



September 20, 2001

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, Maryland 20852

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Re: Docket No. 98N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments; 66 Federal Register 37480; July 18, 2001.

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments on CFSAN priorities for FY 2002. In the above referenced notice FDA requested comments concerning the establishment of program priorities in CFSAN for FY 2002. Specific comments were requested concerning FY 2001 "A" list activities that, if not completed, should be carried over to FY 2002 and which FY 2001 "B" list activities should be elevated to the "A" list for completion in FY 2002.

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 fruits, vegetables and grain products, meat, poultry, and seafood products, snacks, drinks, and juices. In addition NFPA's non-processor members provide ingredients, equipment, supplies, and services to the processed food industry.

NFPA strongly believes that food safety issues should continue as the number one priority of CFSAN. NFPA recommends that CFSAN retain on its 2002 priorities "A" list any items that remain incomplete from the 2001 priorities list. The enumerated priorities are the most significant items requiring attention and resources at FDA, and having been identified as priorities, they should remain on the priority list until completed. Retaining items on the list until completed will also ensure that CFSAN does not undertake work that exceeds its resource allocations. We believe that sufficient progress will be made annually on these priorities and that enough flexibility will remain for CFSAN to accommodate emergent issues.

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- **Food Safety Initiative**

Priorities on the "A" list that have not been completed should be retained on the "A" list for 2002 and given priority to complete.

Strategy 1.1 – Domestic Inspections

The following should be added to the "A" list of priorities for 2002.

Review the current definition of "Pasteurization" and develop a broad definition that is applicable to foods other than milk to include treatments other than heat (e.g., high pressure, irradiation).

Strategy 1.4 – Fruits and Vegetables

Item 1.4 Juice HACCP should be retained as an "A" priority and amended to address training and compliance issues recognizing that, although the final rule was published in January 2001, the critical Question & Answer document was not available until August 31, 2001. Lack of this critical information hampered training efforts of both NFPA and our education affiliate The Food Processors Institute (FPI). Indeed, FDA's delay in providing these important documents, necessitated by the need for detailed legal review, causes concern regarding the ability of industry to receive appropriate training and conduct the in-house evaluation/implementation in all plant facilities subject to the January 22, 2002 compliance date for the regulation. The Juice HACCP Alliance, coordinated by the National Center for Food Safety and Technology, is now preparing training materials following its first meeting in September. These are projected to be available between October 2001 and January 2002.

Maintain Juice HACCP training as an "A" priority for FY 2002 and be prepared to participate in industry training sessions as well as in the training of Federal and State inspection personnel.

Strategy 1.7 – Education

The following item should be added to the "A" list for 2002

Use funds to distribute the "Food Irradiation: A Safe Measure" information brochure so it is used in teaching and school food safety curricula.

- **Major Program Areas**

Strategy 2.2 – Nutrition, Health Claims and Labeling

Complete the following “A” list item.

Regulations/Guidance

(a) Publish a final rule for trans fatty acid labeling. The final rule should provide the maximum time for an orderly label change, as NFPA has requested in comments on the subject.

Move from the “B” list to the “A” list.

1. Regulations/Guidance

(f) Develop a final rule providing for more flexibility in the use of health/nutrient content claims in response to citizen petitions 94P-0390 and 95P-0241.

On April 4, 2000, NFPA commented to FDA that the Agency should implement the court’s decision in *Pearson v. Shalala* for conventional foods in the same manner and on the same schedule as for dietary supplements. NFPA believes most strongly that the *Pearson* decision applies to health claims for conventional food. To implement the *Pearson* decision fully, FDA must ensure that the policy reforms needed to protect truthful, non-misleading health claims from unconstitutional regulation extend equally to both conventional foods and dietary supplements.

To date, CFSAN has enumerated all of its goals and objectives related to the *Pearson* decision on the section of its priorities list related to dietary supplements. NFPA believes that *Pearson*-related goals also need to be included in the strategic category for Nutrition, Health Claims and Labeling. To ensure that important First Amendment concepts reflected in the *Pearson* decision are applied as well to the labeling of conventional foods, NFPA urges CFSAN to include on its 2001 priorities list, in the category of Nutrition, Health Claims, and Labeling, the following item:

Develop a strategy to apply the precepts of the *Pearson* decision to health claims provisions for labeling of conventional foods.

This item should receive the same level of priority as the item that is currently on the CFSAN priorities list:

In response to citizen petitions 94P-0390 and 95P-0241, develop a final rule amending the regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products.

The objective related to these citizen petitions springs, in large part from the petition on health and nutrient content claims flexibility that NFPA filed with FDA in 1994 [Docket No. 94P-0390]. As NFPA reiterated in its April 4, 2000 comment, the reforms sought in our 1994 petition are consistent with the health claims reforms mandated by the *Pearson* decision. Therefore, NFPA believes that it is appropriate for FDA to advance work concurrently, and with the same urgency, on both a *Pearson* strategy with respect to conventional foods and the final rulemaking related to our 1994 petition.

Add the following items to the "B" list for 2002.

Initiate strategy to incorporate NAS DRI work into revisions to RDIs and DRVs. This is a multi-year project but strategic planning should begin as several DRI reports are completed and the NAS/FNB report on macronutrients is expected to be released by early 2002.

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 being 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

Maintain as a "B" priority item for future work.

(b) Develop a proposal to amend FDA regulations for food irradiation labeling.

Strategy 2.3 - Dietary Supplements

Add to the "A" list priority for 2002.

1. Regulations/Guidance

Publish final rule on GMPs for dietary supplements. This is important as a prerequisite for those considering voluntary HACCP for production of these products. These should be at least equivalent to the food GMPs to address any safety concerns.

Strategy 2.4 – Chemical Contaminants, Pesticides and Other Hazards

1. Mycotoxins

Retain on the "A" priority list for 2002.

(a) Issue final patulin guidance.

- Crosscutting Program Areas

Strategy 3.3 – International

Continue the current "A" list priority items into 2002.

(1) Codex Committees and Working Groups. In addition to the listed items which NFPA supports as an "A" priority there is a need to ensure FDA has funding to do extensive outreach before the Codex meetings to educate – especially developing countries – on the issues and the science behind the U.S. positions. This takes funds and resources.

(3) NAFTA TWG's: Participate in Technical Working Groups (TWGs) with Canada and Mexico. Simple participation is not enough – the Agency should 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. Used effectively, TWGs can provide excellent forums to harmonize standards and prevent trade disruptions.

FDA equivalence criteria have been in an unfinished state since 1998. The Codex guideline for the determination of equivalency should be adopted in 2001. FDA should review the proposal to harmonize internationally and advance them. NFPA believes equivalency agreements can be useful to minimize resource needs and facilitate trade.

Move from the "B" to the "A" list.

2. Export Certificates: Achieve progress in defining the needs of exporters for food export certificates and approaches to issuing them, including current and future demands on the Agency for issuing such certificates. Discuss and review with states, industry, trade agencies, consumer groups and other stakeholders. Assure consistency of international guidance regarding export certificates with U.S. practices

"Export Certification Procedures" need to be on the "A" priority list. The US has a positive balance of trade in food products, due primarily to further processed food products (value added food products). The increase in requests from importing countries for official government certification of imported food products threatens to slow or halt this trade. FDA must harmonize U.S. standards with those adopted by Codex in 2001 and continue a leadership role with other federal and state officials and industry representatives to develop a domestic solution for export certification that will meet importing nations' demands in a timely manner, maximize regulatory resources and facilitate trade.

Strategy 3.4 – Emerging Areas

Add to the "A" list for 2002.

1. Biotechnology

Publish final guidance on voluntary food labeling of biotech foods, and a final rule on mandatory pre-market notification for biotech foods.

Develop a consumer education program on biotechnology addressing the safety and benefits of foods and ingredients developed through biotechnology and other issues, which have been identified as consumer concerns.

2. Food Allergens

CFSAN should develop more science in the area of food allergens to describe and predict the relationship between foods and human allergenicity, including threshold levels that may elicit reactions in sensitive individuals.

CFSAN should develop/assess current methods for detecting/quantifying allergens in foods.

CFSAN should develop criteria for determining how changes should be made to the list of major food allergens of concern.

Strategy 3.5 Regulatory Processes

Add the following items to the "A" priority list for 2002.

Enhance regulatory presence in evaluating BSE/TSE risk within the U.S. and increase frequency of inspection of animal feed operations to ensure compliance with existing regulations.

Incorporate Food Chemicals Codex (FCC) standards/specifications 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 recent 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).

Strategy 3.6 – Focused, Economic-based Regulations

Add the following item to the "A" list.

Develop a plan to review and address the current backlog of petitions related to standards of identity in a timely manner. Set up a timetable to get the requested action 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 "B" list for 2001. 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.

The following "B" list item from 2001 should be upgraded to the "A" list for 2002.

2. 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.

National Food Processors Association

Docket No. 98N-0359

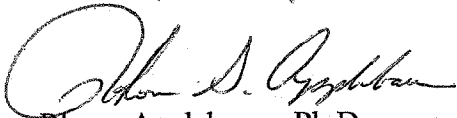
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Thank you for providing this opportunity to comment on the establishment of program priorities for CFSAN for FY 2002.

We understand that CFSAN may need to amend any priorities during the year to address emerging situations (as was done in FY 2001) and to implement any new considerations that may be identified as a part of The President's Management Agenda for FY 2002. Likewise, NFPA will communicate to CFSAN any emerging situations that the association feels require additional attention/resources during the coming year.

Sincerely,

A handwritten signature in cursive script, appearing to read "Rhona D. Applebaum".

Rhona Applebaum, Ph.D.

Executive Vice President

Scientific and Regulatory Affairs