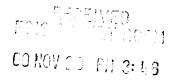


November 20, 2000



FSIS Docket Clerk USDA/FSIS Docket #99-029P

Room 102, Cotton Annex Building

300 12th Street, SW

Washington, DC 20250-3700

99-029P 99-029P-5 Dane T. Bernard

FOOD

NATIONAL

[Docket No. 99-029P] Sharing Recall Information with State and Other Federal Government Agencies; 65 Federal Register 56503; **September 19, 2000**

ASSOCIATION

PROCESSORS

Dear Ms. Moore:

The National Food Processors Association (NFPA) submits the following comments on the docket referenced above.

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

1350 I Street, NW Suite 300 Washington, DC 20005 202-639-5900

NFPA appreciates the opportunity to comment on this important issue.

General Comments

NFPA has extensive experience in assisting our members to remove product from the marketplace promptly and effectively when the need arises. On many occasions, we serve an intermediary role in facilitation of a productive dialogue with various Federal and State regulatory entities during such special situations. When available evidence suggests the need for removal of product from the marketplace to protect public health, we share with the recalling firm and all involved regulatory entities, the desire for a prompt and effective recall.

WASHINGTON, DC DUBLIN, CA SEATTLE, WA

Toward this end, we acknowledge that in certain cases the States have an important role to play in verifying that recalled product has been removed from the trade. In this regard, we believe that the public is best served when resources, whether Federal or State, are highly coordinated to ensure that needless overlap of functions and duplication of effort are minimized to the greatest extent possible.

We wish to point out that we fully support FSIS in its intent to prevent the unauthorized release of trade secret and confidential commercial information that may be made available to State Agencies during a product recall situation. Our comments primarily relate to assuring that a final rule serves that function to the maximum extent possible.

Specific Comments

Proposed Language May Not Provide Intended Effect

As written, proposed section 9 CFR 390.9(a)(1) appears to be misworded. It currently provides that: "..... 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; ..." We believe that the intent of the Agency must have been to require that a sister Federal agency which receives a request for confidential commercial information that had been shared by FSIS, must not share that information with any other person or entity, but rather must refer any such request for information to FSIS for a response to the requester. If this is the intent of the proposed regulation, we suggest that it should read as follows:

"Federal government agencies must provide a written commitment not to disclose the information, and must refer any request for such confidential commercial information to FSIS for response; and ..."

The Specific Nature of Information to be Shared and Not to be Shared Should be Delineated

In order to eliminate any potential ambiguity, we recommend that the specific type of confidential commercial information intended to be covered by this proposal should be expressly delineated in the final rule and the preamble to the final rule should specify those types of information which would not be permitted to be shared under the final rule.

The preamble states that "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." (65 FR 56504) Thus the only type of

proprietary information mentioned in the proposal and, indeed, the only type of proprietary information mentioned by Agency officials in public meetings is distribution lists.

We concur that product distribution lists, which could aid in prompt and effective verification of product removal if shared, are the only form of proprietary information that could and should be addressed in a final rule on this subject. In our experience, other types of information, such as customer lists, are often incomplete and difficult to ascertain since much of this information is not within the reach of the establishment. Thus, we strongly believe that product distribution lists should be clearly delineated in the final rule as the only form of confidential commercial information covered by this rule as including other information would only be making promises that could not be met. To this end, we recommend that 9 *CFR* 390.9 (a) should be reworded in part as follows:

"The Administrator of the Food Safety and Inspection Service (FSIS) or designee, may authorize the disclosure of product distribution lists, a form of confidential commercial information, submitted to FSIS, or incorporated into agency-prepared records, to State and other Federal government agencies...."

Conditions for Sharing, Intent for Sharing and Individuals to Receive Confidential Information Should Be Delineated.

NFPA strongly urges that the dissemination of confidential distribution information should be limited to those other federal agencies or state officials that can assist FSIS in "verifying the removal of products." In other words, the information should only be given to government officials with primary responsibility for food product recalls. Likewise, the dissemination should be limited in terms of geographic scope to those areas where the product was distributed. For example, no public purpose would be served in providing an establishment's confidential information to officials in Maine when the product was distributed exclusively in California and Arizona. Hence, we recommend that the following clause be inserted in subsection (a) immediately before the term "provided": "to verify the removal of the recalled product."

In conjunction with this change, we would recommend the agreement with the state governments include a specific provision restricting the dissemination to those officials charged with verifying product removal. To be most effective, this should be done through an amendment to subsection (a)(1) by inserting the clause: "and to restrict disclosure to those officials charged with assisting in the verification of product removal," immediately after the term "disclosure".

The last change relates to the necessary assurances the state must give FSIS. Since each recall is unique, we strongly recommend that the assurances be specific to each individual recall and not be

of a continuing basis. This can be achieved by inserting the phrase: "in each recall incident" immediately after the phrase "written commitment" in subsection (a)(1).

Confidential Information Should Not Be Shared Unless in the Interest of Public Health

NFPA concurs with subsection (a)(2) of the proposal that requires confidential information be disclosed only following a determination by the Administrator or designee "... that disclosure would be in the interest of public health." However, we wish to emphasize that it would be inappropriate to share confidential data in the absence of true public health issues. For example, in the section of the preamble quoted above, the agency speaks of removing "misbranded" products. We do not believe that a simple misbranding, such as an incorrect net weight statement, rises to a level that would justify the dissemination of an establishment's confidential information.

Accordingly, we recommend the subsection be amended by substituting the following in place of the word "The" that precedes the word "Administrator":

"(2) The 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 and the ..."

In other words, we urge dissemination of confidential information only in those situations where there is a clear public health concern-- Class I recalls.

Need For Coordination of Recall Activities with the States.

As noted above, NFPA urges coordination of recall effort among all participating entities. The needless duplication of effort between the States and the various Federal Agencies is a waste of limited resources. We believe it is imperative, particularly when confidential information is being shared, that coordination of effort should be maximized, both in regard to issuance of press releases and in the conduct of field activities to assure recall effectiveness.

For every recall involving interstate distribution of meat or poultry products, FSIS issues a press release and makes various pieces of recall information available on its website. When an FSIS press release notes that product being recalled was distributed in a particular State, we do not believe that it serves a useful purpose for a State to issue its own press release for the same recall. We strongly believe that a proliferation of recall notices serves to diminish the attention paid by consumers to those recalls that potentially have public health consequences.

We suggest that FSIS include in its MOU with States that may request product distribution lists an understanding that the State will refrain from the issuance of duplicative press releases. In return FSIS and the States might consider the possibility of noting in the FSIS press release the participation of individual States in the recall effort.

Multiple recall notices issued at different times by different authorities can also have the unintended effect of giving the appearance of more than one recall. We would also object to issuance by the States of notices that individual recalls do not involve product distributed in their jurisdiction as such action has no value in assisting the recovery of product from the marketplace.

Sometimes the cooperation of a State may be helpful or even essential in verifying the firm's removal of product from the marketplace. When States have the resources to aid in recall effectiveness checks, we urge that there should be close coordination with FSIS field staff to assure that all resources, Federal and State, are used effectively. We suggest that the sharing of product distribution lists implies an obligation for coordination of visits in the marketplace and an obligation for sharing of information gained by the States during such visits.

Recall Information Not Always Immediately Available.

We caution the Agency and the States that complete product distribution information is generally not immediately available. In order to identify all points of distribution, the scope of the problem that created the need for a recall must be defined. Then once the scope is determined, it takes time to compile distribution records, particularly when secondary distribution and sub-lotting of product has occurred. Depending on the circumstances of the particular recall event, the public, the Agency and the firm involved all may be best served by a reasoned balancing of the need for prompt information with the need for accurate information. In some past cases, quick issuance of recall notices have led to the need for additional notices as the scope of the recall has been expanded. In some cases, waiting for a few hours may have allowed a much more orderly process for removal of all affected product. Thus while the States may desire product distribution lists immediately, it should be realized that this information is not always immediately available; in fact it frequently takes a number of days or even a week to gather the important information regarding distribution.

Enhanced Protections for Commercial Confidential Information.

We request that FSIS make even more clear in the preamble to the final rule just what the consequences would be should a State or Federal employee who had been the recipient of shared confidential commercial information accidentally or purposefully releases this information without authorization.

We appreciate this opportunity to share our views on this important matter and we would be glad to work with the Agency to resolve any lingering issues in this regard.

Sincerely,

Dane Bernard /y
Dane T. Bernard

Vice President, Food Safety Programs

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