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NFPA
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

April 14, 2003

FSIS Docket Room
Docket # 00-011N
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

[Docket No. 00-011N] FSIS Procedures for Notification of New Technology; 68 FR 6873; February 11, 2003

Dear Ms. Riley:

The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, 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 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.

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General Comments

Firms should be permitted to utilize new technologies that have been validated as part of a firm's HACCP plan without Agency prior review.

For a number of years FSIS has pursued a policy of eliminating "command and control" in favor of science-based HACCP. Among the Agency's reasons for eliminating prior approval of blueprints, proprietary substances and even new systems for thermally processing canned food products was a new recognition that industry is responsible for food safety and that it was appropriate to provide industry with flexibility to meet these responsibilities by the most appropriate and efficient means available.

We remind the Agency of statements made when rules were promulgated to eliminate prior approval of partial quality control (PQC) programs, including those related to canning operations.

The following is a portion of the introduction to that rule published on May 30, 2000 (65 *FR* 34381):

> "FSIS also is removing from the thermal processing regulations all requirements concerning PQC programs, the requirements for case-by-case FSIS approval of systems and devices not specified in the regulations, and several other prior approval requirements. The amended regulations will be more consistent with the Pathogen Reduction (PR)/Hazard Analysis and Critical Control Points (HACCP) regulations and inspected establishments will have greater flexibility to adopt new technologies and methods that will improve food safety and other consumer protections."

We believe it was inherent in these fundamental changes to long-standing Agency "command and control" philosophy that it is industry's responsibility to validate the safety of new processing systems and it is the Agency's responsibility to oversee that industry fulfills it responsibility. NFPA strongly supported those changes and other similar changes, such as the elimination of prior approval of equipment used in meat and poultry establishments. Though the term "prior approval" is not mentioned in the recently announced Agency policy on new technologies, the new policy certainly has the feel of a return to the days of "command and control and prior approval that industry had reason to believe the Agency was leaving behind as it evolved into a HACCP-based public health regulatory agency. NFPA opposes any return of the bureaucratic, technology-impeding prior approval programs of old.

Specific Comments

New policy should expedite new technologies, especially those that can enhance food safety.

NFPA concurs with the Agency statement that "…. facilitation of new technology represents an important means of improving the safety of meat, poultry, and egg products." To the extent that this new policy does, in fact, expedite, rather than impede, the ability of companies to develop and to employ new technology that can enhance food safety, without undue burden, we strongly support the new policy. However, if the new policy results in new regulatory hurdles and paperwork exercises that hinder timely use of new food safety tools without providing significant benefit, we strongly object to the new policy.

Guidance on the types of situations that require notification versus those for which notification is not required would be helpful.

The Agency has defined "new technology" as new, or new applications of, equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products. This is a very broad definition. Steam vacuums,

steam pasteurization, and antimicrobials are listed in the preamble to this FSIS notice as examples of advances in food safety technology. Technology that changes the line speed for poultry slaughter and devices for detecting and sorting contaminated carcasses are mentioned as new technologies that may require a waiver of existing regulations and changes to current inspection procedures, respectively.

In circulating the new policy among our membership, many questions arose as to what types of processes and technologies will be covered under the new policy. We believe an expanded list of examples in which notification is required as well as examples of situations in which notification is not expected would be very useful to industry.

We presume that new technologies that are currently in use within establishments will not need to go through this process. Likewise, it would appear that no useful purpose would be served by requiring notification of "new technologies" that are currently used in one establishment prior to use in another establishment under similar circumstances, for example in another plant of a multi-plant firm or any other USDA-regulated facility. Once a technology has been accepted by the Agency, its use elsewhere within the industry should not be considered new. In fact, it would be useful for the Agency to notify industry of new technologies that have been accepted by the Agency, unless such information is proprietary, and to indicate any limitations on use as well as Agency validation expectations for application in other plants.

To the extent possible the Agency should minimize the cases to which the notification process applies.

The Agency projects that the vast majority of new technology notifications (210 of 250 or 85%) that it receives will not warrant the need for pre-use review. If most notifications are such that it is readily apparent that no pre-use review is needed, perhaps there are broad categories of "new technologies" for which notification amounts to no more than a paperwork exercise. If so, we suggest that those categories be excluded from the notification process altogether. This would provide for better utilization of Agency and industry resources toward those new technologies, which truly warrant pre-use review.

Two months is too long for a response to most notifications.

The *Federal Register* notice states that the Agency ".... will make every effort to review the document and notify the firm within 60 calendar days...." When the issue involves potential enhancements to food safety, we believe the Agency has an obligation to facilitate the associated review process and to foster implementation; it should not be an impediment. One means for facilitating rapid review is to assure that the Agency utilizes all of the electronic communications capabilities that are available today and that industry applicants are permitted to do the same.

The Agency must assure that it will have adequate resources to promptly review both submitted notifications and protocols. As is the case with industry, the Agency must be prepared to make proper decisions about the use of limited and valuable resources.

A routine 2-month delay in responses that indicate that no pre-use review is warranted would mean a 2-month delay in a company's ability to use new food safety tools; this would be unacceptable. If the majority of the notifications are somewhat *pro forma*, we suggest that one week rather than 8 weeks should be a targeted response time. We encourage the Agency to state publicly its intent to respond to the majority of notifications within a one or two week period. If there are issues identified in this period that would require more extensive review, the company should be made aware of them at that time together with a commitment that the review will be completed within a specified period of time (ideally not longer that 8 weeks) and a notation concerning any additional information needed to complete the review, the name of the contact officer handling the review, and any other items that need to be addressed.

If the Agency fails to respond to a notification within a specified time frame, companies should be able to utilize new technologies without fear of repercussions.

We understand that the Agency response to some notifications of new technologies will take longer than others. However, the notice appears to suggest that no matter how long the Agency takes to issue a "letter of no objection," the firm will risk having the Agency deem product to be adulterated if it is processed using the new technology before the letter is received. We believe the Agency should have a greater responsibility for timely response, such that a firm can use a new technology after the specified time period (we recommend one to two weeks, but even 30 days would be preferable to 60 days), unless the Agency has notified the firm that additional time is required and indicated why additional review is necessary. Obviously, if the Agency can demonstrate that the product produced by the new technology is in fact adulterated, it can take action against the product. However, a firm's use of a new technology, after the specified time period has elapsed but without having received a letter of no objection, should not be the sole basis for deeming product to be adulterated. Indeed, we would recommend that the Agency expressly provide for "passive approval," that the technology may be used unless the Agency affirmatively notifies the establishment in writing that a pre-use review will be required.

Food additive approval expedition is also needed.

It is not clear exactly how this new technology policy relates to the approval process for new additives that can contribute to food safety. The preamble notes:

> "Substances used as new technology must also meet the requirements for safety and suitability under the Agency's food ingredient approval process. While FDA has the responsibility for determining the safety of food ingredients and additives, as well as prescribing safe conditions of use, FSIS has the authority to determine that new ingredients and new uses of ingredients are suitable for use in meat and poultry products."

NFPA was a leading proponent urging FDA and FSIS to eliminate the duplication of effort regarding new food additive approvals. However, whether we're talking about new approvals for irradiation of multicomponent meat and poultry food products or expanded uses or higher levels of pathogen-inhibiting additives, regulatory approvals are already taking far too long.

In 1999, NFPA submitted on behalf of a broad industry coalition a petition for greatly expanded use of irradiation as one means for enhancing the safety of a wide variety of ready-to-eat foods. Though certain issues have arisen that required the development of and submission of additional data to FDA that has necessitated narrowing the scope of the final rule, it is clear this process is simply taking too long. Likewise, we are aware that industry requests for new uses or use at increased levels of certain inhibitors have taken extremely long periods of time to come to fruition. At a minimum, we respectfully submit that for any GRAS substance, there should be no issue with its use in meat and poultry and no pre-use review, provided the use is consistent with the GRAS regulation.

If this new policy contributes to a shortening of the time to gain new food additive approvals or new uses of approved additives, we strongly approve. However, on the surface, the two measures seem to be independent. If a new additive has received an FDA food additive approval, it should not be necessary for each firm that wants to use the new additive to go through this new notification process before doing so. That could only impede rather than expedite use of such new technologies. Once the Agency has concurred with a notification on the new use the Agency should inform the industry that the new use has been reviewed and is acceptable for general use as outlined in the original notification (unless such use is identified as proprietary).

On a related matter, we are aware of companies that have experienced delay in obtaining approvals not because the technology was ineffective or because it posed a safety concern, rather the delays have been the result of labeling and other technical issues. The new policy does not address these types of issues. We believe that if the Agency wishes to quickly permit the use of food safety interventions, it needs to both streamline the label process and articulate sound policies to govern labeling issues.

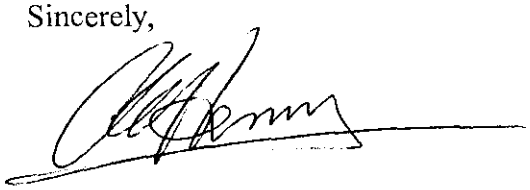
Protection of confidentiality of proprietary information.

We request that the Agency provide assurances that proprietary information contained in protocols or in data from in-plant trials that are subsequently submitted for Agency review will not be available for release under FOIA provisions.

Summary

NFPA strongly encourages government effort to expedite the processes by which new technologies, especially those that can contribute to food safety, are cleared for use by industry. Any elements of the FSIS policy on new technologies that slows rather than speeds the review process should be changed as soon as possible. The best possible public health protection for or Nation's consumers depends on it.

Sincerely,



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