

CFSAN PRIORITIES - 1998

July 27, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857

RE: Docket Number 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 priorities for the Center for Food Safety and Applied Nutrition.

The Federal Register indicated that CFSAN has placed the President's Food Safety Initiative as its highest priority. While we support the President's Initiative, it is merely a small beginning to address an enormous public health problem. For S.T.O.P. victim members, only those actions that tangibly and measurably improve the safety of food and protect consumers deserve our support. Therefore, we advocate that CFSAN's highest priorities should be regulations that promote consumer safety and safety-related product labeling regulations. Because S.T.O.P.'s focus is on pathogenic contamination in food, we will be focused on components that CFSAN may consider part of the FSI, but do not appear to be published in the "List of Major Activities."

Based on reports of the meeting held on June 24, 1998, we would also like to be very specific about S.T.O.P.'s concerns with directives to CFSAN from the food industries. Contrary to what many American food growers/processors would have CFSAN believe, domestic food safety is extremely important to the public. We expect the FDA to set high standards and to demand that U.S. and foreign growers meet them rather than settle for food safety to be dictated by the safety levels in other countries. Food safety in this country is not merely a "food handler" problem, or a problem that will be quickly resolved by telling consumers how to cook their foods. Raw juice outbreaks, repeated outbreaks associated with lettuce and sprouts, an outbreak of *Salmonella agona* from packaged cereal... these are the legacy of American growers. For FDA regulated products, contamination begins back at the farm and processor level. This is where change must be implemented.

S.T.O.P. refutes the ideas that industry will regulate itself or that the states can be responsible for enforcement. Repeatedly, as S.T.O.P. has interacted with food industries over the years, we have found representatives, growers and processors entrenched in their former practices. Repeatedly, we have found them trying to delay

change, to deny that they might ever be responsible for repeated outbreaks, to keep the public from understanding the full extent of contamination in food today. If industry had wanted to be responsible for its products, it would have instituted changes a long time ago in response to personal injury lawsuits. Only federal action and enforcement has ultimately brought about uniform change toward safer food. We therefore ask that CFSAN carefully consider the following areas.

Labeling

FDA has a responsibility to preserve public health. As food risks have emerged faster than FDA has been able to address them, it is incumbent on FDA to give consumers ways to protect themselves until FDA can act to address recognized food safety hazards. The first and most important way in which FDA can help consumers is by sharing with them information about foods that have been recognized as repeated causes of illness. When consumers know what government already knows, they will be able to demand the changes that will improve food safety from food retailers and growers and make informed purchase decisions.

S.T.O.P. strongly supports warning consumers of health hazards related to food types that have been identified as causing multiple outbreaks or that have been associated with diseases that result in chronic illnesses or fatalities. Repeated outbreaks and deaths are signs that:

- 1) the process of producing and delivering the food results in repeated contamination;
- 2) at-risk consumers are not sufficiently warned about the hazards of the food.

Therefore, S.T.O.P. asks that FDA immediately develop and implement warning labels similar to those for unpasteurized juices, for oysters, sprouts and lettuce that by their growing conditions have health consequences. We would also urge FDA to develop a list of food types that represent a potential for public endangerment that are not yet labeled. These industries should be put on notice that they need to clean up or bear a label that explains the threat unclean foods in their industry represent.

Injury Reporting

FDA's current methods for informing consumers of outbreaks and investigations is ineffective. S.T.O.P. asks that CFSAN set as a priority a system for notifying the public immediately under two circumstances:

- 1) A recall is in effect
- 2) An outbreak is under investigation.

Anytime a recall is in effect, the FDA should issue a press release that:

- 1) identifies the product/producer,
- 2) lists retail outlets,

- 3) gives directions to return the food type to the grocer,
- 4) details illness symptoms, and
- 5) advises to seek medical treatment when symptoms occur.

In addition, because press releases are not as easily accessible directly by consumers, the FDA website should promptly post any information about recalls and outbreaks. FDA could develop an e-mail list that distributed information about recalls and outbreaks to major news services, consumer groups and retailers, including non-English speaking communities. S.T.O.P. would expect to see ongoing outbreaks listed which have not had food sources identified, in addition to outbreaks that have been epidemiologically linked to CFSAN foods. Recall and outbreak information should also be posted at the point of purchase site at which any contaminated food was sold. Recall and outbreak information must reach everyone potentially affected in order to best protect the public's health and the information must be specific. If consumers are not informed of the extent of our food safety problems, they cannot understand how badly CFSAN and FDA need budget support.

Manure Control

S.T.O.P. cannot emphasize strongly enough our belief that it is the prevention of contamination at the source that must be the focus in any food safety strategy. One of the single, most obvious farming steps that compromises food safety involves the application of manure or composted animal feces as fertilizer to produce that is consumed uncooked or lightly cooked. FDA must take steps to eliminate the use of unsterilized manure and compost. Manure and compost regulation should be made one of FDA's highest priorities. Scientific studies have proven that the Organic Foods Production Act (OFPA) 60 day limitation on application of raw manure is insufficient based on the survival abilities of pathogens in both feces and soil.(1) Yet, this is one of few recommendations that exist for restricting the application of raw manure. Unfortunately, if soil or water contaminated with *E. coli* O157:H7 comes into contact with fresh produce, it is virtually impossible to eliminate the organism without a killstep such as irradiation, ozonation, or heat treatment. Because consumers can be sickened by ingesting even a minute amount of microbes, it is imperative to resolve contamination issues at a farm level before produce reaches the consumer.

Compliance

CFSAN must begin to set standards among growers for awareness of HACCP. As is apparent from the Produce Guidance document, it will take years for FDA and CFSAN to appropriately address food safety in produce such that improvement is actually seen. S.T.O.P. strongly supports mandatory HACCP for produce from farm-to-fork. Mandatory HACCP is critical to creating cleaner and safer foods because, when applied to all potential points of contamination and control from farm-to-fork, it ensures that safety is addressed at all levels and by all participants. In the meantime while FDA moves in that direction, growers should be encouraged to begin voluntarily implementing HACCP programs of their own. S.T.O.P recommends developing, in conjunction with the state and local agriculture extensions, an education/testing and certification program. Under this program, growers would be required to have staff on site that are certified in understanding HACCP principles and applying them to produce.

S.T.O.P. strongly supports the position that regulating agencies must have the authority to mandate recalls and assess civil penalties and fines as needed. Fines and penalties create strong incentives for food growers and processors to strictly follow food safety standards. Having this authority should be a top priority for the FDA.

Research

CFSAN has indicated that its current research is directed at "Methods Development" ("...research to develop new analytical methods or investigate known analytical methods for detecting and identifying microbial pathogens...") and "Risk Assessment" ("Developing or applying analytical methods to quantify exposure to or determine if a pathogen...poses a public health risk"). We would recommend that CFSAN put together an advisory group including consumers and create an interagency working group similar to USDA's, which included scientists with food safety and public health knowledge from ARS, APHIS, CSREES, ERS, FSIS, ORACBA, and the CDC. In coordination with these groups, FDA could then establish a thorough list that identified many potential research areas critical to food safety and criteria for establishing their priority for research funding.

As one priority area, S.T.O.P. would like to see CFSAN begin to perform testing that addresses potential areas of contamination under realistic scenarios and the extent to which contamination is possible or probable. In this list we include:

1) Microbial testing of produce at retail. CFSAN should begin developing microbial baselines to determine current microbial loads, with the goal of developing a pathogen reduction program that would incorporate microbial performance standards. CFSAN should begin a program of in-store testing for fecal contamination, beginning first with the foods that have most frequently been linked to outbreaks, then with the ones considered more likely to cause outbreaks. The contamination rate of in-store, conventional produce should be compared with that of organic produce.

2) Survival of pathogens in compost. CFSAN should sponsor research that identifies the effectiveness of compost and composting methods in eliminating pathogens. At what rates, time, temperatures, and humidities is compost rendered pathogen-free. In its recent Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, FDA stated that composting was effectively a method for eliminating pathogens. We would like to see CFSAN develop the scientific data that proves or disproves this point so that composting can be evaluated as a pathogen reduction mechanism to determine whether it should be preferred to other fertilizers.

3) Survival of pathogens in manure. It appears that some of the most comprehensive research in this area is being conducted outside of the United States. CFSAN should compare this by developing domestic studies, focusing on time, temperature, humidity, and air exposure for organisms in manure, slurry, and applied in manure to soil.

4) Survival of pathogens on food plants. CFSAN should conduct research to address the survival rates of organisms such as *E. coli* O157:H7 on the stalk, leaf and fruit of food plants, particularly examining in-soil and on-soil grown produce. Can melons absorb pathogens through their stem scars the way tomatoes can? This science is necessary to support or refute the use of potentially contaminated water in irrigation

and application of raw manure to food crops after planting as food safety hazards in need of control.

5) Uptake of pathogens in food plants. CFSAN needs to conduct research to understand how pathogens may contaminate produce through the root system of the plant. Which food plants are most susceptible to uptake? This science is necessary to support or refute the use of potentially contaminated water in irrigation of produce as food safety hazards in need of control.

6) Penetration of skin of fruit. Can *E. coli* O157:H7 and *Campylobacter jejuni* penetrate the surfaces of various types of fruit? Fruit/vegetables to examine would be: melons, carrots, apples, tomatoes, peaches, and berries. We want to address the extent to which *E. coli* may be on the surface of produce or actually IN the produce. At present, produce is often visually culled prior to entering processing. This science is necessary to determine the value of visual inspection and culling of produce in reducing and/or eliminating pathogens.

7) Survival of pathogens inside produce. How long can *E. coli* O157:H7, *Salmonella*, and *Campylobacter jejuni* survive once inside different types of produce? Under what conditions do they multiply? Specifically, CFSAN should address apples, raspberries, peaches, tomatoes, grapes, and sprouts. This science is necessary to support visual inspection and culling of produce.

8) Showering vs. baths. Some fruit and vegetables are floated in water flumes prior to packing. This activity may, in fact, increase cross contamination. We would like CFSAN to examine cross contamination rates pre-flume and post-flume and whether pressure showering produce prior to introducing it to the flumes reduces contamination.

9) Insect transfer of pathogens. Research is needed on the transfer rate of organisms from fecal contamination, such as raw manure, to produce via insects. It is generally believed that leaving fecal matter on soil's surface could result in insect transfer. Science is necessary to prove or disprove that insects could be a significant transfer agent if raw manure were used as fertilizer or deposited by wild animals.

10) Dust blown pathogens. Dale Hancock at the University of Washington is currently studying the impact of dust blown organisms. More research needs to be done to support or refute the issue of organism survival under dry or wind blown circumstances.

11) Affect of pathogens on appearance of produce. At present, industry has argued that by culling specifically bad looking fruit they are improving the safety of the product; science is necessary to support or refute the use of visual inspection in improving pathogen-related food safety.

Outreach

It would be to FDA's and the public's benefit for FDA to develop liaisons with major medical, patient, and at-risk consumer organizations such as:

- American Academy of Pediatrics

- American College of Obstetricians and Gynecologists
- American College of Emergency Physicians
- Arthritis Foundation
- AARP
- PTA

We envision a person at FDA who is responsible for frequent, personal contact with an appropriate individual at each of these organizations. In particular, we would encourage FDA to use these groups as venues for getting information to their constituents about hazardous foods, foodborne illness, and food threats. For example, FDA could encourage these groups to notify their constituents about unpasteurized juice this fall through their traditional publications. Articles addressing foods of particular concern could be developed and disseminated through them. These types of focused education campaigns would be more likely to be successful than some of the general campaigns FDA has developed in the past.

In addition, FSIS regularly faxes a newsletter to all of its constituents about matters that pertain to them. FDA should develop such a system, similar to the "FSIS Constituent Update." FDA must stop relying solely on the Federal Register as a method for notifying these consumer advocates. It is ironic that industry is frequently informed immediately about pending regulations and government activities that affect it, but consumer advocacy groups are not.

Education on Food Safety

S.T.O.P. strongly objects to extensive education cooperatives developed between government and industry without the involvement of consumer groups. S.T.O.P. has found that such groups, devoid of consumer input, often develop watered down messages which do not accurately convey the truly hazardous nature of pathogens in our food. CFSAN should involve consumer organizations in curriculum development and message content.

S.T.O.P. finds it striking that in the area of Outreach, CFSAN limits its initiative to educating the general public, children, and vulnerable populations about food handling and ignores the critically important necessity of educating food processors and growers about safe food production. Consumers can only attempt to defend themselves from pathogens that arrive in their homes. Only industry can prevent contamination in the first place.

Economic Fraud

We disagree somewhat with the basis of question 6 in the Federal Register notice, which states that economic fraud is not a public health issue. There are certain aspects of economic fraud that can very much affect public safety. Three areas are of particular concern to us:

1) The marketing of produce and its unsterilized derivatives as "healthy" or "good for you." FDA has recently released its definition of the term "healthy" and its applicability to various products under FDA jurisdiction. However, some of these products, specifically, fruits and vegetables and their products that have not been heat treated to eliminate pathogens, can, in fact, cause life threatening illness. S.T.O.P. would like to point out that produce and produce products advertised as

"healthy" or construed as healthy with slogans that imply good health are only better for a consumer if they are not contaminated. We would ask that FDA pursue for fraud any companies found guilty of selling contaminated produce and/or its products while advertising these products as healthy.

2) Batching together foods that have different "go bad" dates. It is reported that the egg industry is currently employing a practices where "old" eggs are slipped into cartons that contain more fresh eggs. That FDA has done so little to stop this process is very discouraging. While S.T.O.P. knows of no studies that indicate produce growers engage in similar practices, we would suggest that FDA should examine industries under its purview for this type of practice.

3) Adding water weight to any product, whether shellfish or otherwise.

S.T.O.P. understands that the reason food types are often soaked in water is to quickly chill them to reduce bacterial growth. CFSAN must put a stop to such practices that add weight for the benefit of the producer while potentially jeopardizing the safety of the food product by furthering cross contamination between pieces of produce, shellfish, or other foods. Many of these food industries soak their products in unclean water, some with the purpose of adding weight to the food so that the consumer can be charged more.

Economic fraud issues that are not food safety concerns should receive a substantially lower priority.

In Conclusion

S.T.O.P. agrees with CFSAN's placement of the President's Food Safety Initiative as its highest priority. However, the current implementation of the President's FSI overlooks many key food safety issues, which we have identified in this document. We believe these issues should receive higher priority than non-food safety issues within the agency. We appreciate the opportunity to comment on developing priorities for CFSAN and look forward to working together to find solutions to make America's food supply safer.

Sincerely,

Laurie Girand
Board Member

Nancy Donley
President

(1) Andy Maule, Center for Applied Microbiology and Research, Porton Down, United Kingdom; Cornell Cooperative Extension brochure. See additional description in

S.T.O.P.'s comments on the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, 6/26/98.