

CFSAN PRIORITIES - 1999

September 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: **Docket No. 98N-0359**

Safe Tables Our Priority is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. We count among our members victims of *E. coli* O157:H7 contaminated meat, lettuce and apple juice; hepatitis A contaminated strawberries; *Vibrio vulnificus* in oysters; *Salmonella* contaminated poultry and eggs; and *Campylobacter* contaminated poultry. In all of these cases, the dangers of potentially contaminated products were known to government. And in all of these cases, inadequate efforts by government to warn consumers failed to protect them from life threatening illnesses. We appreciate this opportunity to comment on year 2000 priorities for the Center for Food Safety and Applied Nutrition.

We previously submitted comments on CFSAN priorities on July 27, 1998 for the 1999 fiscal year. As very few of these items were addressed in the final 1999 priorities document, we would like to submit them again for renewed consideration. In addition, we would like to review where and why CFSAN's priorities were not entirely successful this year and how CFSAN might be able to improve in delivering on its priorities.

Issues that Are Not Being Adequately Addressed

The first question in the Federal Register notice for year 2000 CFSAN priorities asked, "With respect to products under the jurisdiction of CFSAN, do you believe there are issues that directly affect consumer safety that are not being adequately addressed?" S.T.O.P. strongly urges CFSAN and the FDA to immediately begin rulemaking on the control and application of manure and manure derivatives and to issue proposed rules before the end of the year 2000. FDA should convene a joint meeting between FDA, USDA's FSIS and the EPA early in the year 2000 to begin to review this critical issue.

In S.T.O.P.'s July 27, 1998 comments, we specifically referred to manure control as a critical area for FDA for 1999. Our April 30, 1998 comments to USDA's Agricultural Marketing Services regarding the National Organics Program (National Organic Program)

(attached) detailed scientific data arguing that the practice of using raw and insufficiently composted manure is furthering the spread of pathogens in the soil, on

food and to people. Animal feces is the source, either directly or indirectly, of the majority of the foodborne illness FDA is addressing outside of shell eggs and molluscan shellfish. Because consumers can be sickened by ingesting even a minute amount of pathogens, it is imperative to resolve contamination issues at a farm level before produce reaches the consumer, particularly for produce that will be served uncooked or lightly cooked.

In addition, in our June 26, 1998, (Docket Number 97N-0451) comments on "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables," S.T.O.P. pointed out several areas that the document, and therefore, CFSAN, had not sufficiently addressed. These included:

- Developing a systematic classification of fruit and vegetables that share common growing, harvesting or processing techniques in order to develop regulations to mandate on-farm GMPS.
- The need for mandatory traceback and farm-of-origin labeling.

Both of these areas deserve CFSAN's immediate attention if CFSAN expects to move from a reactive position in its treatment of food hazards to a proactive position in the next century.

The Highest Priority International Activities

The fourth question of the Federal Register notice asked, "Because so much of the nation's food supply is either imported or exported, what do you believe should be the highest priority international activities?" Going well beyond publishing its Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables, CFSAN needs to develop and *mandate* minimum standards. Once minimum domestic standards are established, an equivalency program should be developed that exporting countries must meet or exceed in order to ship to the U.S. This program could be modeled after FSIS' equivalency program for imported meat and poultry.

1999 Priorities Critique

The juice and sprout priorities in the 1999 CFSAN Priorities document were:

HACCP at Retail: Provide guidance, training and technical assistance to federal, state, and local governments and industry in applying HACCP at the retail level.

Juice HACCP: Publish a final rule regarding HACCP for fruit and vegetable juices.

Sprouts: Develop a strategy and initiate its implementation for assuring the industry use of practices to ensure safe production of sprouts and the control of pathogens.

Citrus juices: Implement accelerated plan to assure that industry achieves a 5-log reduction for pathogens in lieu of the labeling requirement.

In all four of these cases, whatever CFSAN accomplished did not prevent significant foodborne illness outbreaks from sprouts and juice. As a result, at least one person is dead from unpasteurized juice and hundreds of cases have been identified associated

with sprouts and juice. With current estimates of underreporting, this suggests that thousands of cases have gone unidentified.

FDA's objective-- to protect the public's health-- should always be foremost in setting priorities. Therefore, CFSAN's highest priorities should be ones designed to prevent illness. Foods associated with repeated outbreaks and illnesses, such as unpasteurized juice and sprouts, are a logical place to begin developing and implementing intervention strategies to prevent foodborne illness.

Unfortunately, from the outside, CFSAN appears to have several factors that inhibit its ability to deliver swift and effective results. These are:

1) Emphasizing the priority of a task rather than the priority of the objective

If CFSAN is focused on the objective of *preventing and reducing the number of foodborne outbreaks and illnesses*, then it can use many different types of tasks to achieve its objective. Unfortunately, when CFSAN sets the *implementation task* as the priority, and agency workers are rewarded on *tasks*, such as "publish the document," the bigger picture is lost. Thus, as deadlines slip or documents require revision, CFSAN is not thinking of other ways which might contribute to reducing illnesses in the short run. One overlooked area that would have a significant impact on reducing illness immediately is that of building significant, short term consumer warning campaigns. Another would be an education campaign directed toward food insurers and the retail industry.

2) Working with unnecessary bureaucracy

CFSAN relies heavily on documents published by the NACMCF. However, the NACMCF committees move more slowly than necessary to provide recommendations to protect the public. On September 28-29th, 1998, FDA held an open meeting of the NACMCF to review the data on sprouts. Not until nearly six months had gone by did the NACMCF reconvene to review its conclusions and even then they were not finalized until May, 1999, eight months after the initial meeting. This type of time lag is inexcusable when lives are hanging in the balance. If CFSAN cannot rely on the NACMCF committee to promptly review science and turn around recommendations, perhaps CFSAN should find a committee that can.

3) Awaiting the perfect scientific conclusion

CFSAN needs to be able to take action to make food safer with the science that exists when an issue arises. Sometimes, CFSAN is searching for new and innovative solutions to problems that already have solutions, and those solutions could be utilized immediately. At other times, current science may not present any adequate solution, and under that circumstance, while pursuing additional science and data, CFSAN should act quickly to identify the food as hazardous to consumers through labeling and education campaigns or ban the food.

In unpasteurized juice, heat pasteurization is a reasonable viable solution to render juice safe, and the time-temperature curves for milk have proven to be largely successful in the United States. Rather than rely on these two simple facts, CFSAN has spent an inordinate amount of time researching many potential alternatives in

support of a performance standard while leaving consumers exposed to the threat of unpasteurized juices. This endless search for more data in support of creative, as-yet-unproven solutions hinders CFSAN from achieving its real goal, protecting the public health, in a timely fashion.

S.T.O.P. has consistently supported the need for research and science-based data in policy development. However, scientific research is an ongoing process, one that does not necessarily have an endpoint. Therefore, a time comes when the cost of waiting for incremental data is too high and a determination must be made to make decisions based on the sufficient science, common sense and logic that exists already.

4) Abstaining from regulating the retail market

An unsafe food is unsafe regardless of where it is served or the container in which it is served. FDA has the regulatory authority to take action, such as mandating consumer warnings or safe processing techniques, in juice bars, delis and restaurants where unpasteurized juices, sprouts and oysters are served and occasionally processed as well. As long as CFSAN's actions and priorities purposefully exclude these markets, such foods will continue to cause serious illness, injury and death, and FDA's objective, to prevent foodborne illness, will not be achieved. FDA needs to come to grips that the Model Food Code is not sufficient to achieve FDA's objectives and that the agency must think beyond its current focus to the full scope of its authority.

5) Not assigning tangible deliverables to the task

In confronting, serious, repeated food safety risks, CFSAN should respond quickly with tangible results having a direct impact on consumers. For example, one of CFSAN's objectives should be to prevent illness caused by sprouts and therefore its priority should be to create regulations and consumer and industry education that prevent illness caused by sprouts. Unfortunately, CFSAN's 1999 sprout priority was not even focused on rulemaking but instead was described as: "to develop a strategy and initiate its implementation." Yet, by the time the 1999 priorities were published, the sprout industry and the state of California had already developed and implemented strategies that, despite heroic efforts, were not working.

6) Granting of extensions

CFSAN does not need to grant extensions for implementing rules or practices to industry. Not only do such extensions interfere with CFSAN's achievement of its priorities, but the government's regulatory process already proceeds at a pace that industry can easily handle. Extension requests are nothing more than delay tactics.

Year 2000 Priorities Recommendations

In light of 1999, we would recommend that sprout and juice priorities be restated as follows:

Objective: To prevent preventable illnesses associated with juices.

Priority: To finalize a juice HACCP rule that renders all U.S. juice as safe as U.S. milk.

Priority: To build a strong education campaign warning consumers, insurers and retailers of risks associated with unpasteurized juices.

Objective: To prevent preventable illnesses associated with sprouts.

Priority: To propose and finalize a sprout warning label for sprouts sold in any form.

Priority: To propose and finalize a sprout HACCP rule that renders sprouts as safe as possible under current science.

Priority: To build a strong education campaign warning consumers, insurers and retailers of risks associated with sprouts.

We believe that priorities for molluscan shellfish and shell eggs may need to be similarly restated in the CFSAN priorities document.

As we stated earlier herein, CFSAN needs to be more proactive rather than reactive to food hazards in the 21st century. As known risky foods such as sprouts and juice are being addressed, CFSAN should simultaneously be developing and implementing strategies designed to prevent foodborne illness from foods that, to date, have not yet been associated with illness but have the potential to be because of the way they are grown, processed, etc.

Objective: To prevent foodborne illnesses due to pathogens in animal manure contaminating fruits and vegetables.

Priority: To meet with FSIS and the EPA in Q1 to review current science on on-farm fecal contamination of foods.

Priority: Before the end of 2000, to propose regulations that address the control and application of manure and manure derivatives used in the production of fruits and vegetables.

Priority: Before the end of 2000, to publish a draft systematic classification of different types of fruit and vegetables that share common growing, harvesting, or processing techniques.

Priority: Before the end of 2000, to propose a rule mandating on-farm GMPs, including minimum standards, that will also serve as equivalency standards for imported fruits and vegetables.

In Conclusion

S.T.O.P. appreciates the opportunity to review CFSAN's priorities. CFSAN is to be applauded for publicly conducting its annual reviews, and we urge the agency to continue this practice.

We know that CFSAN is committed to improving the safety of the food supply, but in this era of reduced resources and increased rulemaking requirements, substantive

changes take a dangerously long time. The agency needs to be doing more in alerting consumers of the dangers that exist now, even as it works to prevent those dangers. The public deserves this information in order to best protect their families. Our members have tragically realized how the best of intentions, e.g. giving their child "fresh" juice and "healthy" greens, have backfired into near-death experiences. A simple warning message on the package or at point of purchase could have saved lives and prevented much physical pain and emotional heartbreak.

Thank you very much for your consideration.

Sincerely,

Laurie Girand
Advisory Board Member

Nancy Donley
President
Mother of Alex (1987-1993)