure would be in the interest of public health.

(b) This provision does not authorize the disclosure to State or other Federal government agencies of trade secret information, unless otherwise provided by law or pursuant to an express written authorization provided by the submitter of the information.

(c) Information disclosed under this section is not a disclosure of information to the public. Disclosures made under this section do not waive any FOIA exemption protection.

Done in Washington, DC on September 13, 2000.

Thomas J. Billy,
Administrator.

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