NFPA
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

August 8, 2003

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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 98N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments; 68 Federal Register 33727; June 5, 2003.

Dear Sir or Madam:

John R. Cady
President and
Chief Executive Officer

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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, nutrition, technical and regulatory matters, food security 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.

NFPA offers the following comments concerning FY 2004 program priorities for CFSAN.

General Remarks

- NFPA strongly encourages CFSAN to keep implementation of regulations under the Public Health Security and Bioterrorism Preparedness and Security Response Act (P.L. 107-188) as a top priority. The Agency must have regulations in place for registration of food facilities and for prior notice of imported food products with enough lead-time for regulated entities to be in compliance by December 12, 2003. Every effort must be made to complete the rulemaking in a timely manner to meet the Agency goal for publication not later than October 10, 2003. The 60 days provided by an October publication will be critical for the food industry to maximize compliance with the requirements of the final regulations.

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The Agency should also give priority to completing rulemaking on the record keeping and product detention proposals issued under the Bioterrorism Act.

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Although these provisions are self enacting there is a need to have clear, concise regulations in place prior to any emergency situation that may need to be addressed under the law so that Federal and State regulatory officials and the food industry can work together to minimize the risk to the public. FDA should recognize that the best means of addressing the issue of terrorism and food security involves a partnership with the industry that is based on a common understanding and awareness of requirements.

Although anti-terrorism efforts and food safety programs are and should be top priority items for CFSAN, the Agency must continue to provide adequate support for other CFSAN issues and responsibilities as required by the Federal Food, Drug, and Cosmetic Act.

NFPA provides the following comments on CFSAN priorities for FY 2004 using the priority areas as identified in the 2003 CFSAN priorities for reference.

Part I: Assuring Food Safety and Security

1.1 Food Security: Implementing New Legislation

Regulations

FDA should continue to maintain an "A" priority for the issuance of final regulations for 1.1.6 final rule for the establishment of food facility registration requirement and 1.1.7 final rule for the establishment of prior notification requirements for all imported food to meet or beat the target date of October 10, 2003 for publication.

Item 1.1.5, which concerns industry outreach, should also be kept as an "A" priority with clear focus on implementing outreach and providing information and materials for use in FDA as well as industry efforts.

FDA should elevate 1.1.8 final rule for the establishment and maintenance of records to identify immediate previous source and immediate subsequent recipient of food and 1.1.9 final rule for the establishment of administrative detention requirements from "B" priority to "A" priority and strive to meet the announced target date for publication.

Guidance

The guidance documents: 1.1.11 food facility registration, 1.1.12 prior notification requirements, 1.1.13 establishment and maintenance of records, and 1.1.14 establishment of administrative detention requirements should be elevated from "B" priority to "A" priority.

IT Systems

1.1.15 Design and build, in conjunction with the Office of Regulatory Affairs (ORA), a food facility registration system as a requirement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

This should be maintained as an "A" priority with slight modification – **1.1.15** "Maintain and update the food facility registration system, correct any problems as they are identified, and ensure continuous access to the registration web site." This site must be maintained to provide a timely basis for food facility registration by the Congressionally mandated deadline of December 12, 2003, provide for timely updates of information from registered companies, and the registration of new facilities and the deregistration of facilities no longer involved in the food business. Access, simplicity and security should be major priorities.

1.1.16 Design and build, in conjunction with ORA, the electronic system to support prior notification requirements for all imported food shipments as a requirement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

This should be retained as an "A" priority and revised to read **1.1.16** "Design and build, in conjunction with ORA and other federal agencies including the Bureau of Customs and Border Protection, a single system to support prior notification requirements for all imported food shipments as a requirement of the Public Healthy Security and Bioterrorism Preparedness and response Act of 2002 and ensure continuous access to the prior notification web site."

1.2 Food Security: Emergency Preparedness

Laboratory Preparedness

1.2.1 Evaluate rapid analytical tests for their application to foods

This should be retained as an "A" priority with the following modification "Evaluate rapid analytical tests for their application to foods and share this information with States and the affected industry."

Whenever possible the Agency should partner with the food industry in evaluating rapid analytical tests to provide better allocation of resources in assessing whether or not a rapid method is sufficiently accurate to be relied upon by the Agency, the affected industry, and State regulatory officials in a food security situation.

1.2.2 In conjunction with ORA, other federal agencies and the states, support the development, including training, of a nationwide Laboratory Response Network (LRN) for food.

This should remain as an "A" priority with the following modification "In conjunction with ORA, other federal agencies, the states, and private laboratories including food industry laboratories, support the development, including training, of a nationwide Laboratory Response Network (LRN) for food."

FDA should recognize that there are many food laboratories conducting routine food safety and quality testing that could be called upon to assist in an emergency situation. FDA should actively seek the voluntary participation of such laboratories in the LRN to provide a broader base of food expertise to assist in training laboratory personnel. Laboratories registered with the Centers for Disease Control and Prevention (CDC) or the Animal and Plant Health Inspection Service (APHIS) under the Select Agent Registration program should be considered as prime candidates for partnering.

1.2.3 Develop research needs to enhance emergency preparedness against possible terrorist threats.

Elevate to an "A" priority with the following modification **1.2.3** "Identify research needs to enhance emergency preparedness against possible terrorist threats and partner with appropriate research facilities to develop and conduct research."

FDA should strive to expand its limited resources whenever possible through appropriate partnering with suitable research facilities or private entities.

Response Capability

1.2.5 Continue to participate in emergency response exercises

FDA should continue to participate in emergency response exercises as directed by HHS. Recommend this continue as an "A" priority.

Guidance to Industry

1.2.8 Enhance coordination of food security and counter-terrorism issues with federal, state, and local governments and other organizations, including leadership in the Food Threat Preparedness Network (PrepNet)

This should remain as an "A" priority to ensure information/response on threats is provided to all potentially affected parties including food industry contacts. If an

event should occur, accommodation should also be made to conduct a debriefing session with major players as soon after the event as possible to properly evaluate the reactions/responses/outcome of the event.

1.3 Domestic Inspections NFPA agrees that inspection of domestic firms that produce "high risk" foods should remain an "A" priority with an appropriate review of the results to determine priorities for the following year.

1.4 Imports and Foreign Inspection NFPA agrees that inspection of imported food products should remain an "A" priority with a focus on "high risk" foods for FY 2004.

1.5 Seafood Safety

1.5.2 Develop strategy to increase above the level of 85% the number of seafood processors that are in compliance with the seafood HACCP program

NFPA commends FDA and the industry for success in increasing the levels of compliance with the Seafood HACCP Program to 85% as a FY03 "A" list priority. We encourage continued efforts to further increase the rate of compliance by re-identifying segments of the industry that face greater challenges to develop and confirm adequate and practical controls for HACCP implementation. Specifically, improving guidance for controlling histamine in Scombroid species should be elevated from a FY03 "B" list priority to an FY04 "A" priority if such guidance is not completed by September 30, 2003. Other potential hazards that warrant consideration for development of alternative control strategies include: Control of *Listeria monocytogenes* in cold smoked fish, control of *Clostridium botulinum* in products packed in reduced oxygen packaging, and parasite control measures.

As a new priority for FY04, NFPA encourages FDA to develop compliance policy that provides for equal consideration of guidance in the Fish and Fisheries Products Hazards and Controls Guide, as well as industry developed control strategies. We believe that such a policy will foster additional research that will result in science-based solutions to lingering seafood HACCP issues.
As imports comprise 76% of the 4.2 billion pounds of seafood consumed in the US, FDA should continue to focus efforts on identifying high-risk products for import sampling and analysis, as well as ways to identify and facilitate the importation of seafood products that are in compliance with the Act. This would involve assessment of products with regard to both food safety and food security risk. FDA's Compliance Program 7303.844 provides a basis for this assessment, but the Agency must evaluate their resources to make certain this compliance program can be successfully implemented in light of the increased number of import examinations overall due to elevated food security measures. We

recommend FDA place high priority on developing a strategy that provides for effective and efficient import of compliant seafood products.

1.5.3 Continue to work with the ISSC to implement a control strategy for *Vibrio vulificus* in raw oysters

Due to the serious nature of illnesses related to consumption of raw shellfish contaminated with *Vibrio vulnificus*, efforts to develop strategies endorsed by the ISSC should again rank as high priority for the agency work plan. This was identified as an "A" priority item in FY03, but is likely to require additional time to fully educate the industry and implement any controls developed as the result of prioritization in FY03.

1.5.7 Continue a project to develop good aquaculture practices to ensure that aquaculture waters are not a source of pathogens or other contaminants

The development of good aquaculture practices should be considered for elevation to an "A" list priority. There has been an increased concern over both domestic and imported cultured products and the potential for both pathogen and antibiotic residue food safety issues that warrant priority attention in FY04.

1.5.8 Continue to work with the ISSC to develop a final control strategy for *Vibrio parahaemolyticus*

A companion activity to developing controls for *Vibrio vulnificus* are the efforts to also work with the ISSC to develop controls for *Vibrio parahaemolyticus,* a "B" priority in FY03 that is recommended for "A" list consideration in FY04.

1.6 Fruits and Vegetables

1.6.5 Finalize the 1st edition of the draft Juice Hazards and Controls Guide

Juice HACCP should be retained as an "A" priority to address compliance issues. Although FDA has completed the Juice HACCP Training Manual and the initial training of inspection staff, additional items must be completed. The final rule was published in January 2001. The Juice HACCP Alliance, coordinated by the National Center for Food Safety and Technology, has only recently completed and released the training curriculum for both FDA and the industry. The Juice Hazards and Controls Guide and the second set of Juice HACCP Questions and Answers should be completed as an A priority before October 2003 or as soon thereafter as practical. In no case should this be delayed beyond November 2003. The regulations are in effect and guidance is needed to ensure industry compliance now.

NFPA recommends FDA establish Juice HACCP training as an "A" priority for FY 2004 and be prepared to participate in industry training sessions as well as in the training of Federal and State inspection personnel.

1.6.14 Produce and distribute a video on safe juice processing with the California Department of Health Services.

This should be an "A" priority. A video on juice processing would enhance the current Juice HACCP Training Curriculum.

1.8 *Listeria*

1.8.1 Issue the revised risk assessment on *Listeria monocytogenes* contamination in ready-to-eat foods.

This should be retained as an "A" priority and completed early in FY 2004 if it is not completed in FY 2003.

1.8.2 Develop a guidance document advising processors on steps to reduce *Listeria monocytogenes* contamination in ready-to-eat foods.

The food industry has developed guidance documents that address *Listeria monocytogenes* contamination in ready-to-eat foods; therefore, there is no need to expend Agency resources at this time. This should either be deleted or, alternatively, retained as a "B" priority with the goal of evaluating the food industry guidance documents to ensure they adequately address the issues.

1.10 Chemical Contaminants, Pesticides and Other Hazards

1.10.5 Issue draft generic "channels of trade" guidance

We commend FDA for publishing the "channels of trade" guidance for comment in July 2003 and request that FDA maintain this as an "A" priority revised as follows "Issue final 'channels of trade' guidance." By continuing this action through to a final document FDA will effectively use its resources and avoid the need to issue a withdrawal of rulemaking notice at some future date.

1.10.8 Continue implementing FDA's dioxin strategy, including monitoring, method development and identifying opportunities to reduce exposures

FDA should continue implementing its dioxin strategy as an "A" priority.

1.13 Food Allergens

1.13.6 Develop draft guidance on the use of test kits, for regulatory actions, to detect the presence of peanut protein for regulatory purposes

This should be elevated from "B" priority to "A" priority.

1.13.7 Develop a proposed rule for the labeling of most common allergens using consumer and industry input from the August 13, 2001 food allergen public meeting

This should be elevated from "B" priority to "A" priority and be revised to concern major food allergens.

1.13.8 Develop a comprehensive food allergen strategy to address considerations such as cross-contact problems (not including bioengineered foods)

This should be elevated from "B" priority to "A" priority.

II. Assuring Food & Cosmetic Safety & Improving Nutrition Specific Programs Areas

2.1 Food and Color Additives: Premarket Review

2.1.1 Review of Industry Submissions/Statutory Requirements

NFPA recommends that all items under 2.1.1 be retained as "A" priorities for FY 2004.

2.1.3 Protecting and Promoting Public Health with Agency Initiated Actions

k. Develop documents to adopt the specifications in the most recent edition of the Food Chemicals Codex into regulations as appropriate

FDA should raise this from a "B" to an "A" priority and initiate action to update all references to the Food Chemicals Codex (FCC) standards/specifications in its regulations into appropriate sections of 21 CFR.

The specifications and test methods in 21 CFR are frequently out of date. FCC standards are current and revised on an on-going basis. By using the current FCC specifications CFSAN will ensure that the most current information about food additives and GRAS substances is in its regulations, meaning that those

companies following FDA regulations will have the most recent information available to them when preparing purchase specifications.

CFSAN funds the work of the FCC, participated in its meetings, and is involved with the development of the monographs on a continuing basis. Once the monographs are finalized, FDA publishes a Federal Register announcement requesting public comment on them. This notice could be modified to include incorporation into the appropriate standard(s) as a part of the process. Following a review of the comments and a final endorsement of the monographs by the National Academies the final monographs could be included in the appropriate standard(s).

NFPA strongly encourages FDA's continued funding to keep the FCC current and to provide continuity for the Committee on Food Chemicals Codex that oversees this publication. An added benefit is the leveraging of FDA resources to provide current food grade specifications for GRAS food ingredients.

NFPA recommends that this be elevated from a "B' priority to an "A" priority.

2.2 Nutrition Health Claims and Labeling

2.2.2 Review of Industry Submissions/Statutory Requirements

a. Review Premarket notifications for new infant formulas within statutory timeframe.

This should remain an "A" priority.

b. Review nutrient content/health claim notifications and petitions within statutory timeframe.

This should remain an "A" priority.

d. In response to the Farm Security and Rural Investment Act of 2002, develop a proposed rule to revise, as appropriate, the existing regulation that requires irradiated food to be labeled.

This should be elevated to an "A" priority for FY 2004.

2.2.4 Protecting and Promoting Public Health with Agency Initiated Actions

h. Evaluate ways to make the nutrition label more effective in providing science based nutrition guidance to consumers.

Given the guidance for industry and other recommendations/outcomes of the FDA Task Force on Consumer Health Information for Better Nutrition, we believe that evaluation of ways to make the nutrition label more effective in providing science-based nutrition guidance to consumers can remain a "B" priority. However, evaluation of consumer understanding of food labeling information should precede such an activity and should be an "A" priority goal for FY 2004. This goal should be coordinated with goal 2.2.1.f. Develop consumer studies research agenda.

i. Institute of Medicine/ National Academy of Sciences study to develop scientific rationale for methodology to be used to update reference values for use in nutrition labeling will be completed early in FY 2004. When the IOM report is received by the Agency, a new goal for FY 2004 should be established regarding the Agency's role to prepare proposed revisions to nutrition labeling values and related policy matters.

This FDA project should be a "B" priority.

2.2.5 Improve Efficiency/Responsiveness

a. Develop a final rule providing for more flexibility in the use of health/nutrient content claims in response to citizens' petitions.

NFPA recommends elevating this to "A" priority and coordinating with future activities related to the guidance and work from the FDA Task Force on Consumer Health Information for Better Nutrition reflected in priority 2.2.1.

b. Develop a proposed rule for nutrient content claims that are the subject of health claims.

NFPA recommends elevating this to "A" priority and coordinating with future activities related to the guidance and work from the FDA Task Force on Consumer Health Information for Better Nutrition reflected in priority 2.2.1.

c. Develop a final rule to update nutrient values for the voluntary nutrition labeling program

This should be elevated to an "A" priority, particularly in light of the questions related to *trans* fat that were addressed by the final rule on *trans* fat labeling published in July 2003.

2.2.6 Enforcement/Compliance

a. Continue to conduct enforcement activities related to inappropriate labeling of conventional foods.

This should remain an "A" priority.

III. Assuring Food Safety: Crosscutting Areas

3.2 International

Continue the current "A" list priority items into 2003.

3.2.1 Codex Committees and Working Groups

NFPA strongly supports CFSAN's continued strong leadership in Codex Alimentarius and agrees with the list of designated "priority" committees, noting that the ad hoc Intergovernmental task force on Foods Derived from Biotechnology has now completed its work and will not meet in 2004. NFPA also notes that there will be special sessions of the Committee on General Principles in 2003 and 2004 that will require active participation from CFSAN.

In addition to the listed items, which NFPA supports as an "A" priority, there is a need to ensure FDA has the funding to do extensive outreach before Codex meetings to educate, especially developing countries, on the issues and the science behind the U.S. positions.

NFPA also notes that particular attention should be paid to the work of the Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). This committee is considering critical science based issues, on which achieving international consensus as quickly as possible is imperative. For example, this committee is considering scientific substantiation for health claims and fortification with vitamins and minerals as well as standards for foods for special populations. These foods are increasingly important in international trade yet. However, this was the single Codex Committee that advanced no new standards for adoption in the past 2 years. The U.S. government must provide leadership to ensure that CCNFSDU becomes an effective and productive venue to address these important issues.

Trilateral US/Canada/Mexico Activities

Participate in Technical Working Groups (TWGs) with Canada and Mexico. The Agency must take a lead role on food initiatives to make more effective use of the TWGs as a venue to address ongoing cross border issues directed towards

barriers, policy, procedures, and standards in order to facilitate trade under NAFTA. In addition, TWGs will be created under the Free Trade Area of the Americas (FTAA) Agreement and under several other free trade agreements that will require CFSAN participation. Used effectively, TWGs can provide excellent forums to harmonize standards, build support for international for a, reduce trade barriers and prevent trade disruptions.

3.2.2 Working in concert with FDA's Office of International Programs, ensure effective communication with the Office of USTR.

Considering the multitude of on-going trade negotiations and the potential impact these negotiations may have on trade in food products, NFPA believes this communication should be an "A" priority for 2004. Effective interagency communication is essential to enable coordinated U.S. positions to advance in international forums, to ensure U.S. trade commitments are not compromised and to ensure that negotiations are effectively used to reduce technical barriers for U.S. food exports.

NFPA recommends this be elevated from a "B" priority to an "A" priority.

3.2.3 Export Certificates.

NFPA notes that the ongoing efforts under AFDO have been underway for three years at a "B" priority. This work saw significant progress in 2003 and AFDO now expects final recommendations by June of 2004. NFPA strongly suggests that the issue of export certification be elevated to an "A" priority and that "A" priority be given to completion of the AFDO exercise in 2004 with resulting recommendations for changes to U.S. policy and/or procedures.

NFPA recommends this be elevated from a "B" priority to an "A" priority.

3.2.5 Equivalency Criteria: Develop Agency criteria concerning equivalence

The Codex guideline for the determination of equivalency was adopted in 2003. FDA should insure US criteria are consistent with the Codex guidance as the determining international standard. NFPA believes equivalency agreements can be useful to minimize resource needs and facilitate trade.

NFPA recommends this be elevated from a "B" priority to an "A" priority.

3.2.6 Develop proposal to consider adoption of Codex standards

This should be retained as a "B" priority.

3.3 Food Biotechnology

3.3.5 Develop a final rule for the biotechnology notification program. NFPA recommends that this be elevated from a "B" priority to an "A" priority for 2004

3.5 Focused Economic-based Regulations

Prevention of Economic Fraud

CFSAN should make issues related to economic fraud a priority for attention. The Agency must maintain a recognized presence in the area of enforcement to assure that consumers are not cheated, and that the reputable food industry is not at a disadvantage for complying with the law and regulations. Ensuring consumer confidence in the food supply through prevention of economic fraud is a necessary corollary of consumer protection through strong food safety activities. Individuals and companies engaged in fraudulent activities are just as likely to have little regard for the welfare and safety of the public, and should not be allowed to operate. FDA has an obligation to enforce the existing statutory provisions and to continue to pursue and prosecute fraudulent activities.

Develop a plan to review and address the current backlog of petitions related to standards of identity in a timely manner

NFPA recommends that FDA establish as an "A" priority, the setting up of a timetable to get requested actions underway, with priority for petitions addressing outstanding NLEA issues (e.g., tuna drained weight) or products currently packaged under temporary marketing permits.

We suggest that CFSAN review its backlog list of pending petitions to amend standards of identity (especially those associated with temporary marketing permits) and add these to the "A" list for 2004. NFPA's June 4, 1989 petition to amend the canned salmon standard of identity to include the style "skinless, boneless" should be included in that list (Docket No. 88P-0190/CP02). CFSAN should develop a plan to review and complete these items in a timely manner. FDA successfully initiated and completed a notice detailing labeling requirements for catfish in one year. NFPA is encouraged by this accomplishment that more timely completion of actions on pending petitions is possible.

NFPA also requests FDA consider as a "A" priority item for 2004 the 1989 citizens petition (Docket # 88P-0190/CP02) to amend the canned salmon standard of identity at 21 CFR 161.170. NFPA understands that FDA is currently evaluating their "Guiding Principles for Standards"; however until those principles are developed we feel the appropriate amendments to the canned

salmon standard of identity would provide companies the opportunity to introduce innovative new products to the market under the standard that would satisfy the preferences of their consumers. Because of the development of new processing technologies and further identification of consumer desires since 1989, NFPA also would like to advise FDA that further amendments to the petition are being considered for submission to FDA prior to 2004.

NFPA also recommends as an "A" priority completing action on the petition to develop proposed regulations on standard of fill for canned tuna based on the drained weight of the contents, to allow for upgrades in methodology for determining weight and to achieve consistency with international standards.

We appreciate this opportunity to comment on CFSAN priorities for FY 2004 and encourage FDA to consider our points as priorities are established. Please contact us if you have questions or wish to discuss our comments in more detail.

Regards,

John R. Cady