Withdrawal/Redaction Sheet
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Elaine Dodge to Elizabeth Drye re: S.T.O.P. Families (1 page)	03/25/1997	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:
Food Safety Initiative - Comments [1]

2014-0046-S
rc1369

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of *Nutrition Action Healthletter*

February 3, 1997

Juice Comments

Dr. Fred Shank
Director, Center for Food Safety
and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Dr. Shank:

On behalf of the over 800,000 members of the **Center for Science in the Public Interest** and the following members of the Safe Food Coalition: **American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, Public Voice for Food and Health Policy, and STOP (Safe Tables Our Priority)**, we are writing to provide additional comment on the issues raised at the public meeting to discuss the safety of juice products.[1]

While this hearing was highly beneficial and provided a good opportunity to hear the various views on the issue, the failure to invite the families most affected by the recent juice food poisoning outbreaks and other concerned consumers to express their views for the record was a significant oversight.

Families of victims of food poisoning have provided valuable insight and support to other government agencies responsible for assuring the safety of the food supply, and were even included in the Presidential announcement of the meat and poultry HACCP rule on July 6, 1996. Although we understand that FDA attempted to rectify the oversight by assuring availability of the transcript and by extending the comment period, nonetheless, we urge you to assure that, in the future, invitations are made to families and organizations representing the breadth of the consumer and public health community well in advance of the meeting. With this correction, we would encourage the Food and Drug Administration to hold additional hearings to tackle equally pressing food safety issues currently pending in the agency.[2]

---

[1] Laurie Girand, the mother of a 3-year-old girl who survived the Odwalla outbreak, has reviewed these comments and supports the measures being proposed.

[2] An example of another pressing issue is the continuing safety questions regarding raw molluscan shellfish. Despite state oversight facilitated by the Interstate Shellfish Sanitation Conference, shellfish products contaminated with just one pathogen killed over 20 consumers in 1996. There was also a major outbreak from

1875 Connecticut Avenue, N.W., Suite 300, Washington, D.C. 20009-5728 • (202) 332-9110 • FAX (202) 265-4954
Executive Director: *Michael Jacobson, Ph.D.*

Juice Safety is a Serious Public Health Concern

Recent events have raised significant questions about the safety of unpasteurized juice products. Consumers have a right to question whether these products are safe to serve the members of their family most vulnerable to food borne illness, including children, the elderly and the immune-compromised. These examples of food poisoning outbreaks demonstrate that it is time for FDA to consider serious steps to address the safety of these products:

Odwalla Apple Juice: In the western United States, 66 illnesses and one death from *E. coli* O157:H7 were reported from unpasteurized apple juice in October 1996.[3] The juice was produced by Odwalla Inc., a company in Half Moon Bay, California.[4]

Apple Cider: In New Haven County, Connecticut in October 1996, 14 cases of illness from *E. coli* O157:H7 were identified, at least three in children.[5] The illnesses were attributed to apple cider produced at a small cider mill in Cheshire. Five people were hospitalized.

Apple Cider: In October 1996, at least 20 cases of cryptosporidiosis in Cortland County, New York were linked to apple cider produced at a local cider mill.[6]

Orange Juice: From May to June 1995, in Orlando, Florida, 62 people became ill from consuming unpasteurized orange juice contaminated with *Salmonella*.[7] Eight of the people were hospitalized. Florida's Own Juice Company produced the juice.[8]

Norwalk virus traced to shellfish last month, infecting at least 150 people. Your agency estimates that shellfish cause over 100,000 illnesses each year. It is time for FDA to address this serious public health problem.

[3] Centers for Disease Control and Prevention, "Outbreaks of *Escherichia coli* O157:H7 Infection and Cryptosporidiosis Associated with Drinking Unpasteurized Apple Cider -- Connecticut and New York, October 1996", *Morbidity and Mortality Weekly Report*, Vol. 46, No. 1 (1997), p. 4 [hereinafter cited as *Outbreaks Associated with Drinking Unpasteurized Apple Cider*].

[4] "Opting for an Early Warning When *E. coli* is Suspected," *New York Times*, Nov. 20, 1996, p. C3.

[5] "Outbreak of *E. coli* Infection Tied to Cider From Cheshire Mill," *New York Times*, Oct. 19, 1996, p.1-28; *Outbreaks Associated with Drinking Unpasteurized Apple Cider*, p. 4.

[6] *Outbreaks Associated with Drinking Unpasteurized Apple Cider*, p. 4.

[7] "Salmonellosis Orange Juice Outbreak Case Study, Other Research Presented at IFT Technical Sessions," *Food Chemical News*, July 8, 1996, p. 14.

[8] "*Salmonella* in Orange Juice Causes Illnesses, Recall," *Food Chemical News*, Aug. 21, 1995, p. 31.

Apple Cider: In Maine in October 1993, 213 people developed *Cryptosporidia* diarrhea after drinking cider made from apples that had dropped from trees on the edge of a cow pasture.[9]

Apple Cider: In the fall of 1991, an *E. coli* O157:H7 outbreak that sickened 23 people and hospitalized at least four children was traced to apple cider produced by a mill in the Fall River, Massachusetts area.[10]

Apple Cider: In New Jersey, in 1974, 296 people developed *Salmonella* diarrhea after drinking apple cider.[11]

Because of the inadequacies of the passive system utilized by the Center for Disease Control and Prevention to detect food poisoning episodes, these documented outbreaks probably represent only a small proportion of the illnesses actually occurring in the country.

Consumers expect that the juice they serve their family is a safe and healthful product. However, new and old strains of bacteria are regularly surviving the juice making process, and causing illness and even one documented death.

Consumers don't want juice that isn't safe, period. If there are significant safety differences between different types of juice, consumers want to know. They want information quickly and easily as they make purchasing decisions. Consumers also want to be promptly alerted to safety questions following food poisoning outbreaks. Media reports on food poisoning outbreaks are not sufficient to serve this purpose.[12] FDA should issue specific information for dissemination by the media informing consumers about what they can do to protect themselves and their families.

Responsibility for assuring the safety of juice products lies with the producers of the product. Taste and nutrition issues are secondary to safety. Producers must make a concerted effort to address the safety problems with their products, or they should face mandatory

---

[9] Dr. Patricia Griffin, Centers for Disease Control, "Report of O157:H7 Outbreaks Caused by Juices," (Remarks given at meeting of the National Advisory Committee on Microbiological Criteria for Foods, Fresh Produce Subcommittee, Dec. 16, 1996, Arlington, Virginia), hereinafter "Remarks of Dr. Griffin."

[10] Remarks of Dr. Griffin.

[11] Remarks of Dr. Griffin.

[12] As an example, following published and broadcast reports of two outbreaks from unpasteurized apple juice and cider this fall, Washington, DC-area child care facilities continued to allow apple cider to be served to children as part of their holiday festivities. We have even heard of one instance where a preschool brought children to a cider press where the children sampled the product. Despite the media attention, both the care givers and the parents were unaware that the products were potentially hazardous for the children.

pasteurization in the future. In the meantime, labels should be used to alert consumers about the safety issues with the products.

The government should take an incremental approach to regulation, i.e. try less prescriptive approaches before mandating pasteurization. At this time, we are not supporting mandatory pasteurization of juice products. We want the fruit and vegetable industry to find and eliminate the source or sources of contamination of their products. As an alternative, we urge FDA to utilize expedited rulemaking to mandate a label on unpasteurized juice products informing consumers about the risk as soon as possible. Concurrently, the agency should mandate HACCP with microbial testing for verification for all juice manufacturers. This rule should be in effect no later than September 1, 1997. If juice manufacturers, using HACCP, can address the process deficiencies in their production and eliminate the safety questions with their product, then mandatory pasteurization will be unnecessary.

STEP ONE: The Need for Consumer Labeling

The recent outbreaks of *E. coli* O157:H7 traced to juice products have highlighted the need for swift action to prevent more illness caused by pathogens occasionally found in unpasteurized juices. Prompt consumer education is important to give consumers the advice they need to protect their families and to prevent wide-scale avoidance of all juice products, safe or not, which appear on the supermarket shelves.

Therefore, we urge FDA to promulgate an expedited regulation to require producers of unpasteurized juices to label their product to inform consumers about the potential hazard. Such a label is critical to ensure that consumers become aware that unpasteurized juices may be hazardous. However, a consumer label is not a substitute for needed improvements in unpasteurized juice processing.

A consumer label should be placed on all containers of unpasteurized juice.

CSPI has developed this example of a label that could be used on unpasteurized apple juice products. (See Attachment 1 and below.) While the graphic could remain the same, the consumer information may vary for different types of juice products depending on the specific hazards and consumer-oriented solutions (such as heating cider products), if any.

UNPASTEURIZED

Caution: This product is unpasteurized and may contain harmful bacteria known to cause illness and death. Children, the elderly, and persons with weakened immune systems should avoid this product. Consumers can protect themselves by heating this product to 160°F before serving it.

Another labeling alternative, simply labeling the product "unpasteurized", will not adequately inform consumers that bacteria occasionally found in the product has been linked to deaths and illnesses. Instead, the label should give consumers specific information about the risks of foodborne illness and about how to protect themselves and their families.

The label should contain a consumer message that highlights the populations most at risk from foodborne illness, including children, the elderly, and individuals with weakened immune systems. In addition, a graphic symbol should be used to illustrate that the product should not be consumed by these groups.[13]

This labeling requirement should create an incentive for processors who do not want to label their products to pasteurize their juice. Therefore, we recommend that labeling not be required for pasteurized juice if processors can demonstrate, using scientific or process-generated data, that any pathogens present in the juice are destroyed during the pasteurization process.

The consumer label should state the risks of unpasteurized juice and steps consumers can take to protect themselves.

Whether FDA chooses to use the label proposed by CSPI or some other version, there are several important principles to consider when mandating a consumer safety label. The wording of the label should clearly state the risks of consuming the product and should instruct consumers how to protect themselves. However, the message must be concise so consumers can read the message quickly. Studies on the effectiveness of labels show that too much information causes consumers to filter out key elements of the message, or even to ignore the entire message.[14]

To alert consumers to the label, a signal word such as "warning", "danger", or "caution" should precede the statement. Consumers must notice the consumer label for it to be effective, and a signal word will highlight the message.

Placement of the label is also important to ensure that consumers will notice it. The label should be placed on the front panel so that consumers will see the label when purchasing or serving the juice.

---

[13] The graphic could become a universal symbol to alert the public to potentially risky foods which should be completely avoided by certain consumers. Such a symbol would give consumers a quick tool to determine which foods have contamination problems and should be avoided by high risk consumers.

[14] Mark Lehto and James Miller, *Warnings: Fundamentals, Design, and Evaluation Methodologies, Vol. 1,* (Ann Arbor, MI: Fuller Technical Publications, 1987), pp. 61-68.

FDA should rapidly test CSPI's proposed label and other labels to determine the best design alerting consumers to the possible hazards of unpasteurized juice products. Restaurants, grocery stores and fresh juice bars should also be required to post the message in the same manner recommended for consumer warnings in the 1995 Food Code.

A recognizable symbol will improve consumer retention of the message.

To maximize the label's effectiveness, it should use a graphic symbol. This symbol would serve as a reminder that the product may contain harmful bacteria and should be avoided by certain consumers. Ideally, the symbol should be understandable to consumers who cannot read or understand English.

Graphic symbols on the meat and poultry safe handling label convey and support the written message to make it easier for consumers to understand. A symbol on unpasteurized juices would similarly convey and reinforce important information to consumers.

Since other foods can also be hazardous to consumers, the graphic symbol could become a universal signal to alert susceptible populations to the risks of foodborne pathogens in products intended to be consumed in the raw form. An education campaign could be developed to teach susceptible populations and their caregivers about the symbols and about foodborne illnesses.

An example of a highly successful symbol is the "Mr. Yuk" poison warning symbol. (See Attachment 2.) Green stickers with the symbol are given to parents to place on common household products to alert children to their danger. Children who cannot yet read know what Mr. Yuk means, and can protect themselves. These stickers are coupled with public education campaigns to teach people what the symbol means.[15] Parents and teachers can then teach children to avoid products bearing the sticker.

The benefits of consumer labels clearly justify the costs.

The two most recent outbreaks of *E. coli* O157:H7 in unpasteurized apple juice claimed the life of one child, and caused at least 80 other illnesses. Many children who survived suffered lengthy recuperations and long-term health effects from their illnesses.

The benefit of labeling would be in avoiding cases of food poisoning from juice products, including those associated with this particularly virulent strain of *E. coli*. According to USDA,

---

[15] The Pittsburgh Poison Control Center, "How Mr. Yuk Was Developed," (Pittsburgh, PA: Children's Hospital of Pittsburgh).

the average cost of an illness from *E. coli* O157:H7 in medical bills and lost productivity was estimated at $25,000 to $37,500.[16]

The costs of developing, printing and applying the labels are minimal in light of their potential to save even one life. For example, cost estimates by USDA for the meat and poultry safe handling label are $.01 to $.025 per label.[17] This is probably the maximum amount the safety labels for juice would cost. If the safety label were eventually incorporated into the product label, juice producers could avoid any additional cost.

If the savings from avoiding *just one case of illness* from *E. coli* O157:H7 were $25,000, it would pay for one million safe handling labels if the labels cost $.025 each. If the labels cost $.01 each, the savings would pay for 2.5 million safe handling labels. The potential for avoiding unnecessary medical costs and loss of life from another juice-related outbreak would likely greatly outweigh the costs of labeling.

The costs of labeling are also justified by studies that show that labels effectively reach consumers. One survey on the meat and poultry safe handling labels has shown that 66% of the respondents have noticed the safe handling instructions. The survey also found that 70% of parents with children under the age of 12 have noticed the safe handling instructions.[18] Another survey found that six out of 10 shoppers surveyed were aware of the safe handling labels and that 43% of these shoppers had changed their handling practices as a result.[19] These studies show that, while labels are not universally effective, their penetration is adequate to justify their costs to industry.

FDA has the legal authority to mandate a warning label on unpasteurized juice.

FDA has the authority to declare unpasteurized juice "misbranded" unless it bears a warning label. Under the Federal Food, Drug, and Cosmetic Act, a food is "misbranded" if its

---

[16] USDA has estimated the cost of illness and death in 1993 alone from *E. coli* O157:H7 at $200 million to $600 million. Some cases of illness are very severe, requiring lengthy hospitalization, multiple operations and blood transfusions, and kidney dialysis. U.S. Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule, 9 C.F.R. Part 304 et al.," *Federal Register*, Vol. 61, No. 144 (1996), p. 38964 [hereinafter cited as *Pathogen Reduction Final Rule*].

[17] U.S. Department of Agriculture, Food Safety and Inspection Service, "Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products; Final Rule, 9 C.F.R. Parts 317 and 381," *Federal Register*, Vol. 59, No. 59 (1994), p. 14528.

[18] American Meat Institute, "Americans Underestimate Their Role in Preventing Foodborne Illness, New National Survey Says," (Washington, DC: American Meat Institute, August 30, 1996).

[19] Food Marketing Institute, *Trends in the United States: Consumer Attitudes and the Supermarket 1996*, (Washington, D.C., Food Marketing Institute, 1996) p. 50.

label is false or misleading in any particular.[20] A label on a food product may be false or misleading if the label fails to reveal material facts about the consequences of use of the food product.[21] The fact that a food product could cause serious illness or death is the type of material fact that should be revealed on the product's label to prevent the food product from being misbranded.

The courts have upheld FDA's authority to require warning labels on food products that could cause illness or death.

In the 1970s, low calorie protein products used by dieters were implicated in the sudden deaths of at least sixty people, most of them young women. In response to the deaths, FDA issued a regulation requiring a warning label on low calorie protein products, advising that very low calorie protein diets may cause serious illness or death. When the regulation was challenged by industry groups, two federal district courts upheld FDA's authority to require such warning labels. See Council for Responsible Nutrition v. Goyan, Food Drug Cosm. L. Rep. (CCH) ¶ 38,057, p. 38,269 (D.D.C. 1980); National Nutritional Foods Ass'n. v. Novitch, 589 F.Supp. 798, 801 (S.D.N.Y. 1984). The court in Council for Responsible Nutrition stated that FDA's general rulemaking authority set out in section 701(a) of the Food, Drug, and Cosmetic Act, taken together with sections 201(n) and 343(a)(1), gave FDA the authority to require labels on low calorie protein products to make consumers aware of the health risks that might arise from the use of such products. CCH, ¶ 38,057, p. 38,269; 21 U.S.C. §§201(n), 343(a)(1); 701(a).

In another example, a federal court upheld FDA's authority under sections 201(n) and 701(a) of the FDCA to require warnings on the labels of all food, drug and cosmetic products sold in aerosol cans. Cosmetic, Toiletry and Fragrance Association, Inc. v. Schmidt, 409 F.Supp. 57, 64 (D.D.C. 1976). The warnings tell consumers to avoid puncturing or incinerating the cans, and to avoid storing them above 120 degrees F. Warnings are currently used on cans of whipped cream, cheese "whiz" and non-stick cooking sprays.

FDA has recently used its legal authority to require label warning statements on foods in support of its regulation requiring warning statements on iron-containing products.[22] The warning statements are required to help prevent accidental overdoses of iron-containing products by children. In 1994, over 3,210 children were treated for iron overdose and two children died.

---

[20] 21 U.S.C. § 343(a)(1).

[21] 21 U.S.C. § 201(n).

[22] Department of Health and Human Services, "Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Final Rule, 21 C.F.R. Parts 101, 111, and 310," *Federal Register*, Vol. 62, No. 10 (1997), p. 2218.

Without a warning label, unpasteurized juice is "misbranded" under the Food, Drug and Cosmetic Act.

Like low-calorie protein products, aerosol food cans, and iron-containing dietary supplements, unpasteurized juice can cause illness, injury and death. However, the case for a warning label on juice is even more compelling than for aerosol cans and iron-containing dietary supplements. The warning label for each of these products advises consumers that the products can be dangerous when they are misused, i.e., when the can is punctured, or when an overdose of iron- containing products occurs. In the case of unpasteurized juice, the product can be dangerous when consumers use it as intended.

Based on custom and experience, consumers believe that juice consumed right from the bottle without further treatment is safe. However, recurrent food poisoning outbreaks from juice products have demonstrated that these products are not uniformly safe. Containers of such juice currently fail to reveal a material fact: that consuming the juice may result in serious illness or death. Under section 201(n) of the FDCA, the absence of this information is misleading and should cause the product to be declared misbranded.

Ironically, unpasteurized juice may have a reputation among many consumers for being a particularly fresh and healthy food. It is likely to be consumed by some elderly and ill consumers who are attempting to improve their health, and also given to children by many parents who are concerned about nutrition. In fact, most of the victims of the recent Odwalla juice outbreak were children.[23]

When determining whether the current labeling on unpasteurized juice is misleading, FDA has a duty to consider both informed and uninformed consumers, bearing in mind that the purpose of the FDCA is to "protect unwary customers in vital matters of health." U.S. v. Article (Sudden Change), 409 F.2d 734, 741 (2d. Cir. 1969); U.S. v. An Article of Food (Manischewitz . . . Diet Thins), 377 F.Supp. 746, 749 (E.D.N.Y. 1974).[24] FDA should not rely on media reports of foodborne illness outbreaks to protect consumers from the known risks in the food supply. Even if some consumers have heard of the recent outbreaks, a warning statement should be required in order to inform all consumers.[25]

---

[23] "Feds Weigh Fruit Juice Rules," *AP Online*, November 11, 1996.

[24] FDA must consider even "the ignorant, the unthinking and the credulous" consumers. 409 F.2d at 740.

[25] The case of Nancy Donley, a mother in Chicago who lost her son Alex to *E. coli* O157:H7 in 1993, illustrates the importance of warning all consumers. Ms. Donley had heard about the earlier outbreak associated with Jack in the Box hamburgers. She assumed that the government had addressed the problem when, six months later, she gave her child a hamburger that turned out to be contaminated.

STEP 2: The Need for Mandatory HACCP

In 1994, CSPI submitted comments on behalf of itself and ten consumer protection and public health groups in support of mandatory HACCP for all food products. (See Attachment 3.) Since that time, there have been a number of major outbreaks of food poisoning from foods regulated by FDA in addition to four juice outbreaks listed earlier, including:

Eggs: In September 1996, homemade mayonnaise made with raw eggs contaminated with *Salmonella enteritidis* (SE) caused illnesses in 250 patrons of a sandwich shop in Greenville, SC. This outbreak was part of the SE traceback program, and the results of the traceback are not yet available.[26]

Raspberries: During the summer of 1996, at least 1,400 cases of *Cyclospora* infection occurred in 13 eastern states, Colorado, Texas and Ontario.[27] Epidemiologists implicated fresh fruit, particularly imported raspberries, as the source of the protozoa.[28]

Lettuce: In Montana, at least 74 people were sickened by *E. coli* O157:H7 during the summer of 1995. Twelve people were hospitalized. Lettuce was confirmed as the main source of the illness.[29]

Alfalfa Sprouts: From January to July 1995, 181 *Salmonella stanley* infections in 25 states were reported. Case control studies in Arizona and Michigan linked alfalfa sprout consumption to infection.[30]

Since 1994, FDA has finalized its seafood HACCP rules and USDA has both proposed and finalized a rule implementing HACCP for meat and poultry plants. Yet, FDA's advanced notice of proposed rulemaking for HACCP for other food products has not proceeded to a proposed rule.

---

[26] "Shank: Juice Safety Meeting Will Focus on Whether Regulations Should be Changed," *Food Chemical News*, Dec. 16, 1996, p. 35.

[27] "Guatemalan Raspberries Now Believed to be Source of *Cyclospora* Outbreak," *Food Chemical News*, July 22, 1996, p. 31.

[28] Centers for Disease Control and Prevention, "Outbreaks of *Cyclospora cayetanensis* Infection -- United States, 1996," *Morbidity and Mortality Weekly Report*, Vol. 45, No. 25 (1996), p. 549; John Schwartz, "Florida Officials Link Cyclospora to Raspberries," *The Washington Post*, July 6, 1996, p. A3.

[29] "Montana *E. coli* O157:H7 Outbreak May Be From Irrigated Produce," *Food Chemical News*, July 31, 1995, p. 49; "Lettuce was Source of Montana *E. coli* Outbreak: CDC," *Food Chemical News*, Aug. 14, 1995, p. 34.

[30] "Alfalfa Sprouts Confirmed as Linked to *S. stanley* Infections," *Food Chemical News*, July 3, 1995, p. 43.

We still support mandatory HACCP for the food industry and urge the agency to proceed with a proposal. In the meantime, however, FDA should develop an expedited rule requiring the juice industry to implement HACCP, with mandatory microbial testing for verification.

The importance of effective regulatory oversight for HACCP

Mandating HACCP rather than pasturization for the juice industry represents a performance- and industry-driven approach to controlling the pathogens in fresh juices without exposing FDA to the charge of eliminating an entire segment of the juice industry that consumers enjoy. Ultimately, mandatory HACCP should force the fresh juice industry to either ensure that the source of contamination is eliminated from their raw materials or to find methods of pasteurization that are acceptable to consumers.

We have considered the option of supporting mandatory pasteurization of all fruit and vegetable juices. While that approach would offer protection against *E. coli* 0157:H7 and other pathogens, we are not now recommending mandatory pasteurization. If the fresh juice industry does not promptly and effectively address safety problems in its products, we may reconsider our position on mandatory pasteurization in the future.

The juice industry is an excellent candidate for the implementation of HACCP. Unlike seafood, juice processors produce a standard product using fairly standard processing procedures. In the process of converting fruit into juice, a small amount of contamination can easily infect a large quantity of juice. Because of these qualities, microbial testing will also be critically important for HACCP verification.

Assuring the efficacy of HACCP for the fresh juice industry will only occur if FDA mandates appropriate government oversight of HACCP. However, there is wide variation between the three existing regulatory HACCP systems in the critical area of HACCP oversight by the government agencies.

For example, the low-acid canned food rule, 21 C.F.R. §§ 108.35, 113.3-113.100, requires plant registration, filing of all HACCP plans, and mandates a traceback mechanism. It even requires that every processor of low acid canned food notify FDA of any instance "of spoilage" having a "potential health significance" or in which food "may be injurious to health by reason of contamination with micro-organisms" if the food has entered commerce. 21 C.F.R. § 108.35(d), (e).

In comparison, the seafood HACCP rule, 21 C.F.R. §§ 123.3-123.28, 1240.3, fails to institute meaningful government oversight. HACCP plans are not filed with the agency and are

only reviewed during infrequent inspections.[31] Plants are not required to register with FDA, so some may avoid oversight altogether. Validation and verification of the HACCP plans are practically non-existent. This means that if a HACCP plan fails to address critical public health problems with the product, this gap is unlikely to be discovered unless an outbreak occurs that is traced to the product. However, even when an outbreak occurs, linking the product to the processor would be uncertain because — with the exception of shellfish products — no system for traceback of seafood is mandated.

Unlike either the seafood or low-acid canned food industries, the meat and poultry industries are subject to constant inspection by the U.S. Department of Agriculture. Thus, the meat and poultry HACCP model requires plant registration, continuous inspection by USDA inspectors, mandatory validation and verification of the HACCP plans, and regular laboratory testing of products that will provide long-term trend data on the success of HACCP in these industries. USDA has mandated laboratory testing both by the industry and by the government, which will retain intensive oversight in the plant.

For both seafood and meat and poultry proposed rules and the generic foods advanced notice of proposed rulemaking, consumer protection and public health organizations have commented extensively on the role of government oversight in regulatory HACCP systems. So as to not repeat what has already been said, Attachments 3, 4 and 5 contain these positions. The bottom line is that almost every aspect of government oversight for regulatory HACCP systems urged by our organizations is already part of an existing mandatory HACCP regulation. (See Table I on p. 13.)

Mandatory HACCP for the juice industry should include plant registration; filing of HACCP plans; regular inspection oversight (which can only be achieved through an increase in FDA's inspection force); validation and verification of HACCP plans using microbial testing; traceback; and mandatory minimum sanitation requirements.[32]

As demonstrated in Table I, using the seafood HACCP rule -- the most recent one developed by FDA -- as a model would not be adequate to ensure the support of consumer protection and public health organizations.

---

[31] FDA's field staff inspects 1,000 high-risk seafood processing plants once a year, and the remaining 4,000 seafood processing plants and facilities once every two to three years. FDA officials have estimated that the initial approval of HACCP plans under the seafood HACCP inspection rule will likely take twice the current length of time for an inspection, reducing the frequency of FDA's inspections, which would further reduce the frequency of inspection.

[32] Sanitation requirements (including proper cleaning of raw fruit for the juice industry) are an essential foundation for any HACCP program.

Table I. REGULATORY OVERSIGHT OF HACCP

	Low-acid canned food	Seafood HACCP	Meat and poultry HACCP
Plant Registration	YES	NO	YES
Filing of HACCP Plans	YES	NO	NO
Inspection Oversight	MINIMAL	MINIMAL Once every 1 to 5 years	CONSTANT Carcass -by-carcass or continuous
Validation/ Verification	Required/ Not required	Not required/ Required annually	Required/ Required
Mandatory Laboratory Testing for Validation/ Verification	NO	OPTIONAL	YES Both industry and government testing is required
Traceback Mechanism	YES	NO Except for shellfish	NO
Sanitation Requirements	NO	YES	YES

The importance of mandatory laboratory testing to verify HACCP

For raw products, the goal of HACCP shifts from that of eliminating hazards, such as *Clostridium botulinum* in low-acid canned food, to reducing hazards, such as *Salmonella* in poultry. In a fully-processed product with a known "kill step," processors expect no hazard to remain. Any evidence of a hazard on the product would signal a gap in the HACCP system. However, with a raw product, an acceptable HACCP system may only reduce, not eliminate, the hazard on the product.

The steps needed to demonstrate the effectiveness of a HACCP system for juices will vary depending on the product in question. When there is a pasteurization step, HACCP plans should be validated to demonstrate that the process eliminates the hazard, and then periodic microbial testing can be used to verify that the system is working. Any evidence of pathogens in

a fully processed product would require that the product be held for reprocessing or recalled, and that the HACCP system be redesigned to prevent the production of contaminated product.

Measuring the effectiveness of HACCP on raw products is more of a challenge, because the goal of HACCP shifts from elimination of hazards to reduction of hazards. There are fewer or no critical control points that totally eliminate hazards. Instead, the success of the HACCP system may be largely based on the identification and monitoring of critical control points that reduce the likelihood of contamination. Even when perfect control is exercised, some pathogenic bacteria may still exist on the product. Therefore, long-term trend data is needed to show that a HACCP system has properly identified points of contamination and inserted appropriate mechanisms to control it. Collecting this data is part of ongoing HACCP verification.

USDA has developed the best model of mandatory HACCP for raw products. The agency outlined the following requirements for meat and poultry slaughter plants to validate and verify their HACCP plans using microbial testing:

Validation:

USDA requires that each processor validate its HACCP plan to ensure that the plan controls for the pathogens of concern in the product. Initial validation requires each plant to "conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan."[33] Microbial testing for pathogens can play an important role in validation of a HACCP plan, and under some HACCP plans, may be essential.[34]

Verification:

USDA requires slaughter operations for meat and poultry products to test their products for the generic form of the *E. coli* bacteria. This bacterium is common in the intestinal tract of warm-blooded animals and, according to USDA, is the single best indicator of fecal contamination on meat and poultry products.[35] USDA supplements this program with a government testing regime for *Salmonella*, the single biggest pathogenic contributor to foodborne illness.[36] *Salmonella* is also common in many meat and poultry products.[37] These

---

[33] *Pathogen Reduction Final Rule*, p. 38870.

[34] *Pathogen Reduction Final Rule*, Preamble, p. 38827.

[35] *Pathogen Reduction Final Rule*, Preamble, p. 38837 ("There is general agreement within the scientific community that generic *E. coli* is the best single microbial indicator for fecal contamination").

[36] *Pathogen Reduction Final Rule*, Preamble, p. 38846.

[37] *Pathogen Reduction Final Rule*, Appendix A, p. 38965.

testing programs are designed to ensure that the HACCP programs actually achieve a certain level of pathogen control in the meat and poultry industries.[38]

Validation and verification requirement for juice products

Microbial testing for validation and verification is essential if HACCP is going to work to minimize the hazards in juice products. Juice is an excellent candidate for developing a mandatory testing regime to demonstrate that HACCP is working because of the uniformity of the product. A negative result will not guarantee that the product is pathogen-free; nonetheless, over time, testing will give the juice industry an indication of the contamination levels of its products. It can also provide an early warning about the impact on safety of new conditions, such as changing suppliers, adding new equipment, or allowing sanitation deficiencies. (For more information on the importance of microbial testing for raw products, see Attachments 6, 7 and 8.)

Mandatory testing will likely drive the development of faster and better testing technologies, and ultimately testing technology may be available that will allow real time monitoring of product safety. However, that technology does not currently exist, so the best that testing can offer is historical monitoring of the effectiveness of HACCP.

Some may argue that testing is meaningless unless it will provide immediate feedback on the safety of the product. However, the entire goal of HACCP is to develop process controls that reduce or eliminate product contamination. Therefore, any feedback is valuable that will allow companies to make modifications to improve their plans over time. Also, microbial testing would allow for faster recall of contaminated products from the market, before they cause a major outbreak.

In the absence of microbial testing for HACCP verification, ineffective HACCP plans could operate for years until a food poisoning outbreak traced to the product proved that the system did not work. Unfortunately, if enough of these outbreaks occurred, it would ultimately raise questions regarding the overall value of HACCP among those who did not understand that the lack of an earlier feedback mechanism created a flawed design.

Issues to be decided by FDA in designing a verification system

The following issues need further examination by regulators, industry, consumers and public health officials in designing a mandatory testing regime for HACCP verification for juice products:

---

[38] *Pathogen Reduction Final Rule*, Preamble, p. 38846.

1. Should testing be required for a pathogen or an indicator organism? (USDA chose generic *E. coli* for HACCP verification and *Salmonella* for pathogen reduction.)

2. What frequency of testing is appropriate? Should the frequency change over time?

3. What type of testing technology and laboratory certification should be required? Who should do the testing -- industry, government, or both?

4. What impact should various pasteurization processes have on the testing frequency? Are there alternatives to heat pasteurization that will improve the safety of fresh juices without affecting the quality? Should use of these techniques affect the labeling requirements?

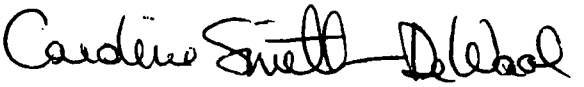
We recommend that over the next few months these issues be resolved in a public, open process like that used by USDA in finalizing the meat and poultry HACCP rule.

Conclusion

The undersigned consumer protection and public health organizations urge FDA to take swift action to address the problems of juice safety. First, FDA should engage in immediate consumer notification by mandating a label for fresh juice products that informs the public of the risk, mentions consumers who should avoid the products, and gives consumers information on how to protect themselves. This label should include a graphic symbol, which could also be used on other raw products that may contain hazardous pathogens, with an appropriate consumer message.

Second, FDA should publish an expedited rule mandating HACCP for the juice industry. This HACCP system should include adequate government oversight and microbial testing as part of HACCP verification and validation.

Respectfully submitted,



Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
on behalf of the

American Public Health Association
Consumer Federation of America
Government Accountability Project
National Consumers League
Public Voice for Food and Health Policy
STOP (Safe Tables Our Priority)

*Elizabeth Dahl, Lucy Alderton and Kimberly Loui provided invaluable assistance in the development of these comments.

Attachments for CSPI's Written Comments on the Need for Labels and Mandatory HACCP for Fresh Juices

Attachment 1	Example of a label for an unpasteurized apple juice product.
Attachment 2	"How Mr. Yuk Was Developed"
Attachment 3	Comments of American Public Heath Association, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, Food and Allied Service Trades Department, AFL-CIO, Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, STOP, United Food and Commercial Workers Union on "Advanced Notice of Proposed Rulemaking on the Development of Hazard Analyisis and Critical Control Points for the Food Industry," December 2, 1994.
Attachment 4	Excerpts from Comments of the Center for Science in the Public Interest on behalf of the following members of the Safe Food Coalition: American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, United Food and Commercial Workers International Union on "Proposed Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," July 5, 1995.
Attachment 5	Comments of American Public Health Association, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union, Food and Allied Service Trades Department of AFL-CIO, Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, and United Food and Commercial Workers International Union on "Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products," May 27, 1994.
Attachment 6	Remarks of Caroline Smith DeWaal, Center for Science in the Public Interest, on "Sampling for Human Pathogens: Essential for HACCP Monitoring, Verification and Enforcement," April 1995.
Attachment 7	Comments submitted by Michael Mullins, Cargill, on behalf of Dr. Dell Allen, Excel Corporation, on Proposed HACCP Regulation and the Issue of Microbial Testing, December 13, 1995.
Attachment 8	Letter from James V. Lochner, IBP, Inc., to Michael Taylor, U.S. Department of Agriculture, on HACCP/Pathogen Reduction, November 13, 1995.

Shellfish Label

Warning: Eating raw oysters can cause life threatening illness if you are elderly or suffer from liver disease; chronic alcohol abuse; diabetes; stomach, blood, or immune disorders. If unsure, cook before eating.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition for Regulatory Action to Require That (1) Warning Labels About the Risks of *Salmonella enteritidis* (SE) Be Placed on Shell Egg Cartons and (2) SE Control HACCP Programs Be Implemented on All Egg-Producing Farms	)	Docket No. _____

Submitted by the

Center for Science in the Public Interest

May 14, 1997

Michael F. Jacobson, Ph.D.
Executive Director
Caroline Smith DeWaal
Director of Food Safety
1875 Connecticut Ave., N.W.
Suite 300
Washington, D.C. 20009
202-332-9110

May 14, 1997

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 10857

CITIZEN PETITION

The Center for Science in the Public Interest (CSPI) submits this petition pursuant to section 4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e), sections 201(n), 403(a)(1), and 701(a) of the federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 321(n), 343(a)(1), 371(a), and section 361 of the Public Health Service Act, 42 U.S.C. § 264. We request that the Food and Drug Administration (FDA) take regulatory action to require that all shell egg cartons bear a label cautioning consumers that the eggs may contain harmful bacteria, and that consumers should not eat raw or undercooked eggs. We also request that FDA require all egg producers to implement on-farm HACCP programs to minimize the risk that their eggs will be contaminated with *Salmonella enteritidis* (SE).[1]

[1] Petitioner has not addressed this petition to the U.S. Department of Agriculture (USDA) because Congress has cut the funding for USDA's SE control activities, which has prevented USDA employees from working on the problem. Committee Report, House Report 104-172, "Food Safety and Inspection Service: Committee Provisions," Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 1996 ("Funding is not included to continue the Salmonella enteritidis program.") *See also* "Animal Production Food Safety Efforts Will Be Non-HACCP, Industry-Oriented: Taylor," *Food Chemical News*, November 6, 1995, p. 28.

I. INTRODUCTION

Eggs, once considered a safe food, have increasingly become contaminated over the last 15 years by a strain of *Salmonella* bacteria known as *Salmonella enteritidis*, or SE. SE caused an estimated 200,000 to one million illnesses in 1994 alone and can be fatal to the elderly, children, and those with weakened immune systems.[2] The SE bacteria caused more deaths between 1988 and 1992 than any other pathogen, and accounted for a third of all food poisoning outbreaks where the cause was known. Contaminated eggs caused at least 80 percent of these illnesses for which the food source is known, according to data from CDC.[3]

SE is found in normal-looking eggs laid by SE-infected hens. Usually, the hens appear healthy and show no signs of infection. Consumers have no way to tell which of the eggs in the cartons they purchase at the supermarket are contaminated. Although thorough cooking kills the SE bacteria, many consumers consider eggs to be properly cooked even when they have not been sufficiently cooked to eliminate SE. As long as eggs may be contaminated with SE, consumers must be provided with information about the risk to their health of SE in eggs and must be advised to avoid raw or undercooked eggs. Eggs sold without a label advising consumers of the risk that the eggs could be contaminated with SE are mislabeled under the FFDCA.

The responsibility for eliminating SE in the food supply lies with egg producers. FDA has the power under the Public Health Service Act to issue regulations requiring on-farm SE testing and control measures to stop this communicable disease from spreading further.

---

[2] Statement of David Satcher, Director of Centers for Disease Control and Prevention, before the Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations, U.S. House of Representatives, May 23, 1996, p. 13 [hereinafter cited as *Satcher Statement*].

[3] *Satcher Statement*, p. 13-14.

Producers should be required to implement HACCP systems to control the risks of SE during egg production.

II. ACTION REQUESTED

We request that the FDA take regulatory action to require that shell eggs sold in cartons or in the large-sized boxes of eggs purchased by restaurants and institutions bear labels advising consumers to cook eggs until the yolk is firm in order to avoid the risk of SE.[4] The following label is suggested:

Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm.

We also request that FDA require programs to reduce the risk of SE for all egg producers. Producers should be required to implement SE control HACCP programs, including mandatory testing of their poultry house environments. Eggs from poultry houses that test positive for SE should be diverted from the fresh egg market to pasteurization plants. In the alternative, or before mandatory HACCP programs are implemented, FDA should encourage producers to voluntarily adopt such programs. FDA could provide an incentive for voluntary adoption by allowing producers with SE control programs monitored by FDA to place a symbol or logo on their egg cartons indicating that the eggs were produced under such programs. However, the symbol or logo should not state that the eggs are safe to eat raw or undercooked.

---

[4] Once effective on-farm HACCP programs were in place, FDA could review the data on the prevalence of SE in eggs and the rate of human illness from SE to determine whether the labels on egg cartons were still needed.

III. STATEMENT OF GROUNDS

A. Factual Grounds

1. SE in Eggs Is a Serious Public Health Problem

SE causes an estimated 200,000 to 1,000,000 illnesses every year, according to the Centers for Disease Control and Prevention (CDC). This means that, even though SE has a low fatality rate, hundreds or even thousands of people die every year.[5] The estimated annual cost of human illness from eggs infected with SE ranges from $118 million to $767 million.[6]

Infection with SE causes flu-like symptoms in humans, such as diarrhea, abdominal pain, nausea, fever, and chills, and can be fatal in the elderly, children, and the immunocompromised. An infective dose of only 10 to 100 SE organisms may be sufficient to cause illness in these more susceptible consumers.

SE will continue to pose a public health threat unless government intervenes. As many as 45 percent of all egg-laying flocks in the U.S. are now infected with SE, according to government estimates.[7] Voluntary industry programs have not kept SE from becoming a national problem.

---

[5] This figure is based on Satcher's estimate that there are as many as one million cases of SE illness each year. *Satcher Statement*, p. 13. The SE fatality rate is estimated at 0.1 to 0.5 percent, according to Jeremy Sobel of CDC.

[6] $118 million estimate from *Salmonella Control Efforts*, p. 2; $767 million estimate derived from U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, Table 1A, "The 20 Most Frequently Reported *Salmonella* Serotypes from Human Sources Reported to the CDC in 1993," *Salmonella Surveillance: Annual Tabulation Summary 1993-1995* (Atlanta: U.S. Department of Health and Human Services) [hereinafter cited as *CDC Salmonella Surveillance 1993-95*]. SE represented 21.9 percent of all *Salmonella* serotypes reported in 1993. U.S. Department of Agriculture, Economic Research Service, Agricultural Economic Report Number 741, Jean C. Buzby, et al., Table 7, "Cost Summary for U.S. Salmonellosis Cases, 1993," *Bacterial Foodborne Disease: Medical Costs & Productivity Losses*, (Washington, D.C.: U.S. Department of Agriculture, August 1996), p. 19. U.S. foodborne salmonellosis cases from all types of *Salmonella* cost a maximum of $3.5 billion annually.

[7] Allan Hogue and Eric Ebel, "1995 Spent Hen Survey of *Salmonella enteritidis*," *APHIS Report of Accomplishments in Animal Production Food Safety FY 1995*, March 1996, p. 2.2-1.

2. *SE Has Increased Throughout the Nation*

Between 1980 and 1995, the number of SE cases reported in the U.S. increased by more than fivefold.[8] SE, which had been present in low levels, began growing out of control in the northeastern United States and then steadily increased across the country.

By 1984, SE began appearing in larger numbers outside the Northeast.[9] (See Figures 3 and 4 and Appendix.) By 1986, the year CDC first linked SE to consumption of raw and undercooked eggs that were internally contaminated, the incidence of SE in the Northeast had increased more than sixfold over 1976 levels.[10] While the number of cases of illness leveled off in the Northeast between 1990 and 1994, cases in the Rocky Mountain region doubled and cases in the Pacific region quadrupled during that same time period.[11] In 1994, California accounted for about a quarter of the nation's laboratory-confirmed cases of SE.[12] A USDA survey showed

---

[8] Table 3, "*Salmonella* Isolations from Human Sources by Serotype and Year Reported to CDC, 1985-1995," *CDC Salmonella Surveillance 1993-1995*; U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Infectious Diseases, Division of Bacterial Diseases, Enteric Diseases Branch, Table 3, "*Salmonella* Isolations from Human Sources by Serotype and Year Reported to CDC, 1980-1990," *Salmonella Surveillance: Annual Summary 1990*, (Atlanta: U.S. Department of Health and Human Services) [hereinafter cited as *CDC Salmonella Surveillance 1990*]; U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Infectious Diseases, Division of Bacterial and Mycotic Diseases, Foodborne and Diarrheal Diseases Branch, *Salmonella Surveillance: Annual Summary 1985-1995*, (Atlanta: U.S. Department of Health and Human Services).

[9] *Satcher Statement*, p. 13.

[10] Michael St. Louis, et al., "The Emergence of Grade A Eggs as a Major Source of *Salmonella enteritidis* Infections," *Journal of the American Medical Association*, Vol. 259, No. 14 (1988), p. 2103.

[11] Table 6, "*Salmonella* Reported from Human Sources, 1990," *CDC Salmonella Surveillance 1990*; Table 5B, "*Salmonella* Reported from Human Sources by Geographic Region and Serotype, 1994," *CDC Salmonella Surveillance 1993-94*. In 1990, 1,125 laboratory-confirmed SE cases were reported in New England, 195 from the Mountain region, and 659 from the Pacific region. In 1994, there were 1,209 SE cases reported from New England, 417 from the Mountain region, and 2,790 from the Pacific region. According to a CDC official, these reported illnesses likely represent only 5 percent of total SE illnesses.

[12] Centers for Disease Control and Prevention, "Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs--U.S., 1994-1995," *Morbidity and Mortality Weekly Reports*, Vol. 45, No. 34 (Atlanta: U.S. Department of Health and Human Services, August 30, 1996), p. 741.

that the frequency of SE isolates in unpasteurized liquid eggs nearly doubled in the northeastern and western U.S. between 1991 and 1995.[13]

To make matters worse, a more virulent form of SE, known as SE phage type 4, has appeared in five SE outbreaks in California and has also appeared in Utah, Arizona and Nevada.[14] Although scientists do not yet know why, this new phage type causes five times as many human illnesses as other types of SE in the regions where it appears.[15] Regulatory action is urgently needed to help prevent the further spread of SE and the resulting increase in illnesses and deaths.

3. Consumers Are at Risk of Illness from SE in Raw or Undercooked Eggs

SE is found inside eggs laid by otherwise healthy hens that are infected by the bacteria.[16] It is estimated that one out of every 10,000 eggs, or about 4.5 million eggs each year, are infected with SE.[17] Consumers have no way of knowing which eggs are infected. The SE bacteria multiply inside eggs that are not properly refrigerated (to an internal temperature of

---

[13] U.S. Department of Agriculture, "APHIS Report of Accomplishments in Animal Production Food Safety FY 1995," March 1996, p. 2.1-1.

[14] Memorandum from Robert V. Tauxe, Acting Chief, Foodborne and Diarrheal Diseases Branch, and Mitchell L. Cohen, Director, Division of Mycotic Diseases, National Center for Infectious Diseases, CDC, Update on Surveillance for Outbreaks of *Salmonella* serotype Enteritidis (SE) Infections, October 18, 1995.

[15] Telephone conversation with Jeremy Sobel, M.D., Centers for Disease Control, Atlanta, Georgia, on March 7, 1997.

[16] Telephone conversation with David Kradel, Coordinator of Food Safety Activities, Pennsylvania Poultry Federation, Harrisburg, PA, April 23, 1997. Although a vaccine against SE exists, it has not been widely used because it is not 100% effective and can cause a reaction in some birds.

[17] Thomas L. Schwarz, Center for Food Safety and Nutrition, Food and Drug Administration, quoted in "BSE Threat to Humans Cannot Be Ignored: European Researcher," Food Chemical News, August 15, 1994, p. 40.

45 degrees F.) As few as 10 to 100 SE organisms may be enough to cause illness in elderly people, children, and the immuno-compromised.[18]

The elderly residents of nursing homes are especially at risk of death from SE: 85 percent of reported deaths from SE between 1988 and 1992 were from this group.[19] SE infection causes flu-like symptoms, such as diarrhea, abdominal pain, nausea, fever and chills, and can have more serious complications, such as rheumatoid arthritis, meningitis, kidney or heart disease, and death.

Thorough cooking of eggs will kill the bacteria. However, many common egg-preparation practices are not sufficient to kill SE. Some high-risk practices include:

- serving eggs "sunny side up," lightly poached, soft-boiled, or any other style where the yolk is still runny;
- preparing French toast with an egg coating that is not thoroughly cooked;
- using raw eggs in cookie dough or cake batter that is consumed before cooking;
- using raw eggs in salad dressing, such as Caesar salad or homemade mayonnaise;
- using raw eggs in eggnog;
- using lightly cooked eggs in desserts, such as meringue and tiramisu.

Another high-risk practice common in restaurants, nursing homes, and other institutions is pooling eggs in a large container after breaking and before cooking them. One SE-positive egg can contaminate dozens of others. This practice can result in major outbreaks of human

---

[18] A.C. Baird-Parker, "Foodborne Illness," *The Lancet*, Vol. 336, November 17, 1990, p. 1232.

[19] *CDC Surveillance Summaries 1988-92*, p. 11.

illness if the pooled eggs are allowed to remain too long at room temperature and then are not fully cooked.

Many consumers are still unaware of the risk of many of the above-named egg dishes. A recent government survey found that half of all consumers surveyed had eaten undercooked eggs in the last year.[20] Although the SE problem in eggs has been fully documented for well over 10 years, that survey combined with the increase in human illnesses during that time demonstrate that both the egg industry and the federal government have not done enough to educate consumers about the risk of eating undercooked eggs.

4. A Caution Label Should Be Required on All Egg Cartons.

FDA should immediately require labels on egg cartons to make consumers aware of the hazards of eating undercooked eggs and to provide them with the information they need to protect themselves. The label's language should plainly state to consumers that the ways they are accustomed to eating eggs may no longer be safe.[21]

CSPI has developed this example of a label that could be used on egg cartons:

Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook until yolk is firm.

---

[20] 1995 Food Safety Module of the Behavioral Risk Factor Surveillance System, reported in "Survey Data Show Regional Differences in High-Risk Food Consumption Behaviors," *Food Chemical News*, January 13, 1997, p. 24.

[21] Government and industry should also make efforts to inform consumers of the benefits of using pasteurized egg products in place of shell eggs where customers wish to use raw or undercooked eggs, for example, in salad dressing or cookie dough. Pasteurizing eggs reduces the incidence of infection from SE to almost zero. Even SE-positive eggs are nearly always safe for human consumption once they have been pasteurized.

FDA should expeditiously test CSPI's proposed label and other labels to determine the best language and design for alerting consumers to the possible hazards of eating raw or undercooked eggs. Whether FDA uses the label proposed by CSPI or another version, the label should include these elements:

- *The message must be concise so consumers can read the message quickly.* Studies on the effectiveness of labels show that too much information causes consumers to filter out key elements of the message.[22] However, the message must not be so oversimplified that it omits necessary information. For example, the use of the word "undercooked," without further explanation, may be confusing.[23]
- *A signal word such as "warning," "danger," or "caution" should precede the statement and should be in bold type.* Consumers must notice the label for it to be effective. The words should be in a single, easy-to-read type style and in type size no smaller than 8 point. The label should be enclosed by a box rule with adequate space around the statement and the words should be printed in a dark color on a light background.[24]
- *The label should be prominently placed on the lid of the egg carton.* The label should also be placed prominently on the large-sized boxes of eggs purchased by restaurants and institutions.

---

[22] Mark Lehto and James Miller, *Warnings: Fundamentals, Design, and Evaluation Methodologies, Vol. 1,* (Ann Arbor, MI: Fuller Technical Publications, 1987), pp. 61-68.

[23] Focus groups recently convened by FDA to analyze consumer advisories on restaurant menus revealed consumer confusion about the meaning of the word "undercooked." Tom Schwarz, FDA, North American Food Safety Education Workshop, College Park, MD, March 10, 1997.

[24] *See, e.g.*, 21 CFR 867(e) (specifications for olestra warning label).

- *The label should include a graphic symbol to improve consumer retention of the message.* To maximize the label's effectiveness, it should use a graphic symbol, such as the exclamation point inside a triangle on CSPI's proposed label. This symbol would serve as a reminder that eggs may contain harmful bacteria and that consumers must take precautions when preparing eggs to protect themselves. Ideally, the symbol should be understandable to consumers who read or understand little or no English.

Since other foods can also be hazardous to consumers, the graphic symbol could become a universal signal to alert susceptible populations to the risks of foodborne pathogens in those foods. An education campaign could be developed to teach the public, particularly susceptible populations and their caregivers, about the symbols and about foodborne illnesses.

An example of a highly successful symbol is the "Mr. Yuk" poison warning symbol. Green stickers with the symbol are given to parents to place on common household products to alert children to their danger. Public education campaigns are used to teach parents and teachers what the symbol means, so that they can then teach children who cannot yet read to avoid products bearing the sticker.[25]

Another example is the meat and poultry safe handling label, with its graphic symbols that convey and support the written message to make it easier for consumers to understand. A symbol on egg cartons would similarly convey and reinforce the important written information to consumers.

---

[25] The Pittsburgh Poison Control Center, "How Mr. Yuk Was Developed," (Pittsburgh, PA: Children's Hospital of Pittsburgh).

5. *Producers Should Be Required to Implement On-Farm SE Control Programs to Make Eggs Safer for Consumers.*

Egg producers can take steps to greatly reduce the incidence of SE in their flocks. Proper sanitary precautions can be taken to keep SE from being introduced into laying houses and prevent it from spreading.

For example, the SE organism has been found in rodent droppings. If hens are allowed to consume the droppings, they may become infected. Rodent control in laying houses can prevent this route of infection. Likewise, contaminated feed may be a source of SE. Producers should take care to use only feed that is free of contaminants. In addition, if laying hens are purchased from SE-infected breeder flocks, they are more likely to be infected, and to produce infected eggs. Producers should obtain hens only from SE-free flocks.

Control of SE is possible when government and producers demonstrate a commitment to eliminating the human health risk from this pathogen. In Sweden, for example, only five SE-infected flocks have been identified in the entire country since 1987.[26] The Swedish government has a rigorous control program directed at all types of *Salmonella* in both laying hens and broilers. The program requires testing of laying flocks at least three times during their lives, with destruction of all flocks that are found to be SE-positive.[27]

Stronger efforts to control SE should be made in this country. FDA should require egg producers to implement government-approved Hazard Analysis and Critical Control Point (HACCP) programs for minimizing SE contamination on their farms that include repeated, ongoing testing of laying houses.

---

[26] M. Wierup, et al., "Control of *Salmonella enteritidis* in Sweden," International Journal of Food Microbiology 25 (1995) p. 223.

[27] *Ibid.*, p. 224.

In the alternative, or before mandatory control programs are implemented, FDA should encourage producers to voluntarily implement control programs that comply with FDA requirements. Producers who establish voluntary HACCP programs, and whose compliance has been verified by neutral third parties, should be allowed to notify consumers that their eggs were produced under such programs by placing a symbol or logo on egg cartons. Producers could also use such symbols in marketing their products. The symbol should not imply that such eggs are safe to eat raw or undercooked, since no control program can guarantee total elimination of SE.

6. *The SE Control Program Should Be Modeled on the Successful Pennsylvania Egg Quality Assurance Program*

FDA should model its on-farm SE control program on a pilot program in Pennsylvania developed by Pennsylvania state agencies, Pennsylvania egg producers, and the U.S. Department of Agriculture. The program reduced the incidence of SE in the flocks of participating producers. When the program was implemented in 1992, multiple manure and other samples were taken from the houses of 70 laying flocks. In 1992, 38 percent of laying houses had at least one SE positive sample, but by 1995, only 13 percent of flocks had a positive SE sample. The percentage of SE-positive flocks has continued to drop and and is now down to 8 percent.[28] In 1992, 23 percent of all the samples taken tested positive for SE, down to only 3.2 percent of samples in 1995.[29] Human illness from SE in the market area for Pennsylvania eggs (New York, New Jersey, and Pennsylvania) also decreased between 1992 and 1995.[30] A team of 15 scientists

---

[28] Telephone conversation with David Kradel, Pennsylvania Poultry Federation, Harrisburg, PA, on May 6, 1997.

[29] "A New Layer of Food Safety Assurance?," *Food Safety Digest*, March/April 1996, p. 5; Telephone conversation with David Henzler, Pennsylvania Department of Agriculture, Harrisburg, PA, April 18, 1997.

[30] Allan Hogue, et al., *Salmonella Enteritidis Review Team Report*, Final, January 18, 1997, pp. 3, 9-10.

from federal and state government agencies attributed at least part of this decrease to the Pennsylvania program and recently recommended that the interventions in the Pennsylvania program be implemented by all egg producers.[31]

The program includes the following requirements for producers, which should be incorporated into FDA's regulation:

a.) Chicks for layer flocks must be obtained from breeder flocks monitored for SE. Manure samples from the chicks must be tested at the time the chicks are delivered, and then again when the chicks are 10 to 15 weeks old.

b.) Manure samples from layer flocks must be regularly tested for SE when the hens are 29 to 31 weeks of age and again at 44 to 46 weeks of age. If the samples are positive, the houses must be thoroughly cleaned and disinfected between flocks.

c.) When manure samples are positive, eggs must also be tested. A total of 480 eggs must be tested, cultured in pools of 20 eggs each, every two weeks for eight weeks. Even if the eggs test negative, monthly egg sampling is required for the life of the flock.

d.) Where testing of eggs shows that some are positive for SE, all eggs from that flock must be diverted to pasteurization plants. Before the eggs from that flock can be sold as shell eggs again, a total of 4,000 eggs over eight weeks must test negative for SE.

e.) Biosecurity programs and rodent control measures for layer houses must be implemented.

f.) Eggs must be kept refrigerated at all times.[32]

---

[31] *Ibid.*, pp. 1-3, 9-10.

[32] Pennsylvania Poultry Federation, "Pennsylvania Egg Quality Assurance Program," May 1994.

Eggs should be refrigerated to an internal temperature of 41 degrees F as soon as possible after they are laid, and then kept at that temperature at all points up to and including the point of retail sale. A temperature of 41 degrees F or less ensures that SE bacteria cannot multiply and provides a margin of safety for temperature abuse.

FDA's regulation should incorporate the principles of HACCP. Under HACCP, producers are responsible for identifying potential hazards and critical control points in their own operations. Producers should keep records to establish compliance with their program. FDA inspectors should verify producer compliance by reviewing records and conducting occasional testing of manure samples and eggs.

B. Legal Grounds

1. FDA Has the Legal Authority to Mandate a Caution Label on Egg Cartons.

FDA has the authority to declare eggs misbranded unless they bear a label advising consumers how to avoid the risk of food poisoning from SE. Under the Federal Food, Drug, and Cosmetic Act, a food is "misbranded" if its label is false or misleading in any particular.[33] A label on a food may be false or misleading if the label fails to reveal material facts about the consequences of use of the food.[34] The fact that a food that is generally considered safe could cause serious illness or death is the type of material fact that should be revealed on the food's label to prevent the food from being misbranded. A label for eggs is particularly important since a survey shows as many as half of all consumers may not be aware of the risk of eating them raw or undercooked.

---

[33] 21 U.S.C. § 343(a)(1).

[34] 21 U.S.C. § 321(n).

a. FDA Has the Authority to Require Warning Labels on Food Products That Could Cause Illness or Death.

FDA can require food to be labeled where "information is necessary to ensure that consumers are aware of special health risks associated with consumption of a particular product."[35] FDA has used this authority to require warning labels on diet foods, foods sold in aerosol cans, and iron-containing food products. FDA has also required warning labels for food additives that can cause adverse effects, including olestra, aspartame, sorbitol and mannitol.[36]

In the 1970s, low-calorie protein products used by dieters were implicated in the sudden deaths of at least sixty people, most of them young women. In response to the deaths, FDA issued a regulation requiring a warning label on low-calorie protein products, advising that very low-calorie protein diets may cause serious illness or death. When the regulation was challenged by industry groups, two federal district courts upheld FDA's authority to require such warning labels.[37] The court in Council for Responsible Nutrition stated that FDA's general rulemaking authority set out in section 701(a) of the Food, Drug, and Cosmetic Act, taken together with sections 201(n) and 403(a)(1), gave FDA the authority to require labels on low-calorie protein products to make consumers aware of the health risks that might arise from the use of such products.[38]

---

[35] 61 Fed. Reg. 3160, Jan. 30, 1996, "Food Additives Permitted for Direct Addition to Food for Human Consumption: Olestra; Final Rule."

[36] *Id.*; 21 CFR §§ 172.804(2); 180.25(e); 184.1835(e).

[37] See Council for Responsible Nutrition v. Goyan, Food Drug Cosm. L. Rep. (CCH) ¶ 38,057, p. 38,269 (D.D.C. 1980); National Nutritional Foods Ass'n. v. Novitch, 589 F.Supp. 798, 801 (S.D.N.Y. 1984).

[38] CCH, ¶ 38,057, p. 38,269; 21 U.S.C. §§321(n), 343(a)(1), 371(a).

In another example, a federal court upheld FDA's authority under sections 201(n) and 701(a) of the FFDCA to require warnings on the labels of all food, drug and cosmetic products sold in aerosol cans.[39] The warnings tell consumers to avoid puncturing or incinerating the cans, and to avoid storing them above 120 degrees F. Warnings are currently used on aerosol cans of whipped cream, processed cheese product and non-stick cooking sprays.

FDA has recently used its legal authority to require label warning statements on foods in support of its regulation requiring warning statements on iron-containing supplements and drugs.[40] The warning statements are required to help prevent accidental overdoses of iron-containing products by children. In 1994, over 3,210 children were treated for iron overdose and two children died.

Like those three product groups, eggs present a risk to consumers. Each year, SE in eggs causes between 200,000 to one million illnesses and at least several hundred deaths. FDA is clearly justified in exercising its legal authority to require a consumer advisory label for SE.

b. Without a Caution Label, Shell Eggs Are "Misbranded" under the Food, Drug and Cosmetic Act.

Aerosol food cans and iron-containing products can cause illness, injury or death when they are misused, i.e., when the can is punctured, or when an overdose of iron-containing products occurs. The label for each of those products advises consumers that the products can be dangerous when they are *misused.* Shell eggs, however, can be dangerous when consumers use them in dishes and with preparation methods that have long been part of American cuisine. Based on custom and tradition, many consumers assume that eating homemade mayonnaise,

---

[39] Cosmetic, Toiletry and Fragrance Association, Inc. v. Schmidt, 409 F.Supp. 57, 64 (D.D.C. 1976).

[40] Department of Health and Human Services, "Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Final Rule, 21 C.F.R. Parts 101, 111, and 310," *Federal Register*, Vol. 62, No. 10 (1997), p. 2218.

eggnog, or eggs fried "sunny-side up" or "over-easy" is safe. Consumers consider eggs to be properly cooked even when the yolks are still runny.[41]

Recurrent SE outbreaks from raw or undercooked eggs have demonstrated that such foods are not always safe. Thus, egg cartons currently fail to reveal a material fact: that consuming the eggs in a raw or undercooked state may result in serious illness or death. Under section 201(n) of the FFDCA, the absence of this information is misleading and should cause the product to be declared misbranded.

When determining whether the current labeling on shell eggs is misleading, FDA has a duty to consider both informed and uninformed consumers, bearing in mind that the purpose of the FFDCA is to "protect unwary customers in vital matters of health."[42] FDA should not rely on sporadic media reports of foodborne illness outbreaks or poorly distributed and easily lost brochures to protect consumers from known risks in the food supply. Even if some consumers have heard of egg-related outbreaks, outbreak information is not the same as a clear instruction to consumers on how to protect their families. A clear, concise statement about the risks of SE on egg cartons -- exactly where and when consumers need the information -- should be required.[43]

---

[41] Cf. Texas Food Industry Association v. Espy, 870 F.Supp. 143, 149 (W.D.Tex. 1994) (the court observed that consumers often consider hamburger, which can contain the deadly form of *E. coli*, to be properly cooked even when it is still rare or medium rare).

[42] U.S. v. Article (Sudden Change), 409 F.2d 734, 741 (2d. Cir. 1969); U.S. v. An Article of Food (Manischewitz . . . Diet Thins), 377 F.Supp. 746, 749 (E.D.N.Y. 1974). FDA must consider even "the ignorant, the unthinking and the credulous" consumers. 409 F.2d at 740.

[43] The case of Nancy Donley, a mother in Chicago who lost her son Alex to *E. coli* O157:H7 in 1993, illustrates the importance of warning all consumers. Ms. Donley had heard about the earlier outbreak associated with Jack in the Box hamburgers. She assumed that the government had addressed the problem when, six months later, she gave her child a hamburger that turned out to be contaminated.

2. *FDA Has the Authority to Require SE Control HACCP Programs That Include Testing of Flocks and the Diversion of Eggs from Positive Flocks to Pasteurization Plants.*

The Public Health Service Act (PHSA) gives FDA broad authority to issue regulations to prevent the spread of communicable diseases in the U.S.[44] SE is a "communicable disease" under the statute. A communicable disease includes one that can be transmitted from an infected animal to a person through an indirect vector, or carrier.[45] SE is transmitted from infected hens to humans through eggs and thus falls under FDA's jurisdiction under the PHSA.

FDA has wide latitude under the PHSA to regulate the food industry when its products pose a public health risk. FDA can exercise its regulatory authority to require that producers of a food product take steps to ensure that the product is free of microbiological contaminants before selling it for human consumption in interstate commerce. In 1987, FDA issued a rule requiring pasteurization of milk and milk products before they are sold in interstate commerce.[46] The regulation provides specific time and temperature specifications for pasteurizing the products.

FDA took this step because of epidemiological and other data linking raw milk and other raw dairy products with illnesses from *Salmonella dublin.*[47] In the state of California, half of all *Salmonella dublin* cases were linked to raw milk. There is a similarly convincing link between

---

[44] 42 U.S.C. § 264.

[45] 21 C.F.R. § 1240.3(b).

[46] 21 C.F.R. § 1240.61.

[47] Department of Health and Human Services, Food and Drug Administration, "Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce; Final Rule, 21 CFR Part 1240," *Federal Register*, Vol. 52, No. 153, Aug. 10, 1987, p. 29511-12 [hereinafter cited as *Requirements Affecting Raw Milk*].

consumption of raw or undercooked eggs and illnesses and deaths from SE.[48] Eighty percent of SE outbreaks are linked to eggs. In fact, the case for regulating eggs is even stronger than for raw milk, since many more consumers are exposed to eggs than were exposed to raw milk at the time the pasteurization regulation was issued.[49] Raw milk was a specialty product, whereas 3.75 billion cartons of eggs are consumed each year in this country.[50]

FDA chose to require pasteurization of milk because it was "a practical measure."[51] Although FDA could require pasteurization of all eggs, such a measure would not be practical, nor would it reflect consumer preferences. Placing an advisory label on egg cartons, along with mandating on-farm SE control programs, is a practical solution that would also protect consumers.

Just as with raw milk, FDA may prescribe control measures to reduce the prevalence of SE in eggs. Just as the milk pasteurization regulation does, FDA's HACCP regulation for egg producers can specify the steps to be taken to ensure the reduction of SE, including sampling and testing frequencies for manure and eggs. FDA has the authority to require in its regulation the elements of the Pennsylvania program described above.

---

[48] Michael St. Louis, et al., "The Emergence of Grade A Eggs as a Major Source of *Salmonella enteritidis* Infections," *Journal of the American Medical Association*, Vol. 259, No. 14 (1988), p. 2103-2107; Centers for Disease Control and Prevention, "Outbreaks of *Salmonella* Serotype Enteritidis Infection Associated with Consumption of Raw Shell Eggs - United States, 1994-1995," *Journal of the American Medical Association*, Vol. 276, No. 13, October 2, 1996, p.1017-1018.

[49] The preamble to the rule stated, "It is true that the population exposed to certified raw milk in interstate commerce is relatively small compared to the population exposed to other sources of *S. dublin* and that one would, therefore, not expect a significant change in the rate of *Salmonella* infection in the overall population..." *Requirements Affecting Raw Milk*, p. 29512. The preamble concluded, however, that the raw milk ban was justified because of the sizeable risk of illness to those consumers who did drink raw milk. Id.

[50] Rose Acre Farms, Inc., Citizen Petition to FDA, FSIS, APHIS, and AMS, November 4, 1996, p. 8.

[51] *Requirements Affecting Raw Milk*, p. 29512.

FDA's broad rulemaking authority under the PHSA has been upheld by the court system. In the face of evidence that as many as 280,000 cases of salmonellosis each year were related to small turtles, FDA issued a regulation banning the sale of all such turtles in both intra- and interstate commerce.[52] A federal court upheld the regulation, citing the health hazard posed by turtles as justification for FDA's action.[53] The health hazard posed by SE in eggs is at best comparable, causing an estimated 200,000 to one million illnesses and a significant number of deaths each year.

FDA's intra-state ban on the sale of turtles was upheld as well as the interstate one. The court noted that it would be "difficult or impossible" for FDA to stop the interstate transmission of the disease without an intra-state ban.[54] Thus, the intra-state ban was authorized by law and was "clearly reasonable."[55] In the same way, it would be difficult for FDA to stop the interstate transmission of SE "under modern conditions of transportation and commerce" without an intra-state ban.[56] FDA should not be required to expend scarce resources to ensure that eggs from SE-infected laying houses stay out of interstate commerce. FDA's SE control regulation should therefore extend to all commercial egg-producing flocks, whether their eggs are sold intra- or interstate.

---

[52] 37 Fed. Reg. 7005, Vol. 37, No. 60, April 7, 1972; 21 CFR § 1240.62

[53] Louisiana v. Mathews, 427 F.Supp. 174, 176 (E.D.La. 1977).

[54] Id.

[55] Id.

[56] See id.

IV. ENVIRONMENTAL IMPACT

The action requested in this petition has no negative environmental impact. Any environmental impact would be positive, because the prevalence of SE in the natural environment near the laying houses with SE control programs would likely be reduced.

V. ECONOMIC IMPACT

A. The Benefits of Consumer Labels on Egg Cartons Justify Their Costs.

A caution label on egg cartons would help to reduce the number of illnesses and deaths caused each year by SE. In addition to the tragedy of unnecessary deaths and the personal discomfort and inconvenience of illness, SE takes a heavy economic toll. As noted above, the annual estimated cost to the economy of human illness from eggs infected with SE is $118 million to $767 million, which includes lost productivity, medical and hospitalization costs, and death.

The costs of printing the labels on egg cartons are minimal in light of their potential to save even one life. For example, cost estimates by USDA for the meat and poultry safe handling label are $.01 to $.025 per label.[57] However, because the label could be incorporated into the lid of the egg carton, labels on egg cartons would cost nothing after one-time design changes were made. Even if the labels cost one tenth of a cent each, the cost of labeling the up to 3.75 billion cartons of fresh shell eggs sold every year in the U.S. would be fully covered if the labels prevented just over *three percent* of the annual costs of human illness and death from SE.[58]

---

[57] U.S. Department of Agriculture, Food Safety and Inspection Service, "Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products; Final Rule, 9 C.F.R. Parts 317 and 381," *Federal Register*, Vol. 59, No. 59 (1994), p. 14528.

[58] 3.75 billion labels at $.001 each would cost $3.75 million. Three percent of $118 million, the low figure in the range of estimated costs from SE, is $3.54 billion.

The costs of labeling are also justified by studies that show that labels effectively reach consumers. One survey on the meat and poultry safe-handling labels found that 66% of the respondents have noticed the safe-handling instructions. The survey also found that 70% of parents with children under the age of 12 have noticed the safe-handling instructions.[59] Another survey found that six out of 10 shoppers surveyed were aware of the safe-handling labels and that 43% of these shoppers had changed their handling practices as a result.[60] These studies show that, while labels are not universally effective, their penetration is adequate to justify their minimal costs to industry and, ultimately, consumers.

B. The Benefit of SE Control Programs Outweighs Their Cost.

A mandatory testing requirement for all commercial egg-laying flocks in the U.S. has an estimated cost of $6 million to $10 million per year.[61] The estimated cost of food poisonings from SE ranges from $118 million to $767 million each year in lost productivity, medical and hospitalization costs, and death. Even if the on-farm control program reduced the number of illnesses and deaths of SE by only ten percent, the economic impact of the SE control regulations would be a net savings for the national economy. The success rate of the Pennsylvania control program suggests that a nationwide control program would reduce the number of deaths and illnesses by far more than ten percent. As described above, the Pennsylvania program reduced the percentage of SE-infected laying houses in the program from 38 percent to 13 percent in less

---

[59] American Meat Institute, "Americans Underestimate Their Role in Preventing Foodborne Illness, New National Survey Says," (Washington, DC: American Meat Institute, August 30, 1996).

[60] Food Marketing Institute, *Trends in the United States: Consumer Attitudes and the Supermarket 1996,* (Washington, D.C., Food Marketing Institute, 1996), p. 30.

[61] *Salmonella Control Efforts*, p. 19.

than three years. A decrease in human illness from SE in the Pennsylvania egg market area was partially attributed to the program.

The federal government has been willing to spend large amounts of money to fight poultry diseases that do not affect human health. Federal regulation requires that the government reimburse poultry producers for hens and materials that must be destroyed because of contamination with certain diseases that jeopardize animal health.[62]

USDA spent $60 million to fight a 1983-84 outbreak of Avian Influenza, which does not harm humans. That amount of money could pay for nationwide SE testing of laying houses for up to ten years. SE, which sickens and sometimes kills humans, should be at least as high a priority for the U.S. government as an animal disease.

---

[62] 9 CFR § 53.2(b). In contrast, Canada's federal government requires destruction of laying flocks that are linked to human illnesses from SE, and provides full compensation to the producers. Telephone conversation on April 23, 1997 with Rebecca Irwin, D.V.M., M.S.C., Health Canada.

VI. CERTIFICATION

The undersigned party certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Elizabeth Dahl
Staff Attorney, Food Safety Program

The following organizations endorse this petition:

American Public Health Association
S.T.O.P. -- Safe Tables Our Priority
National Consumers League
Consumer Federation of America
Public Voice for Food and Health Policy
Government Accountability Project

Carol Tucker Foreman, former Under Secretary of Agriculture, also endorses this petition.

FYI

NJO NEWS FLASH

Instant news around the clock.

News Categories
NewsFlash
National
International
Washington
Sports
NJ Region
Weather

NJO Sections
NJO Home
News
Sports
NJ Talks
Business
E-Guide
Life
Marketplace
User Guide
What's New

THE FULL STORY

Health group urges food poisoning warnings on egg cartons

By JOHN D. McCLAIN
The Associated Press
05/14/97 5:04 PM Eastern

WASHINGTON (AP) — Egg cartons should carry labels warning consumers that eating raw or undercooked eggs can poison them, a health advocacy group urges.

"Eggs have become the number one contributor to food poisoning outbreaks, with hundreds of thousands of Americans getting sick or dying every year," Caroline Smith DeWaal, food safety director for the Center for Science in the Public Interest, said Wednesday.

DeWaal told a news conference the center is formally petitioning the Food and Drug Administration to require the warning: "Caution: Eggs may contain illness-causing bacteria. Do not eat raw. Cook eggs until the yolk is firm."

If followed, the warning would relegate to the past the practice of children licking the bowl of cake or cookie dough prepared with raw eggs, or their parents eating sunny-side-up eggs with runny yolks.

DeWaal said 45 billion eggs are produced annually in the United States and only a small fraction are contaminated. But, she added, consumers don't know which ones will make them sick.

The center's message is similar to the message the egg industry's Egg Nutrition Center has stressed in consumer education materials for a dozen years. That is, said executive director Donald McNamara: "'Keep eggs refrigerated and cook them thoroughly before eating.' It's the standard things recommended for any perishable item."

McNamara said, however, that the industry opposes the label wording the Center for Science in the Public Interest is proposing. It gives the wrong impression that all 12 eggs in any carton are contaminated, when only a minute fraction of eggs pose a danger, mostly from undercooking and temperature abuse, he said.

Public Interest officials praised the Clinton administration's $43.2 million program announced this week to protect the nation's food supplies, including measures designed to ensure that fresh eggs are safe.

Both the administration and the center's egg-safety programs recommend additional research, testing, early warning systems, government coordination and consumer education.

But until those measures are put in place, food poisoning will remain a threat to thousands.

The government says 128,000 to 640,000 cases of food poisoning are caused annually by a strain of salmonella called enteritidis associated with eggs.

Salmonella causes diarrhea and systemic infections in victims and can be fatal, especially among the very young and elderly.

The Center for Science in the Public Interest said that until the 1980s, eggs generally were safe. Then salmonella enteritidis entered the production chain, and contaminated eggs now are found coast to coast.

Although the Agriculture Department checks eggs for quality, the FDA is responsible for controlling harmful bacteria in them. The center said the cash-strapped agency is able to inspect egg plants only an average of once every 10 years.

NewsFlash | National | International | Washington | Sports | NJ Region | Weather

Please send any questions or comments to newsflash@nj.com.

KETCHUM PUBLIC RELATIONS
WORLDWIDE

Fax

To: ELIZABETH DRYE	**From:** JERRY KLEPNER
Fax: 456-5581	**Pages:** 3
Phone: 835-8811	**Date:** 4.7.97
Re:	**CC:**

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• **Comments:**

Suite 600
Los Angeles, CA 90048-4163
(213) 651-1040

House of Representatives
Washington, DC 20515-0529
HENRY A. WAXMAN
29TH DISTRICT, CALIFORNIA

FEDERAL GOVERNMENT MUST DO MORE FOR FOOD SAFETY

HEPATITIS A OUTBREAK HIGHLIGHTS URGENT NEED FOR GREATER EFFORT, RESOURCES, AND ADMINISTRATION'S NEW FOOD SAFETY INITIATIVE, SAYS CONGRESSMAN WAXMAN.

FOR IMMEDIATE RELEASE
April 7, 1997

For more information, contact Paul Kim (202) 225-3976

WASHINGTON, D.C.— The outbreak of hepatitis A from imported strawberries highlights the urgent need to strengthen our country's oversight of food safety, said Congressman Henry A. Waxman, who wrote today to Department of Health and Human Services Secretary Donna Shalala, urging her to include hepatitis A in the food pathogens targeted by the Clinton Administration's new National Food Safety Initiative.

Over 9,000 students, teachers and others in the Los Angeles school district consumed the strawberries implicated in a Michigan hepatitis A outbreak which has sickened over 150 children and adults.

"We have the world's safest food supply, but more can be done. Outbreaks like this highlight the dangers of lowering our vigil," said Waxman. "Congress has an opportunity this year to improve our food safety protections. This outbreak should send a clear signal to my colleagues."

The Congress is in the midst of deciding on the federal government's annual appropriations, including the National Food Safety Initiative and food safety budgets for the Food and Drug Administration (FDA), U.S. Department of Agriculture and the Centers for Disease Control and Prevention (CDC).

The National Food Safety Initiative is directed at preventing foodborne illnesses and responding more quickly to outbreaks. The $43 million initiative would establish an early-warning system and enhanced surveillance, inspections and education.

Imports regulated by the FDA have tripled from 500,000 shipments in 1971 to one and a half million in 1993. The government is investigating whether the shipment of contaminated strawberries was grown in Mexico and illegally supplied to a government-sponsored school lunch program.

"Illegal, contaminated strawberries are just the tip of the iceberg. Food imports have soared and the FDA's food safety budget has flatlined. More resources must be dedicated to stopping unsafe imports from reaching American consumers," said Waxman.

###

2408 Rayburn House Office Building
Washington, DC 20515-0529
(202) 225-3976

District Office:
8436 West 3d Street
Suite 600
Los Angeles, CA 90048-4115
(213) 651-1040

Committees
Commerce
Government Reform and Oversight

Philip M. Schiliro
Administrative Assistant

Congress of the United States
House of Representatives
Washington, DC 20515-0529

HENRY A. WAXMAN
29th District, California

April 7, 1997

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala,

I am writing to express my concern over the recent outbreak of hepatitis A attributed to the distribution of contaminated, imported frozen strawberries.

As you know, over 150 children and adults have fallen ill in Michigan and schoolchildren in another five states, including California, may have been exposed to the virus from the same shipments of contaminated fruit. In Los Angeles County alone, thousands of families have been affected by fear and uncertainty during this public health emergency.

While hepatitis A is treatable through injections of gamma globulin, the disease is now entirely preventable by vaccine. Recently, the Food and Drug Administration (FDA) approved two vaccines which afford long-term protection against hepatitis A and which are available to States through the Administration's Vaccines for Children (VFC) program.

As a strong advocate for the President's new National Food Safety Initiative, I urge you to include hepatitis A as a covered pathogen targeted by the initiative. The $42 million in funding for a new early-warning system and enhanced surveillance, inspections and education, may also be appropriated focused on the risks from hepatitis A, the leading viral source of foodborne illness in this country.

In addition to asking the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture to investigate immediate measures to prevent future outbreaks of hepatitis A, I urge you to review whether hepatitis A vaccines are being adequately utilized among food handlers and in other areas of highest risk.

Sincerely,

HENRY A. WAXMAN

FOREMAN & HEIDEPRIEM, INC.

Carol Tucker Foreman

Suite 1030 • 1100 New York Avenue, N.W. • Washington, D.C. 20005
(202) 822-8060 • FAX (202) 822-9088

SAFE FOOD COALITION

1100 New York Avenue, NW, Suite 1030 Washington, DC 20005 (202) 822-8060

March 11, 1997

The Honorable Joe Skeen
Chairman
House Subcommittee on Agriculture, Rural Development,
FDA, and Related Agencies
2362 Rayburn House Office Building
Washington, D.C. 20515-6016

Dear Mr. Chairman:

The undersigned organizations write to oppose the Administration's FY 1998 budget proposal to assess $390 million in user fees for meat, poultry, and egg inspection. We oppose these fees for the following reasons:

1. MEAT, POULTRY AND EGG INSPECTION ARE BASIC AND ESSENTIAL PUBLIC HEALTH FUNCTIONS, AND, AS SUCH, SHOULD BE SUPPORTED BY THE AMERICAN PEOPLE.

Food borne illness is a serious public health threat. The Council on Agricultural Science and Technology (CAST) estimates that there are between 6 and 33 million cases of food borne illness in the United States each year and about 9,000 deaths. Conservative estimates are that meat and poultry products are responsible for about 5 million cases of bacterial food borne illness and 4,000 deaths annually. The cost to the nation in medical care and lost wages runs between $5.6 billion and $9.4 billion annually. Without an effective inspection program, devoted to protecting public health, the cost to the public would likely increase substantially. In comparison to such an increase, the $600 million in taxpayer funds devoted to meat and poultry inspection is not great.

Congress has recognized the special hazards presented by meat and poultry products by requiring the continuous, in-plant presence of federal inspectors sworn to protect public health.

2. CONTRARY TO THE ASSERTION IN THE ADMINISTRATION'S FY 1998 BUDGET DOCUMENT THAT MEAT AND POULTRY PLANTS BENEFIT FROM THE INSPECTION PROGRAM AND SHOULD, THEREFORE, PAY MOST OF THE COST,

IN-PLANT INSPECTION SPECIFICALLY IS NOT DESIGNED TO PROVIDE A SERVICE TO MEAT AND POULTRY PRODUCERS OR TO PROMOTE THE SALE OF MEAT AND POULTRY PRODUCTS.

Congress, in the 1996 Farm Act, responded to concerns that USDA's charge to protect public health often took second place to its mandate to promote the sale of meat and poultry products. In order to emphasize the separation between the Department's marketing and public health functions, the 1996 Act removed meat, poultry and egg inspection from the jurisdiction of the Assistant Secretary in charge of marketing and created a new Under Secretary for Food Safety. The language of the 1996 law makes clear the public health functions of the Under Secretary for Food Safety who is charged solely with administering regulatory programs designed to protect public health and safety -- the meat, poultry and egg products inspection programs. Inspection functions that govern relations between producers and processors, such as the Federal Grain Inspection Service, the Perishable Agricultural Commodities Act programs, and the Packers and Stockyards Act remain with the Assistant Secretary for Marketing.

Any benefit that processors receive from increased public confidence is inferential compared to the public health benefits that accrue directly to the public.

3. THE IMPOSITION OF USER FEES WOULD SERIOUSLY THREATEN THE SUCCESSFUL IMPLEMENTATION OF THE NEW MEAT AND POULTRY INSPECTION SYSTEM.

On January 27, 1997, USDA and industry began implementing the program, based on Hazard Analysis and Critical Control Point (HACCP) and performance standards. It is an entirely new paradigm for a ninety-year old system and implementing it successfully will challenge both industry and government. There is always a risk of serious unanticipated problems in a new system. The new program, poorly implemented, could actually increase the threat of food borne illness and call into question the move to HACCP in seafood and other segments of the food supply.

Imposing user fees for the first time in the 91 year history of meat inspection would also be a major change. It would require working out myriad details and would add an enormous burden to the same individuals in industry and USDA now absorbed in implementing HACCP.

We believe this new inspection system, which holds so much promise both for improved health protection and more efficient use of public resources, is worth the complete attention of all involved. The stakes are very high. We urge that both

government and industry officials be allowed to concentrate fully on making this important change successfully.

4. SHIFTING MEAT, POULTRY AND EGG INSPECTION FROM PUBLIC TO PRIVATE RESPONSIBILITY WOULD UNDERMINE PUBLIC CONFIDENCE IN THE SAFETY OF INSPECTED PRODUCTS.

The news media regularly carry reports of outbreaks of food borne illness and the possibility of threats to human health from newly emerging animal diseases such as bovine spongiform encephalopathy (Mad Cow Disease). Public opinion research indicates that Americans are concerned about the safety of the food they purchase for themselves and their families. They expect the federal government to assure a safe food supply. In the last four years, both Congress and the Administration have responded to those reported concerns and acted vigorously and responsibly to assure the public a safe and clean food supply. Ending the public funding of meat, poultry and egg inspection would surely call into question whether the federal government remains committed to that goal.

Finally, the fact that all meat and poultry products carry the seal, "Inspected and Approved, US Department of Agriculture," presents a special problem in ending federal funding of meat and poultry inspection. The federal seal of inspection holds out the promise of an official and uncompromised public health police force working to protect the public. We do not believe that federal inspectors forced to depend upon the inspected industry to finance their jobs would invoke the same confidence and respect from the consumers of meat and poultry products. Inevitably, questions about the quality of inspection and the safety of meat, poultry and egg products will affect consumer purchasing decisions.

We urge you to reject this ill-conceived and poorly-timed proposal to impose massive new user fees on meat and poultry processors and concentrate full funding on the newly emerging meat and poultry inspection system. The FY 1998 budget proposal contains other areas of fat -- for instance, in agricultural subsidies -- which would more sensibly be cut before placing our new meat and poultry inspection system in jeopardy.

Sincerely yours,

Carol Tucker Foreman
Coordinator, Safe Food Coalition

Bob Hahn
Public Voice for Food and Health Policy

Dr. Mohammad Akhter, M.D., M.P.H.
American Public Health Association

Elaine Dodge
Safe Tables Our Priority

Caroline Smith DeWaal
Center for Science in the Public Interest

Gary Sauter
United Food and Commercial Workers
International Union

Diana Neidle
Consumer Federation of America

cc: The Honorable Daniel R. Glickman
T. J. Glauthier, OMB
Thomas J. Billy, FSIS

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Elaine Dodge to Elizabeth Drye re: S.T.O.P. Families (1 page)	03/25/1997	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10451

FOLDER TITLE:
Food Safety Initiative - Comments [1]

2014-0046-S
rc1369

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

S.T.O.P.--Safe Tables Our Priority

P.O. Box 4442
Oceanside, CA 92052-4442

Victims Hotline 800/350-STOP
Phone 619/439-2969
Fax 619/439-1696
Email stop@msd.cts.com

March 24, 1997

Elizabeth Dry
Domestic Policy Counsel
OEOB, Room 213
White House
Washington, DC 20502

Re: S.T.O.P.'s comments on the President's Food Safety Initiative

Thank you for soliciting the comments of S.T.O.P. -- Safe Tables Our Priority on the "National Food Safety Initiative." S.T.O.P. is a national non-profit grassroots organization devoted to assisting victims of foodborne illness, public education, and policy advocacy for safe food and public health. The organization was founded in 1993 by family and friends of people who became ill or died from *E. coli* 0157:H7. Since then, our membership has grown to include victims of other pathogenic bacteria from a variety of foods, and their family members, consumers, and concerned members of the public health and public interest communities.

We are grateful that the President has continued to make food safety a priority. It was extremely meaningful to members of our organization to be present at President Clinton's July 6, 1996 radio address when he announced the publication of the Pathogen Reduction and Hazard Analysis Critical Control Points (HACCP) regulation designed to promote safety in raw meat and poultry products. We are pleased that his efforts have not stopped.

We also appreciate the hard work Secretaries Glickman and Shalala and Administrator Browner and their staffs have put into the "Discussion Draft and Current Thinking: A National Food Safety Initiative" document. We take seriously the caveat that this document is intended to reflect only the current thinking of your food safety experts at this, the initial stage of this formidable project. Hence our comments are intended not only to address the individual issues identified in the Draft document but to suggest that entirely new approaches may be necessary to achieve the goals you have identified, and to raise additional problems and concerns long recognized by the consumer community but missing from the Discussion Draft.

Process

As a preliminary matter, we would like to comment upon process. This Administration has distinguished itself by its effort to bring all affected parties to the table. The Discussion Draft emphasizes the necessity of creating a cooperative effort between public health and regulatory agencies at the federal, state, tribal and local levels as well as consumers, industry and academia at the outset of the project. The cover letter to the Discussion Draft encourages stakeholders to think critically about the document and bring other issues not raised in the draft to the March 5th meeting. We arrived at the meeting with the expectation that it would be an open forum with audience participation. This was not the case.

S.T.O.P. had representatives from as far away as New York and Illinois at the meeting. We were disappointed that we spent resources bringing people to a meeting that was largely devoted to presenting information that our

representatives already had. Since audience participants were required to put their questions in writing and only a handful of questions were addressed by the panel, the question and answer period did not justify the expense of attending the meeting. We consider this format inferior to an open dialog where follow-up clarification and additional comments and suggestions from other audience participants are welcome. We are concerned that this first meeting is indicative that the Administration, USDA, HHS and EPA are already committed to the course of action outlined in the Discussion Draft and not genuinely open to other issues and approaches.

Our other concern about process is the date of the second meeting. Our membership consists primarily of ordinary citizens who happen to be foodborne illness victims -- not paid professionals. In order for S.T.O.P. representatives to be present at the meeting we have to fly in Saturday night to be able to afford the discounted Saturday night stay over airline fare. Sunday, March 30th -- the day before you have convened your three day meeting-- is Easter. Asking our members to attend your meeting forces them to choose between contributing their thoughts and experience on an issue that has had life and death implications for them already versus missing a major family and religious holiday. It is a painful choice for people whose families have already suffered so much.

Information

The effectiveness of the National Food Safety initiative will only be as good as the information upon which it is based. To this end we found one statistic in this draft particularly disturbing. The Discussion Draft states that the estimated number of deaths annually attributed to *E. coli* 0157: H7 is 6. We were relieved to hear that figure acknowledged as inaccurate at the March 5th meeting. We rely on the Centers for Disease Control and Prevention (CDC) estimate of 500. However, the fact that the first figure of 6 made it past your "food safety experts" and current coordinating committee gives us pause. In the future, an error such as this could lead to disastrous policy decisions.

Secondly, in order to comprehensively address the issue of food safety, efforts must be focused on all significant foodborne threats. We find your list of hazards targeted for immediate attention to be incomplete. Consideration of Salmonella, Campylobacter, *Escherichia coli* 0157:H7, Toxoplasma gondii, cryptosporidium paravum and Norwalk virus ignores other serious foodborne health risks. At a minimum, we urge you to add to your list Listeria, *Vibrio vulnificus*, Hepatitis A and all other emerging enterohemorraghic *E. coli* strains.

Likewise, in appreciating the risks of foodborne illness it is necessary to understand the life threatening conditions brought on by food contamination. A significant condition overlooked in your discussion is Thrombotic Thrombocytopenic Purpura (TTP) which can be caused by *E. coli* 0157:H7. TTP can lead to strokes and death, particularly in the elderly and in pregnant women. Perhaps most noticeably absent was any discussion of Creutzfeld Jackob Disease and its relaltionship to Bovine Spongiform Encephalopathy in cows and similar central nervous system disorders observed by USDA in 1978 in hogs. The fact that little is known about these diseases is arguably greater reason to include them in consideration of foodborne illness prevention.

Finally, a comprehensive system must include all the possible sources of foodborne contamination. One of the major sources of contamination that is totally overlooked is manure. More and more food groups are becoming contaminated from animal-reservoir pathogens, some due to the use of contaminated manure. For example, *E. coli* 0157 H:7 has been reported to live up to 70 days in cow manure. It is considered one of the sources of *E. coli* contamination of plant products, including lettuce and alfalfa sprouts, and has possible links to natural juices and apple cider. There are no rules, regulations, or safeguards for manure used in commercial farms. No federal agency has jurisdiction over manure -- which is probably why it was omitted from your Discussion Draft.

Focus

We feel that the Discussion Draft has two fundamental flaws in its emphasis and focus. We believe that a preventive strategy is superior to a reactive one. The areas emphasized in this initiative--public health surveillance, risk assessment, communication and coordination between agencies, education--are all important and merit attention. But they will not prevent foodborne illness and death. For any type of prevention program to be successful, the problem must be attacked at its source. Attention must therefore be focused on the source of foodborne pathogens: the farms and fields. Instead, the Discussion Draft emphasizes consumer responsibility. We find this objectionable and misguided.

Secondly, we believe that the Initiative would have a better chance at achieving its goal of reducing foodborne illness if it were focused on dangerous foods rather than on a limited number of pathogens. The logical first step is to identify all the existing and emerging pathogens and then identify which foods and food groups are most likely to be contaminated. The government currently regulates foods not pathogens and for good reason. Many raw foods can be contaminated with more than one pathogen while certain processed food products are extremely unlikely to become contaminated. Also, consumers, in general, understand which foods are potentially dangerous but they don't necessarily understand the microbiology or epidemiology of foodborne illness. A successful consumer education program must emphasize precautionary measures taken vis a vis foods not pathogens.

Public Health Surveillance

We agree that a key element in an early warning system is the ability to detect problems. You don't know you have a problem unless you look for it and test for it. That is why S.T.O.P. has long been a proponent of mandatory stool sampling for people with concurrent symptoms of diarrhea and severe abdominal cramps. We have learned through the experiences of our members that children are routinely turned away from pediatricians' offices and hospital emergency rooms having been misdiagnosed with the flu. Because stool culturing is not mandatory, these misdiagnosed children completely elude any early warning detection system. Even though HUS has now become the leading cause of kidney failure in children, pediatricians are still failing to recommend their patients be tested for pathogenic *E. coli*. This failure can and has had devastating consequences. The infected children can be subjected unnecessary and often compromising medical treatments like appendectomies and antibiotics. Others, who don't develop life threatening cases, recover without ever being accurately diagnosed and counted.

To facilitate better information about the cause of foodborne illnesses and the nature of various foodborne pathogens, we recommend that routine traceback of foodborne illness be pursued to the farm level. The source of foodborne pathogens should be determined for each and every incidence of illness to prevent further illnesses.

S.T.O.P.'s experience with state and local health departments raises concerns about the initiative's focus on state and federal cooperation. The initiative will only be as good as its participants. Not all public health agencies are tracing important foodborne pathogens such as *E. coli* 0157:H7. Further, some public health departments do not protect the public health when foodborne illness threatens a community. State agricultural disparagement laws and other statutes protecting business concerns prevent agencies from disseminating important foodborne illness information to the public.

We agree that states should have better surveillance systems, but it should be consistent nation-wide. Currently there is a substantial lack of uniformity in reporting requirements. Lack of consistent reporting has caused much recent confusion over the interpretation of illness sources. Because we keep our own list of incidents and outbreaks and compare our records with those kept by local and state public health agencies, we have discovered wide discrepancies in record keeping criteria. For example, sometimes cases of foodborne illness are only recorded if the victim is over 14 years old. In other jurisdictions, there must be two cases in the same county before the information merits recordation. It is quite possible that an emerging pathogen could be identified in an individual case or small cluster of cases that would be overlooked if only outbreaks were studied. Currently, individual cases are not routinely evaluated by the CDC. Therefore, the surveillance program should track individual foodborne illness cases and clusters in addition to outbreaks. States should be required to test for all the foodborne pathogens and report those test results. Mandatory reporting of these test results should be the law in all 50 states and not just in 38 as is currently the situation

push on States?

Public health agencies must follow uniform procedures to protect public health. For instance, the forms used to report outbreaks should be completed in a consistent manner across the country. Just as the initiative recommends standard procedures for detecting and responding to the discovery of foodborne pathogens with increased antimicrobial resistance, we recommend that Food Net write foodborne illness response standards for state and local heath departments and that the government require participating states to adopt mandatory reporting laws for foodborne pathogens such as *E. coli* 0157:H7. Further, the initiative should examine state laws that impede public health and require that states receiving government resources for the initiative rescind laws that obstruct public health.

During foodborne illness events, public health concerns are weighed against financial interests of farmers, producers, and retailers. In light of ethics issues raised during these incidents and the government's competing responsibilities

to consumers and businesses, we recommend that the initiative either 1) establish a food safety ethics board composed of bioethicists or 2) utilize the National Bioethics Advisory Committee to evaluate the challenges presented when determining the appropriate response to a foodborne illness incident and prepare recommendations for addressing conflicts of interest. In the spirit of HACCP, the ethics board could develop a clear decision making tree for use when responding to foodborne illness incidents. Other decision making chains could be developed for responding to situations where local or state agencies resist cooperation with federal officials.

It is our understanding that investigations of adverse foodborne incidents are rare. We recommend that the initiative include a program to recruit and train additional inspectors and other foodborne illness public health professionals at the federal level. Perhaps this can be achieved through a scholarship and/or apprenticeship program.

We strongly encourage updating the collection and sharing of data by linking sentinel sites and developing a national bacterial "fingerprints" database. Since these networks would be developed with taxpayer money, we expect that the information in them would be publicly available.

We recommend that the government give incentives to insurance companies to encourage them to provide records regarding foodborne illness cases. These records would not only be helpful in tracking illnesses, but would provide valuable information about the average severity, cost, and length of the illnesses. It would also offer a glimpse of the long term effects of relatively new pathogens.

Summary records

Risk Assessment

Risk assessment is a very subjective endeavor. As noted in the Draft, there are significant data gaps that prevent one from drawing meaningful conclusions from the present data and therefore, from making sound policy decisions upon the existing data. Research is frequently conducted by parties who have or are funded by entities with a financial interest in particular outcomes. Public policy should not be based upon incomplete or biased information.

S.T.O.P. has concerns about the recommendation to create a federal risk assessment consortium. First, only agencies concerned with food safety should participate in this effort. Second, the consortium should reflect a move away from the "old school" of food policy. Consumers simply don't trust foodborne illness data collected by agribusiness institutions -- including academics funded by agribusiness. The government has stated that emphasis on food safety policy should shift from animal health and other typical agriculturally-based concerns, to public health. A risk assessment consortium would be most appropriately comprised of medical doctors and epidemiologists and housed at a premier research hospital or academic institution noted for top public health or medical departments.

The effects of recently discovered foodborne illnesses such as *E. coli* 0157:H7 are not well known. Therefore cost estimates of the illness are not accurate. Those stricken with these newly identified illnesses face dwindling insurance options and uncertain health futures. The government should research the lasting effects of these diseases to make more accurate cost analyses and to give health providers and victims a better sense of the illnesses' repercussions.

We recommend that the government address risk assessment issues by developing a high-profile foodborne illness research program similar to the Genome Project. Researchers without ties to agribusiness could systematically assess issues such as dose-response and exposure assessment pathogen by pathogen. Research on biomarkers and antimicrobial resistance could be incorporated into this effort.

With regard to assessing data and modeling techniques to assess exposure to microbial risks, although important, S.T.O.P. places less importance upon determining typical behaviors within commercial and home preparation operations. It is our understanding that some research on this issue has occurred. Further, the percentage of food prepared and eaten at home is decreasing significantly, and commercial food preparation operations should be assessing their own behaviors as part of HACCP. Emphasis should be placed on the other areas outlined in the draft: exposure assessment, intake data regarding sensitive subpopulations, incidence and prevalence of pathogens, and sources and carriers of foodborne pathogens.

Bioscience Research

We agree completely that improved detection methods are needed for identifying foodborne pathogens. For instance, in the case of pathogenic *E. coli*, government regulators should be doing verotoxin testing which looks for all enterohemorraghic strains that result in illness. Narrow testing for only 0157:H7 will miss the emerging pathogens such as 0111. Tests that are broader in scope that will detect all illness-causing bacteria, toxins, viruses, etc. are crucial. The same effort the initiative recommends for detection methods should also apply to dose response and exposure assessment data collection.

We strongly support "regulation of transportation of meat, poultry, seafood, eggs and other foods ..." in order to safeguard the public from pathogenic microorganisms. It is ridiculous and irresponsible of government to tell consumers that they must keep their refrigerators and freezers below 40 and 0 degrees respectively, while there are no regulations on temperatures for shipping raw poultry and meat from processing plants to retail distributors or for shipping live animals, plants and foods. We recommend that the ANPR published on November 22, 1996 be expanded to include shipping live animals, plants and foods.

We also recommend that the government require the widespread use of temperature recording devices in food transportation vehicles and, where applicable, on individual food packages. Recent media attention on grocery stores that do not refrigerate eggs emphasizes the need for use of these devices on individual products.

S.T.O.P. has some concerns about the possible research recommendations made to address significant foodborne pathogens. First, with the exception of drugs and other therapies to prevent initial colonization, these techniques are not preventive. Emphasis should be placed on research that prevents contamination. The government's role is to inspect for contaminated food products and remove them from the market place. It is not appropriate for the government to prioritize research that "cleans up" dirty food at the processing or retail levels.

The government could encourage pathogen control, reduction and elimination cheaply by simply requiring food companies to place brand names on their products. Consumers can choose to avoid restaurants that served food that made them sick, but too frequently grocery items implicated in food poisoning cases are protected by anonymity. Market forces could provide an appropriate and powerful incentive for voluntary industry prevention strategies.

Consistent with our policy of placing more information and control in the hands of consumers, we recommend that the initiative prioritize the evaluation and approval of declarative labels that allow consumers to choose between foods that have received special treatment to reduce the likelihood of containing pathogens. We also support the quick evaluation and approval of antimicrobial food treatments for use by consumers.

Inspections

Not included in your Discussion Draft, but a part of the President's 1998 budget proposal is $390 million in user fees for meat, poultry and egg inspection . While we recognize the need to cut government expenses, we are certain that the assessment of user fees would seriously compromise the effective implementation of HACCP. HACCP is the most significant food safety action initiated by this Administration. A fully funded independent inspection force to implement and enforce HACCP is elemental to its success. Requiring industry in essence to pay for the federal inspectors would certainly undermine HACCP's effectiveness and credibility with consumers.

We are greatly troubled by the existing inspection resources at USDA and FDA. The ideas proposed in the Discussion Draft are not comprehensive enough to address the immediate needs of either agency. USDA for some time has engaged in the practice of not filling inspector vacancies, resulting in a 13% vacancy rate. The idea of asking an understaffed FSIS inspection force to take on additional FDA inspection duties defies common sense. At the same time we recognize that government resources are limited, and that it is unlikely that an ideal inspection system will be realized. However, if consumers must live with decreased inspection forces, the decreases should be offset by increasing food safety enforcement in other ways. For instance, fines and penalties for violators of food safety laws could be increased.

We agree that federal/state inspection partnerships would be enhanced by establishing a process of certifying laboratories. However, laboratory certification should be conducted by a neutral, third party or government agency. We urge that you enlarge that program to certify laboratories providing services under USDA programs as well. We have long advocated laboratory certification for the generic *E. coli* program required under the USDA HACCP program.

We are alarmed about the lack of FDA inspections of imported foods. We understand that FDA is so grossly understaffed at its import sites that product is passed for importation without an inspection despite legal requirements to the contrary. This practice presents an identifiable threat to consumers given the volume of seafood imported into this country. Seafood is probably the next most dangerous food category after raw meat and poultry and eggs. Shellfish, including raw molluscan shellfish, was responsible for three major foodborne illness outbreaks last year affecting several hundred people. It deserves a rigorous inpection program.

On the other hand, we reject the notion that Mutual Recognition Agreements (MRAs) ensure the safety of imported product by identifying those countries employing equivalent procedures. Likewise we have the same concerns with FSIS equivalency determinations for those countries using same or similar inspection standards as our own. It is impossible to guarantee that another country's inspectors will be as vigilant when examining products destined for export. USDA is even entertaining the idea of allowing foreign imports to be inspected by company employees in their country of origin. We unequivocally reject this consideration.

Education

The entire thrust of the education section is troubling. The underlying assumption that everybody would do the right thing if they only knew what it was, may apply to consumers who stand to benefit directly by protecting themselves from foodborne illness. But it is absurd to think the same of industry. It is indisputable that industry passes product they know or suspect to be contaminated on to consumers. For just that reason, one of the fundamental purposes of government regulation is to set standards of safety for industry and to enforce those standards with inspection and penalties imposed on those who fail to comply.

That aside, as a victims organization, we are ardent supporters of consumer education. We would embrace a joint consumer-industry food safety awareness campaign. We support the thrust of the upcoming Food Safety Educators conference towards including behavior modification messages as well as consumer warnings. However, the messages crafted for consumers must be accurate and comprehensive. For example, with the exception of a few pathogens, consumers do not contaminate food. Animal muscle and fruit flesh do not normally contain pathogens. They are tainted when a contaminant is introduced. The vast majority of contaminants are introduced at the processing level. Therefore, it is important that any consumer education campaign honestly address the fact that the consumer's primary role is controlling pathogens that are usually present on foods when they are purchased. The consumer should know the likelihood that their food products contain pathogens so that they fully understand the seriousness of taking precautions to prevent further microbial growth, prevent the spread of pathogens to other foods, and cook foods properly to substantially reduce or eliminate contamination.

The current "brown in the middle" government and industry food safety campaign is a case in point. It is not acceptable to merely tell consumers that a hamburger cooked until the meat is brown in the middle is safe, when industry and government know that is simply not always true. A brown in the middle hamburger can be brown not because of cooking, which would have killed the bacteria, but because of oxidation. And every bite of a hamburger must be cooked to an internal temperature of 155 degrees. It is a scientifically established possibility that a hamburger can be brown in the middle but not cooked to an internal temperature of 155 degrees throughout. If the goal is to educate consumers to take responsibility for their safety when it comes to food, they must have all the information necessary to take the appropriate steps to protect themselves. Likewise, if we are going to effectively educate consumers that their hamburgers must be cooked to 155 degrees, for example, then we must require the food service industry to cook those hamburgers accordingly. Anything less is sending mixed messages.

Preparation and consumption of food no longer takes place predominantly within the home. More and more often, responsibility for food preparation lies with retail food establishments. The initiative's own example linking 85% of *S. Enteritidis* cases with nursing home residents, emphasizes the need for improved food handler education in commercial establishments. It is not sufficient to merely educate retail food service workers about the provisions contained in the 1997 Model Food Code. The federal government should be embarking on a campaign to see that the Food Code is adopted in all 50 states as law, including a federal enforcement and penalty system. We also recommend that the government address the challenge of retail food by supporting state food handler food safety certification requirements. This certification should be a requirement for government foodborne illness surveillance assistance to states. States could charge a small fee for certification to generate addition resources or offset costs associated with participation in the food safety initiative programs.

Educating consumers is not only a moral priority, but also a practical last step in preventing foodborne illness. The emphasis on prevention must begin on the farm with mandatory education of the producers, enforced with government regulations. The same is true of the transportation, retail, and food service industries.

Independent Food Safety Organization

In light of the fact that the nation's food safety policy is currently spread over a patchwork of agencies, we agree that at a minimum, coordination between the numerous state, local and federal agencies responsible for ensuring the safety of the nation's food supply is vital. The government should be doing that now. As an organization representing many individuals who have suffered from poor public health practices, S.T.O.P. is concerned about the cooperation strategies outlined in the Discussion Draft. Neither the Foodborne Outbreak Response Coordinating Group nor the proposed national meeting with federal, state and local officials would offer an opportunity for victim input in developing public health agency policies to manage and respond to foodborne illness.

J.M.

After thorough review and careful consideration of the Discussion Draft for the National Food Safety Initiative we think that the approach is significantly flawed. Much of the success of the programs outlined for consideration are predicated upon effective government coordination. Through no fault of their own, interagency coordination is an oxymoron. Products and substances destined for human consumption originate from farms, fields and waters. To pass jurisdiction back and forth between different agencies only guarantees that aspects of our food supply are going to fall through the cracks. Duplication of resources, confusion, and misdirected funding are guaranteed under such a system.

While we support your efforts to address gaps in the nation's food safety net, we think the best way to guarantee that our food supply is as safe as it can be, is to create a single, comprehensive, food safety organization that can regulate safe practices from farm to fork. Four years ago, the Safe Food Coalition advocated the food and cosmetic regulatory activities from FDA, meat and poultry inspection from USDA, food advertising regulation from FTC, seafood inspection programs of the Department of Commerce, and pesticide programs from EPA be combined. One possibility is to combine these programs with the Consumer Product Safety Commission. With a single administrator for all of the above programs, such an agency would certainly save on administrative costs and surely provide a more coherent focus for food and consumer safety.

Sincerely,

Nancy Donley

Nancy Donley
President

Elaine J. Dodge

Elaine J. Dodge
Executive Director

With My Compliments

Re: International Food Safety Rules

MARSHA A. ECHOLS
1529 WISCONSIN AVENUE, N.W.
WASHINGTON, D.C. 20007
202-625-1452 202-625-9126 fax.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

THE WORLD TRADE ORGANIZATION

THE MULTILATERAL TRADE FRAMEWORK FOR THE 21st CENTURY AND U.S. IMPLEMENTING LEGISLATION

by
Marsha A. Echols

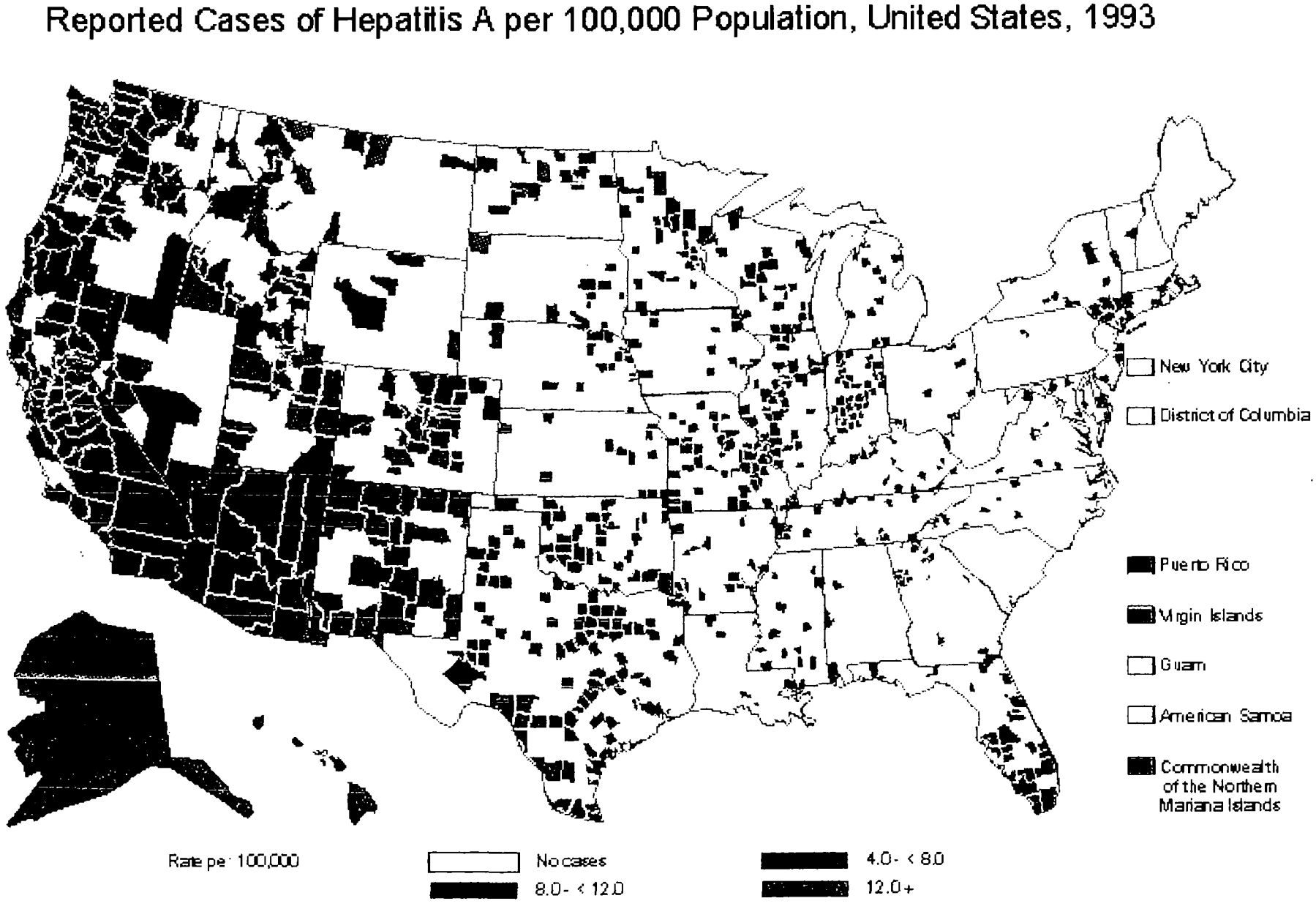
American Bar Association
Section of International Law and Practice

SmithKline Beecham

Eleanor W. Kerr
Senior Director, Government Relations

1020 19th Street, N.W., Suite 420, Washington, D.C. 20036
Telephone (202) 452 8490 Fax (202) 452 8489

Figure 3A.



Source: MMWR

Q & A on a Proposal to Include Hepatitis A in the President's Food Safety Initiative

Q: Is foodborne hepatitis A an important problem?

A: Yes, especially economically. Foodhandlers infected with hepatitis A can cause significant economic losses for food service companies. They also cause a significant diversion of resources at local and state health departments.

Q: How many cases of disease are caused by foodborne hepatitis A outbreaks compared to *E. coli*?

A: The following table shows data published by the CDC[3] for the years 1988 through 1992:

	Outbreaks	Cases	Deaths	Number of Outbreaks in Restaurants or Delis
E. coli	11	244	0	2
Hepatitis A	43	2,109	6	23

The CDC pointed out that "the number of foodborne outbreaks reported by this surveillance system represents only a small proportion of those that occur." Many outbreaks are never reported.

Q: When a foodhandler is infected with hepatitis A, isn't that the fault of the restaurant?

A: No. There is nothing that a restaurant can do, short of vaccinating all foodhandlers, to prevent the appearance of an HAV-infected foodhandler. Hepatitis A infections are acquired out in the community, not in the restaurant. Usually, the restaurant first learns of the infection when the employee shows up to work with symptoms of hepatitis A.

Q: Why doesn't the restaurant industry just vaccinate all their foodhandlers? That would take care of the problem.

A: Vaccination of all foodhandlers is not currently practical. Because of high personnel turnover in the industry, the cost of universal vaccination would be prohibitive. Some restaurants are now vaccinating their workers in areas where hepatitis A outbreaks are occurring.

Q: Why are government funds needed for foodborne hepatitis A?

A: For most of the same reasons cited by the President in his food safety initiative for other pathogens: surveillance, coordination, education, risk assessment, and research.

---

[3] Centers for Disease Control and Prevention. Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992. CDC Surveillance Summaries, October 25, 1996. MMWR 1996;45(No. SS-5).

Proposal to Include Hepatitis A in the President's Food Safety Initiative

Background: Hepatitis A is an infectious disease of the liver caused by the hepatitis A virus (HAV). The virus is transmitted through fecal contamination. The federal Centers for Disease Control estimates that 130,000 infections occurred in 1994 in the U.S., of which 80,000 included clinical symptoms such as jaundice (yellowing of the eyes and skin) lasting 7 to 10 days, nausea, vomiting, and exhaustion, among others.[1]

Hepatitis A is the most commonly reported viral source of foodborne outbreaks in the United States (Norwalk virus outbreaks may occur more frequently but are less likely to be reported).[2] The disease is costly in terms of work loss and medical expenses. The average patient with hepatitis A loses 12 to 27 days of work.[3] Complete clinical and biochemical recovery takes one to two months,[4] and patients routinely report weakness and easy fatigability for up to three months. Up to 15% of patients have prolonged or relapsing disease lasting several months, and 10% of cases are hospitalized. The overall fatality rate is about 0.2%, but it rises quickly in older persons, reaching above 3% in person age 50 and above.[5] The death rate is also elevated in persons with chronic liver disease. The average cost per adult case is $1,817-$2,459 (1990-91 dollars).[6]

Most cases of hepatitis A in the U.S. occur as the result of direct person-to-person transmission, usually as part of a community-wide outbreak. However, **every year a few hundred to a few thousand persons contract hepatitis A through contaminated food.** This occurs when a foodhandler, infected with HAV, inadvertently contaminates food that is later eaten by patrons of a restaurant or other food service operation. Epidemics of hepatitis A traced to contaminated food occur about 6-12 times per year in the U.S., with a few dozen to a few hundred people infected in each epidemic.[7]

Foodborne epidemics of hepatitis A are expensive for the food service industry. In one recent epidemic in Denver caused by an infected worker at a catering company, the company nearly went bankrupt after revenue losses of $750,000.[8] In order to cause problems, however, HAV need not actually transmit to patrons. The mere discovery of an HAV-infected foodhandler in a restaurant is enough to create expensive disruptions for the restaurant and for the local health department. The infected employee must be evaluated by health department personnel, who may recommend that all patrons of the restaurant receive a protective injection of immune globulin (a human-serum-derived product that provides temporary protection against hepatitis A). This is usually done through announcements in the news media. Public announcements cause immediate and severe business losses for the restaurant – up to 80% of sales may be lost for weeks or months.

---

[1] Centers for Disease Control and Prevention. Prevention of hepatitis A through active or passive immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1996;45(No. RR-15).

[2] Centers for Disease Control and Prevention. Surveillance for foodborne-disease outbreaks – United States, 1988-1992. October 25, 1996. MMWR 1996;45(No. SS-5).

[3] See footnote 1.

[4] Dienstag JL, Isselbacher KJ. Acute Hepatitis. In Isselbacher KJ et al., eds. Harrison's Principles of Internal Medicine, 13th ed. McGraw-Hill, Inc., 1994.

[5] Hepatitis Surveillance Report No. 56. Atlanta: Centers for Disease Control and Prevention, 1995.

[6] See footnote 1.

[7] See footnote 2.

[8] Dalton CB, Haddix A, Hoffman RE, Mast EE. The cost of a food-borne outbreak of hepatitis A in Denver, Colo. Arch Intern Med 1996;156:1013-1016.

Foodborne epidemics of hepatitis A are also expensive for the nation's state and local health departments. Food handler evaluations and public announcements place heavy demands on personnel and budgets. In the Denver example above, disease control costs were $689,000. Immunoglobulin was given to 16,000 Denver residents at a cost of $450,000.

Until the advent of hepatitis A vaccine in 1995, a restaurant could do little to protect against such losses. HAV-infected foodhandlers acquire their infections not in the restaurant, but out in the local community. The restaurant first learns of the infection when the foodhandler shows up at work with symptoms of hepatitis. Handwashing programs and food protection procedures do nothing to prevent the appearance of infected foodhandlers in restaurants, although they are crucial public health measures for other reasons.

The first vaccine against hepatitis A was licensed in February 1995. Two such vaccines are now on the market. They offer safe and effective protection against hepatitis A. Universal vaccination of foodhandlers in the U.S. would eliminate hepatitis A as a significant food pathogen, but such a program is not economically practical.

Points in favor of adding hepatitis A to the President's Initiative:

- **Hepatitis A causes more deaths and severe disease than Norwalk virus, which is listed specifically in the Discussion Draft.** In the "Discussion Draft and Current Thinking" document circulated at the recent March 5th meeting, Norwalk virus is included on a list of "foodborne hazards of particular public health concern," which "would be targeted for immediate attention by this initiative." Hepatitis A should be added to this list and specifically discussed in the draft. Hepatitis A is the most commonly reported viral source of foodborne outbreaks in the United States. Norwalk virus outbreaks may occur more frequently but are less likely to be reported. In addition, the disease caused by hepatitis A is significantly more severe than Norwalk illness. Norwalk virus causes a mild to moderate diarrheal illness lasting 2 to 3 days. According to the Discussion Draft, of an estimated 181,000 cases of Norwalk illness occurring annually, there are "no known associated deaths." In contrast, hepatitis A illness lasts several weeks to several months. In 1993, the number of deaths due to hepatitis A reported to CDC was 150, and this is known to be an under-count due to inadequate reporting.
- **Hepatitis A is the only vaccine preventable foodborne disease.** None of the foodborne illnesses listed in the Discussion Draft are vaccine-preventable, although some will become vaccine-preventable in the 21st century. Hepatitis A is now fully preventable by safe and effective vaccines. Including a vaccine-preventable foodborne illness as part of the Initiative would provide an opportunity to learn valuable lessons about the application of vaccines to the nation's food safety problem. These lessons could prove invaluable as new vaccines against other foodborne agents become available in the 21st century.
- **Control of hepatitis A-related foodborne illness provides a perfect opportunity for public-private partnerships.** As the President said in his January 25th speech, he wants Secretaries Glickman and Shalala and Administrator Browner "to focus on what sort of partnerships the government can form with the private sector to meet our goals." Hepatitis A is the largest viral foodborne disease problem facing the food service industry, causing multi-million dollar losses each year. FDA, CDC, EPA and USDA could provide valuable assistance to the food service industry in researching and strategizing how to control hepatitis A in food handlers. Vaccine manufacturers could also participate in this work.

- **The Initiative's goal to strengthen surveillance of foodborne illnesses at the State level fits well with hepatitis A control.** As noted above, hepatitis A-infected food handlers come not from restaurants, but from the community. Yet, surveillance for hepatitis A in the community is insensitive – detecting only about 30% to 40% of clinical cases. Resources provided by the Initiative ($1 million plus) could be used by CDC and the States to improve viral hepatitis surveillance, which would help predict where hepatitis A will appear in food service operations. This should include the possibility of laboratory-based surveillance, whereby laboratories would report cases of hepatitis A directly to the appropriate health authority.
- **Further study of hepatitis A is needed to determine what proportion of hepatitis A is attributable to foodborne transmission.** Control of foodborne hepatitis A should be based on scientific research. This research should be done by CDC through earmarked resources of $1 million.

Q & A on a Proposal to Include Hepatitis A in the President's Food Safety Initiative

Q: Is foodborne hepatitis A an important problem?

A: Yes, especially economically. Foodhandlers infected with hepatitis A can cause significant economic losses for food service companies. They also cause a significant diversion of resources at local and state health departments.

Q: How many cases of disease are caused by foodborne hepatitis A outbreaks compared to *E. coli*?

A: The following table shows data published by the CDC[9] for the years 1988 through 1992:

	Outbreaks	Cases	Deaths	Number of Outbreaks in Restaurants or Delis
E. coli	11	244	0	2
Hepatitis A	43	2,109	6	23

The CDC pointed out that "the number of foodborne outbreaks reported by this surveillance system represents only a small proportion of those that occur." Many outbreaks are never reported. Additionally, important outbreaks of *E. coli* occurred after 1992, the end-date of this report, including two lethal outbreaks related to undercooked hamburger meat and contaminated apple juice.

Q: When a foodhandler is infected with hepatitis A, isn't that the fault of the restaurant?

A: No. There is nothing that a restaurant can do, short of vaccinating all foodhandlers, to prevent the appearance of an HAV-infected foodhandler. Hepatitis A infections are acquired out in the community, not in the restaurant. Usually, the restaurant first learns of the infection when the employee shows up to work with symptoms of hepatitis A.

Q: Why doesn't the restaurant industry just vaccinate all their foodhandlers? That would take care of the problem.

A: It is not economically practical to vaccinate all 9,000,000 persons who work in U.S. eating establishments. Because of high personnel turnover in the industry, the cost of universal vaccination would be prohibitive. Some restaurants are now vaccinating their workers in areas where hepatitis A outbreaks are occurring.

---

[9] See footnote 2.

Outbreak watch

State, location	Type of outbreak	Approximate onset date	Incidence	Age profile	Comments
Alabama, Mobile County	Hepatitis A — communitywide	Late 1994	36 cases in 1995. 72 cases in 1996 (to Oct. 9)	Children and adults	The outbreak is diminishing. Prior to this outbreak, Mobile had not had a significant number of hepatitis A cases since 1981. Cases have also occurred in Baldwin County, which is adjacent to Mobile County on the coast. State and county are using IG in case contacts.
Arkansas, central and northwest	Hepatitis A — communitywide	Mar. 1995	663 cases in 1995. 368 cases in 1996 (to Oct. 1). Previous 5-year average was about 270	Young adults	Highest incidence rate currently is in Benton County, in the extreme northwest on the border of Oklahoma and Missouri (1996 cases = 84). State is using IG in case contacts, and has recommended IG in two infected foodhandler situations.
California, Kern County	Hepatitis A — communitywide	Hepatitis A has been endemic in recent years, but rate jumped in 1992-1995.	257 county cases in 1995. 134 cases in 1996 (to Oct. 5) (pop. approx. 545,000)	45% of cases occurred in children under age 19	In two highly-affected towns, Taft and Ridgecrest, state, county and school health authorities instituted aggressive vaccination programs in the schools beginning in January 1996. Coverage rates exceeded 80%. Over 3,500 doses were administered. The outbreak has since waned, although it had begun to diminish in 1995.
California, San Francisco	Hepatitis A — communitywide	Hepatitis A rate has been high for the past two years.	450 cases for 1995. 412 cases for 1996 (to Oct.5)	Initially young men. Now women and a few children	Previous outbreaks have occurred in the gay community. The current outbreak does not appear to be based in gay men. City officials have emphasized restaurant inspections and handwashing.
California, Shasta County	Hepatitis A — communitywide	Late 1994	567 county cases in 1995 (pop. approx. 173,000). 97 cases in 1996 (to Sept. 30)	Mostly adults. 45% of cases are in 20-34 age group	County-run hepatitis A vaccination program gave about 11,000 doses, mostly to children age 2-18.
Indiana, Vanderburgh County	Hepatitis A — communitywide	Summer 1995	26 cases in 1995. 45 cases in 1996 (to Aug. 31) (pop. 165,000)	Adults	Young white adults. Authorities are using IG for household and sexual contacts. 924 doses of IG given in 1995, approx. 200 in 1996.
Iowa, Sioux City	Hepatitis A — communitywide	Nov. 1995	329 cases since onset of outbreak in Nov. (pop. approx. 120,000)	Mainly adults age 20-40, although cases are slowly shifting into lower age groups	Young white adults. Epidemic was initially associated with use of methamphetamine and with lower socio-economic status, but has now affected general population. District health department is using IG in case contacts. CDC sent an EIS Officer to investigate.
Kansas, Crawford and Cherokee Counties	Hepatitis A — communitywide	Summer 1996	70 cases in 1996 (to Sept. 1)	Young adults	Outbreak is waning in the past two months. State and local health departments have been giving IG to household contacts.
Mississippi, Leflore, Tunica and Union Counties	Hepatitis A — communitywide	End of 1995	40-50 outbreak-associated cases (pop. approx. 20,000)	Mainly older adolescents and early 20s	The outbreak is apparently over. The State Health Department began a vaccination program in May, using geographical targeting into high-incidence areas of the county, especially in the city of Greenwood. 7,634 persons (2-dose regimen) were vaccinated. Earlier, the Department had used vaccine to control an outbreak in Tunica County, where a coverage rate of 60-70% was attained in persons < 35 years. Persons in Union County were also vaccinated.
Missouri, southwestern counties	Hepatitis A — communitywide	Early 1996	880 cases statewide in 1996 (to Sept.1); 274 cases in affected southwestern counties, compared to 68 in 1995	Young adults	Outbreak in the southwestern counties is associated with illegal drug use (heroin, methamphetamine, marijuana). State has spent over $20,000 on IG in 1996 to date.
North Dakota, Turtle Mountain Chippewa Reservation	Hepatitis A — communitywide	Spring 1996	60 cases in 1996 (to Sept. 1)	Children age 0-14	Outbreak accelerated in July. Indian Health Service is now in the process of vaccinating 3,500 children ages 2-12 and 1,000 adults. The Reservation has experienced periodic outbreaks.
Ohio, Cuyahoga, Lorraine and Clark Counties	Hepatitis A — communitywide	Cuyahoga County outbreak began in 1993. Others started in 1995.	In 1995, 1,187 cases occurred in Cuyahoga County, 105 in Lorraine County, and 118 in Clark County. In 1996 (to September 27), 299 cases occurred in Cuyahoga, 7 in Lorraine, and 35 in Clark	In the Cuyahoga outbreak, peak incidence is in the mid-20s	All outbreaks are rapidly diminishing.
Ohio, Allen County	Hepatitis B	Mar. 1996	10 cases met serologic or clinical case definition	Elderly residents of a nursing home, all diabetic	The State Health Department believes that transmission was caused by re-use of a glucometer that utilized a spring-loaded needle to stick patients' fingers for glucose determinations.
Oklahoma, eastern	Hepatitis A — communitywide	Late 1994	In 1995, over 1,400 cases statewide (46/100,000). 1,785 cases in 1996 (to Sept. 30)	60% of cases are 20-40 year olds	This is the largest outbreak in Oklahoma history. Strong association with illegal drug use. 45% of cases admit to drug use, but local nurses say a higher percentage, up to 70%, are drug abuse-associated. Methamphetamine is mentioned most often. State is using IG aggressively — over 14,000 doses administered this year.
Oregon, several counties; highest incidence in Douglas and Linn Counties	Hepatitis A — communitywide	Mid 1994	In 1995, 2,956 cases were reported (94/100,000). In 1996, approximately 550 cases (to mid-Sept.)	Mostly adults, age 15-40	This very large outbreak was associated with adult drug use — mostly methamphetamine and marijuana. Monthly case incidence has now returned to inter-epidemic levels. The Oregon State Health Department conducted a trial of hepatitis A vaccine among social contacts of cases, including large case-control and seroprevalence studies. The results are still under analysis.
Texas, San Antonio	Hepatitis A — communitywide	1996	The city experiences a high baseline incidence of hepatitis A. In 1996, a small outbreak (about 70 cases) began in gay men	Young gay men	The San Antonio health department had begun an education program aimed at the gay community.
South Dakota, Cheyenne River, Lower Brule, and Rosebud Reservations	Hepatitis A — communitywide	1995	Small number of cases on three reservations	Mainly children 0-9	Indian Health Service has vaccinated children in Cheyenne River, Lower Brule, and Rosebud, which appears to have aborted outbreaks there. Vaccination coverage rates reached 80-90%. IHS hopes to begin vaccinations in Pine Ridge soon, pending tribe approval.
Tennessee, Memphis	Hepatitis A — communitywide	July 1994	Approximately 2,000 outbreak-associated cases since July 1994	Classic bimodal, with peak in 0-9 and 20-29 age groups	This is the largest outbreak ever recorded in Memphis. The incidence rate decreased significantly in 1996 (see *HCR*, spring 1996). Over 35,000 children were vaccinated.
Utah, Salt Lake City	Hepatitis A — communitywide	Late Dec. 1994	In 1995, 558 cases were reported. In 1996, 510 (to mid. Oct.). Annualized rate is ne 81 per 100,000 population	Young adults	This large outbreak began in 1995 as restaurant-associated, followed by a communitywide outbreak in adults. The outbreak has not and is associated with heroin and methamphetamine use. The county health department is conducting a study on risk factors for foodborne hepatitis A. It is also designing a case-control study to study the drug abuse association.

Note: Outbreak Watch lists larger acute viral hepatitis outbreaks in the U.S. that come to the attention of the editor. Data are obtained from public health

HEPATITIS A RESTAURANT OUTBREAKS MAKE NEWS...

Restaurant	Date	City	State	Media Impact	# Of People Affected
Arby's (C)	7/96	Shawnee	OK	South Dakota paper reports at-risk dates and health department information for Oklahoma Arby's. Sandwiches are linked to outbreak.	No number listed.
Bartolino's (I)	10/96	St. Louis	MO	Front page article. Restaurant closed for a week. Outbreak among food handlers.	Outbreak among restaurant staff.
Boathouse Restaurant (I)	5/96	Mason County	WA	Local paper reports at-risk dates and health department information. Infected food handler may have exposed patrons to hepatitis A.	No number listed.
Coastal Mart (C)	8/96	Milton	PA	Store lost $3,000 in business. Infected sandwich maker may have exposed customers to hepatitis A. Article ran in local paper.	20 customers receive IG.
Columbia Best Western Hotel Haymarket Restaurant and Bar (C)	8/96	Columbia	MO	2 Missouri local papers reports at risk dates and health department information. Infected food handler may have infected patrons who consumed iced beverages.	Hundreds vaccinated with IG.
Dairy Bar (I)	8/96	Hillsboro	ND	At-risk dates and health department vaccine information reported in 2 local papers. Infected food handler may have spread hepatitis A.	No number listed.
Fort Smith Hardscrabble Country Club (I)	6/96	Fort Smith	AR	Local members voiced frustration that more information was not readily available from club or health department staff.	One-third of county's total cases attributed to country club staff.
Georgetown Subway Sandwiches and Salads (I)	8/96	Seattle	WA	Local paper reports at-risk dates and health department information. One infected food handler may have exposed 2,400 people to hepatitis A.	2,400 at risk.
Grub-Steak House (I)	6/96	Ft. Cobb	OK	Local paper reports at-risk dates and health department information. Uncooked foods cited as source.	No number listed.
Hillside Restaurant (I)	10/96	Rockaway Beach	MO	Article appeared same day as Bartolino's. Employee may have infected patrons with hepatitis A. Local paper states exposure dates which can or cannot be aided by vaccination.	No number listed.

C = chain I = independent

Restaurant	Date	City	State	Media Impact	# Of People Affected
International House of Pancakes (C)	7/96	Seattle	WA	Local paper reports at-risk dates and health department information. Infected food handler exposed patrons to hepatitis A.	No number listed.
Kentucky Fried Chicken (C)	8/96	Neosho	MO	Restaurant closed. Business dropped by 80% after media coverage. Worker had contracted hepatitis A. Owner leaves restaurant business.	250 received IG on first day of clinic.
Kmart/Little Caesars Pizza (C)	8/96	Flint	MI	Ran in Flint paper -- Pizza customers experiencing great delays in getting IG.	233 received IG.
McDonald's (C)	9/96	Miami Beach	FL	Infected worker produced articles in major Florida papers and stories in broadcast media for 3 days.	500 at risk 200 vaccinated with IG.
McDonald's (C)	10/96	Sullivan	MO	Restaurant spokesperson issued statement saying this "was an isolated case." Infected worker will not return to work until medical officials give him a clean bill of health.	No number listed.
Mostly Mexican (I)	8/96	Denver	CO	Major Denver paper listed dates of exposure risk (when infected employee may have exposed customers to hepatitis A) and 2 day clinic available for public.	No number listed.
Newport Steak and Seafood (I)	6/96	Newport	OR	Local paper reports at-risk dates (when infected employee may have exposed customers to hepatitis A) and health department information.	No number listed.
Odyssey Cruises (I)	7/96	Chicago	IL	Chef contracts hepatitis A. Ship ceases sailing.	50 crew members receive IG.
Olive Garden (C)	8/96	Indianapolis	IN	Article appeared in major Indianapolis paper. Ill worker sparks IG vaccination for restaurant employees.	30 restaurant employees received IG.
Olive Garden (C)	3/96	Raleigh	NC	Business noticeably lighter since hepatitis A outbreak was reported.	600 received vaccine IG and 500 more expected to receive IG.
Peaches 'N'Cream Restaurant (I)	7/96	Schenectady	NY	Health officials released health advisory through local paper for cookies bought on risk dates.	No number listed.
Penelope's West Restaurant (I)	9/96	Branson	MO	Articles in Arkansas, Illinois, Kansas, Missouri dated throughout month of September. Vaccination Clinics held in 4 counties. Food handler may have exposed tourists to hepatitis A.	800 at risk 1 diagnosed case.

C = chain I = independent

Restaurant	Date	City	State	Media Impact	# Of People Affected
Shoney's (C)	4/96 & 10/96	Tulsa	OK	13 articles appeared for 2 days. They were printed in Oklahoma, Florida, California, Georgia and Washington. Restaurant closed due to hepatitis A outbreak in food handler.	2,100 patrons exposed 2,900 IG vaccinations given at a cost of $35,000-$40,000.
Smith's Food and Drug (I)	4/96	Salt Lake City	UT	Local paper reports at risk dates (when employee may have exposed customers to hepatitis A) and health department information. Uncooked food is cited as source.	No number listed.
Sodbuster (I)	10/96	Twin Falls	ID	Articles in Washington D.C., major Idaho papers dated throughout month of September. Last article in October. Deli worker contracted hepatitis A. Business dropped 75% after Health District announcement.	500 IG vaccinations given.
Sonic Drive-In (I)	8/96	Longview	TX	Restaurant closed after an employee contracted hepatitis A, but company spokesperson stated they will re-open.	No number listed.
Stormy Harbor Restaurant (I)	6/96	Provincetown	MA	Run in Boston Globe. At-risk dates listed (food handler contracted hepatitis A).	No number listed.
Waffle House (C)	7/96	Bentonville	AR	Local paper reports at-risk dates (infected food handler exposed patrons to hepatitis A) and health department information.	No number listed.
Waffle House (C)	9/96	Springfield	MO	Employee found infected with hepatitis A. Articles in Arkansas, Washington D.C. dated throughout month of September. By Mid-September only 12 doses of IG remained available in the county.	350 at risk 35 diagnosed cases in area more expected. Some employees are past the date where IG can be of use.
Winn Dixie (food court) (C)	10/96	Clermont	FL	Store offers free vaccinations after supermarket employee contracted hepatitis A.	1 diagnosed case.
Wright's Steak and Lobster House (I)	6/96	Chickasha	OK	Local paper reports at-risk dates and health department information.	No number listed.

C = chain I = independent

HEPATITIS FOUNDATION
INTERNATIONAL

March 7, 1997

The Honorable Joe Skeen
United States House of Representatives
2367 Rayburn House Office Building
Washington, DC 20515

Dear Representative Skeen:

On behalf of the Hepatitis Foundation International (HFI), I am writing to you to urge Congress to amend President Clinton's food safety initiative to include measures to prevent the spread of hepatitis A virus via food, including education and training programs, food safety certification programs, improved reporting and surveillance, and hepatitis A vaccination targeted in outbreak areas such as New Mexico where there is a high baseline incidence of the disease due to the proximity to the Mexican border. Hepatitis A is a highly contagious and debilitating viral disease that attacks the liver.

Recently, St. Louis (Missouri Board of Alderman), took a pro-active approach to preventing hepatitis A by passing a hepatitis A control law that gained the full support of the St. Louis City Health Department. The ordinance directs the St. Louis Department of Health to provide and administer hepatitis A vaccine, at reasonable cost, to "proprietors and employees of restaurants, day care facilities and other entities deemed 'at-risk' by the Health Commissioner." This local initiative and innovative law should be used as a model for other localities faced with hepatitis A endemics and encouraged by the Federal government.

As you know, there is a hearing on March 12 before the Agriculture Appropriations Subcommittee, of which you are the Chairman, on the subject of the President's food safety initiative, we urge you to encourage that hepatitis A be included as a covered food-borne pathogen.

30 Sunrise Terrace, Cedar Grove, NJ 07009-1423 201-239-1035 Fax 201-857-5044

The statistics on hepatitis A are quite alarming. The Centers for Disease Control and Prevention (CDC) estimates that 130,000 infections occurred in the U.S., of which 80,000 included clinical symptoms such as jaundice (yellowing of the eyes and skin), nausea, vomiting, and exhaustion, among others. While the disease rarely kills, it is costly in terms of work loss and medical expenses. The average patient with hepatitis A loses, on average, 30 days of work. Ten percent of hepatitis A cases are hospitalized with the average cost per adult case ranging from $1,817 to 2,459. While there remains no specific treatment for the disease there are two, safe and highly effective vaccines currently available for protection against this highly debilitating disease.

In addition, national data indicate that Hispanics have a higher risk for the hepatitis A infection than non-hispanics. In a 1992 study, the CDC showed a national incidence rate of 17.6 per 100,000 in persons of Hispanic ethnicity, versus a rate of 7.5 per 100,000 in non-Hispanics. Hispanics are also over-represented in travel-related hepatitis A cases. In 1993, 47% of international travel-related hepatitis A cases reported to the CDC's Viral Hepatitis Surveillance Program occurred in Hispanics and among all the travel-related cases, 67% were associated with travel to Mexico and Central or South America.

During the past few years, a number of community-wide outbreaks have occurred here in the United States which have been attributed to contaminated food or transmission by infected food handlers. HFI has turned up hundreds of newsclips reporting on restaurant hepatitis A outbreaks. These outbreaks do not discriminate. We have newsclips reporting on hepatitis A outbreaks in the smallest of restaurants to the largest, including independent restaurants and national chains from Schenectady, New York, to Seattle, Washington. Food-borne epidemics of hepatitis A are expensive. In one recent epidemic in Denver, caused by an infected worker at a catering company, the company nearly went bankrupt after revenue losses of $750,000. The cost to the local health department was $689,000.

HFI was established to provide current information to the public, especially to those who have contracted one or more of several hepatitis viruses, and to increase awareness of viral hepatitis. We face new challenges every day involving food safety and thus require more research to determine the proper approach to controlling food-borne hepatitis A through education, surveillance, improved reporting, vaccination and other measures.

We urge you to express your interest in hepatitis A prevention when the Administration testifies next week. The health of individuals with hepatitis A and the future progress of hepatitis research are at stake.

Thank you for your attention to this important matter.

Sincerely,

Thelma King Thiel
Chairman and Chief
Executive Officer

ST. LOUIS HEPATITIS A CONTROL LAW

An ordinance pertaining to health care services, authorizing, and directing the Health Commissioner of the City of St. Louis to immunize proprieters and employees of restaurants, day care facilities and other entities deemed "at-risk" against hepatitis "A" providing reasonable fees for administration and delivery of said inoculations; authorizing and directing the Department of Health and Hospitals to issues certificates of voluntary compliance; and authorizing and directing the Comptroller to establish a special purpose account where said funds from said immunizations shall be placed to be used only for health services and containing an emergency clause.

BE IT ORDAINED BY THE CITY OF ST. LOUIS AS FOLLOWS:

SECTION ONE: The Health Commissioner is hereby authorized and directed to provide hepatitis "A" vaccinations to proprieters and employees of restaurants, day care facilities and other entities deemed "at-risk" by the Health Commissioner. The Department of Health and Hospitals shall make its facilities and staff available to provide immunizations. The Department of Health and Hospitals shall establish and collect reasonable fees for providing such services.

SECTION TWO: The Health Commissioner is further authorized and directed to issue to restaurants, day care facilities and other entities in voluntary compliance with this ordinance a certificate of compliance appropriate for public display. The Department of Health and Hospitals shall establish rules and regulations for a voluntary compliance program.

SECTION THREE: The Comptroller is hereby authorized and directed to establish a special purpose account where funds from said immunizations shall be placed and said funds shall only be used for the purchasing, delivery and maintenance of hepatitis "A" vaccines.

SECTION FOUR: Emergency Clause. This being an ordinance for the preservation of public peace, health and safety, it is hereby declared to be an emergency measure within the meaning of Sections 19 and 20 of Article IV of the Charter of the City of St. Louis and therefore this ordinance shall become effective immediately upon its passage and approval by the Mayor.

Hepatitis Vaccine,0893
Hepatitis vaccine gaining in popularity in food industry

BRANSON, Mo. (AP) Linn Smith watched warily for two years as a stubborn wave of hepatitis A washed across the Midwest, making its way toward Branson, where 60,000 tourists a day visit restaurants, ice cream stands and concession booths.

At the same time, she saw the needs of the U.S. military and a manufacturer's recall gobbling up the local supply of immune globulin or IG medicine used to stifle hepatitis infections in exposed people.

Ms. Smith, head of Branson's health department, had good reason to fear the potentially explosive effects of the contagious disease among food-service workers: Through 1996, cases in southwestern Missouri rose almost 400 percent over those in 1995, to 637 from 127. And everyone who comes in contact with a carrier should have a shot of immune globulin.

``I truthfully thought, `What am I going to do if I don't have any IG and they send me a war to fight?''' she said.

Late last year, she took up the only weapon she could find: a year-old vaccine gaining popularity across the country as other tourism-dependent communities consider mandatory immunization of food workers.

Hepatitis A, passed orally or through human waste, usually by people with poor personal hygiene, causes liver inflammation. Symptoms include fatigue, abdominal discomfort, vomiting, fever, dark urine and jaundice.

The disease runs in cycles, according to the Centers for Disease Control and Prevention, sticking to one region for three years or so, then backing off for a decade or more.

Although food workers make up less than 5 percent of hepatitis A cases, the greater worry is exposure. A single infected worker can create a logistical nightmare when authorities try to warn people who had contact with him, especially if they are tourists on the move.

And with the low supply and rising costs of immune globulin, Ms. Smith said preventing the illness rather than curing it becomes the paramount concern.

The hepatitis A vaccine gained federal approval last year. Unlike vaccines for polio and measles, however, the CDC does not recommend blanket inoculation because of the cost and because the disease responds to treatment.

In December, the CDC shifted slightly and began recommending the vaccine for food-service workers.

Ms. Smith's initiative in Branson was touted recently in the Food Protection Report, a monthly newsletter that monitors the activities of the CDC and the U.S. Food and Drug Administration and goes to thousands of health officials across the country.

``I don't know of any other jurisdiction in the country that's

taken the progressive step that Branson has taken in getting people immunized against hepatitis A,'' said Charles Felix, the newsletter's publisher. ``In that sense, it really is a model.''

The first shot of vaccine gives a person immunity for up to 10 years. A booster shot can make that immunity last a lifetime. Each shot of vaccine costs $40, more than double the immune globulin shots, but lifetime immunity would make the vaccine cheaper in the long run.

The price of immune globulin has soared in recent years. In 1990, a dose cost about 50 cents. It now runs about $18. Most of the increase has to do with supply and demand.

Immune globulin is now made in only two places the state health departments in Massachusetts and Michigan. A private company pulled its product from the shelves last year and declined to upgrade its process when federal officials changed manufacturing standards. Military activity in the Persian Gulf and Haiti had further depleted the supply.

Immune globulin shots contain antibodies taken from donors that provide temporary resistance to the disease. In contrast, the vaccine contains killed hepatitis A virus, which causes the body to create antibodies of its own and provides much longer-lasting protection.

Hoping to keep at bay an epidemic that would require large quantities of the immune globulin, health officials in St. Louis, Seattle and San Diego, as well as Branson, are considering making vaccines mandatory, beginning with food workers, Ms. Smith said.

``A contagious food worker has the very great opportunity if a lot of things go bad or are done wrong to infect or put at high risk a great number of people in a very short time,'' said Bill St. Gemme, the state health department's representative in southwestern Missouri.

That factor was not lost on Ken Roten, owner of the Branson Cafe. Roten paid $640 for shots for himself and his 15 employees, and has encouraged fellow restaurant owners to join the vaccination drive.

``It's not just dollars and cents,'' he said. ``It's a moral obligation.''

So far, 900 of the 4,000 food service workers in Branson have been immunized and that number was expected to rise quickly with a mobile vaccination center that arrived Thursday.

``I was really the first one in line,'' said Linda Bracy, kitchen manager at the Branson Cafe. ``I couldn't handle it if I made someone sick.''

Maxwell TECHNOLOGIES

THOMAS E. KELLY III
Vice President
Business Development

22900 Shaw Road
Sterling, VA 20166

Telephone: (703) 708-9634
Fax: (703) 708-9644
E-mail: tkelly@maxwell.com

Maxwell TECHNOLOGIES

February 27, 1997

Ms. Elizabeth Drye
Domestic Policy Council
Executive Office of the President
OEOB-222
Washington, DC 20500

Dear Ms. Drye:

As a member of the food processing industry, Maxwell Technologies, Inc., is very interested in supporting the President's Food Safety Initiative. We would like to actively participate in the process of developing and implementing policies and technologies designed to make our country's food supply the safest in the world.

Our Pure Pulse subsidiary has been working in partnership with the U.S. Army over the past few years, to develop a dual use food processing technology to increase food safety, yet retain fresh taste, nutrition and texture. The U.S. Army's interest is in higher quality, safer rations.

The technology (summarized in the attached presentation made at the FDA's recent fresh juice conference) works by passing pumpable foods through a 30 to 50 kV/cm electric field. This high power field kills vegetative bacteria in a few millionths of a second, without affecting nutritional or organoleptic properties, enzymes, color, or texture. In short, treated apple or orange juices are undistinguishable from fresh pressed or squeezed juices.

In summary, Maxwell would like to be included in the government's initiative to improve food safety. Please contact me at (703) 708-9634 and inform me as to how we can assist the government team in setting forth a game plan for developing the standards, procedures and technologies necessary to keep our food safe.

Sincerely,

Thomas E. Kelly, III
Vice President

cc: Eric Olsen, Dept. of Agriculture

Enclosures: a/s

22900 Shaw Rd., Suite 101-4, Sterling, VA 20166 Tel.: (703) 708-9634 Fax: (703) 708-9644

PUREPULSE TECHNOLOGIES

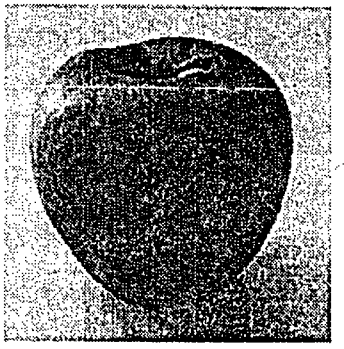
FDA PRESENTATION

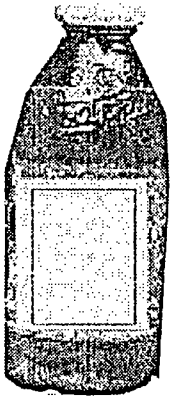
DECEMBER 17, 1996

WASHINGTON D.C.

PUREPULSE TECHNOLOGIES

The Fresh Juice Dilemma





- Fresh juice: excellent taste, nutrients

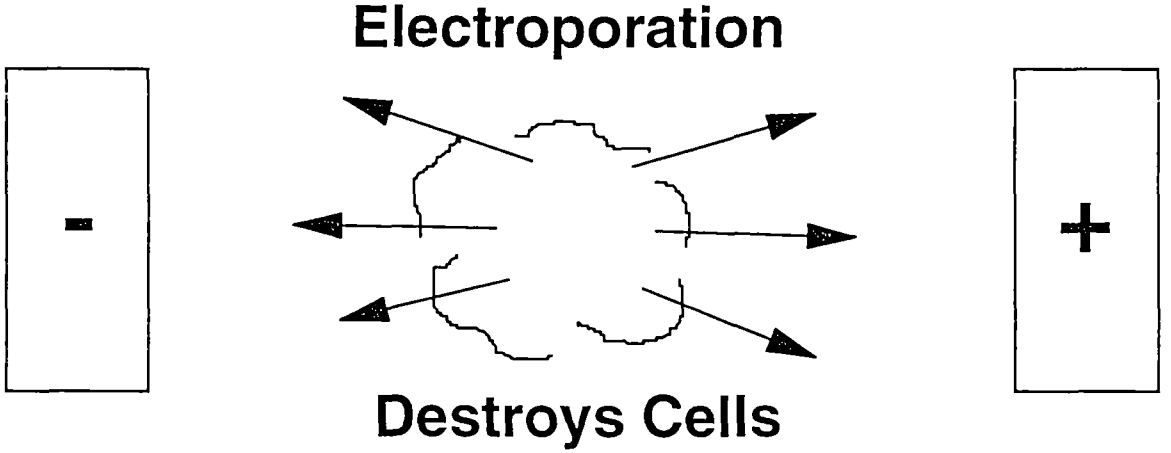
  But: Potential safety issues and short shelf life

- Pasteurized juice: Longer shelf life and safety

  But: Poorer quality

PUREPULSE TECHNOLOGIES

CoolPure Solves the Fresh Juice Dilemma



- Short pulses of electrical energy (millionths of a second)
- Kills vegetative microorganisms very effectively
- No heat damage to product

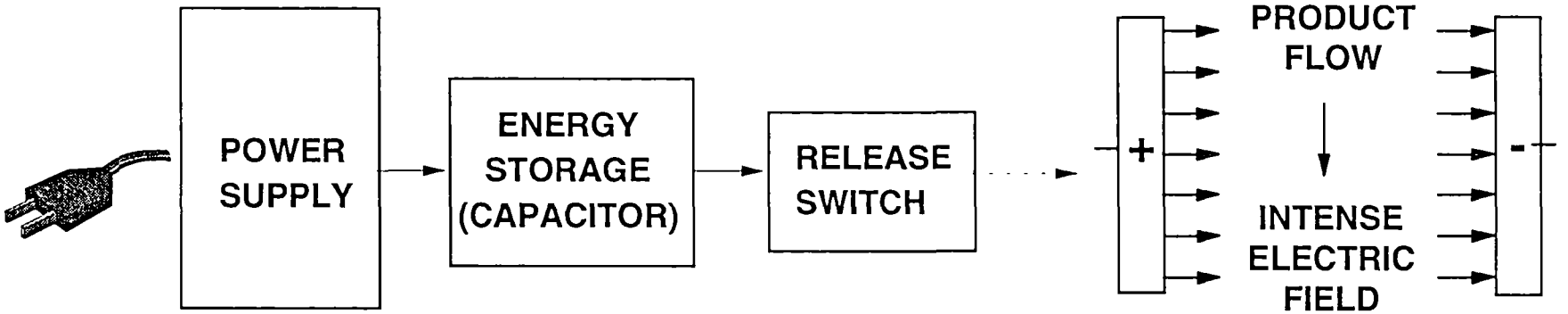
Provides fresh juice quality with safety and longer shelf life

PUREPULSE TECHNOLOGIES

The *CoolPure* Process

PULSED ENERGY SOURCE

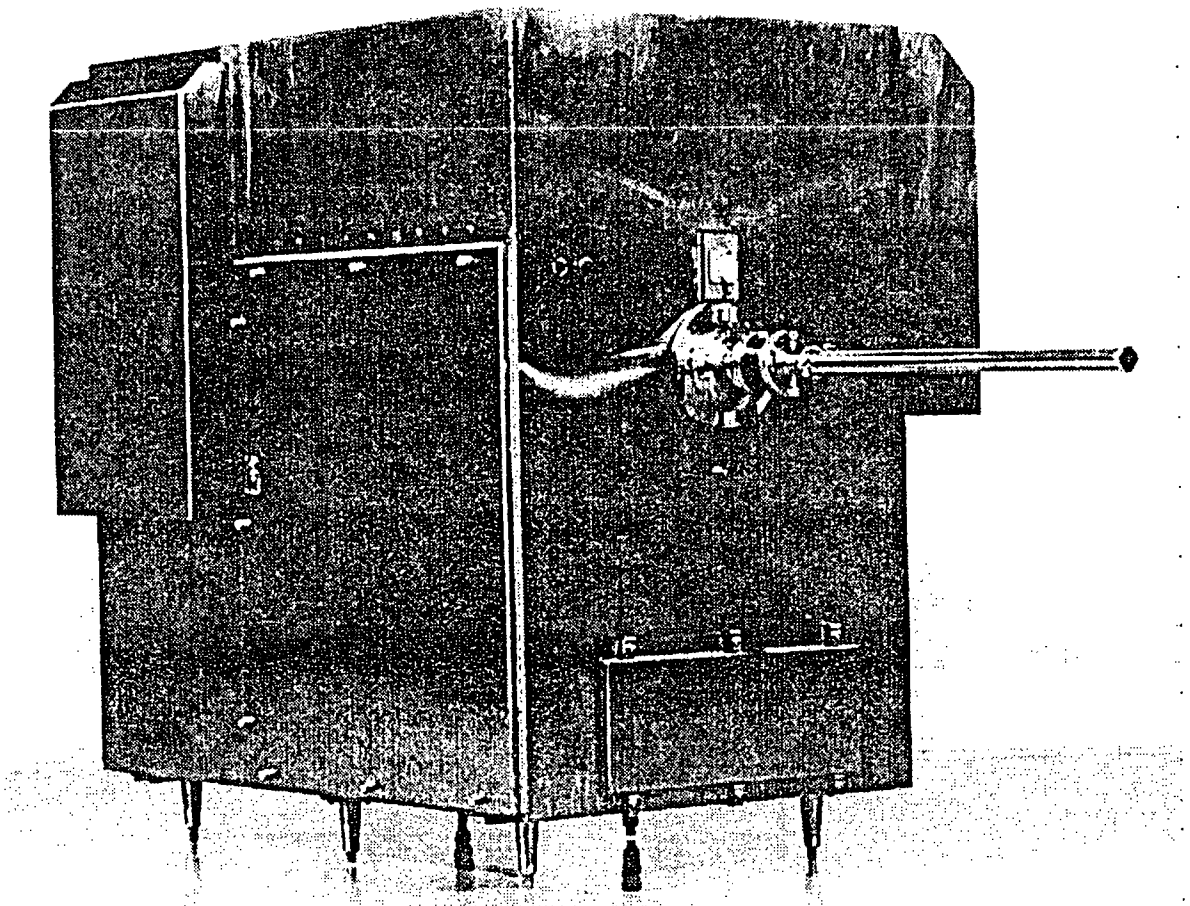
APPLICATION OF PULSED ENERGY
CoolPure



CONVENTIONAL
AC POWER

PUREPULSE TECHNOLOGIES

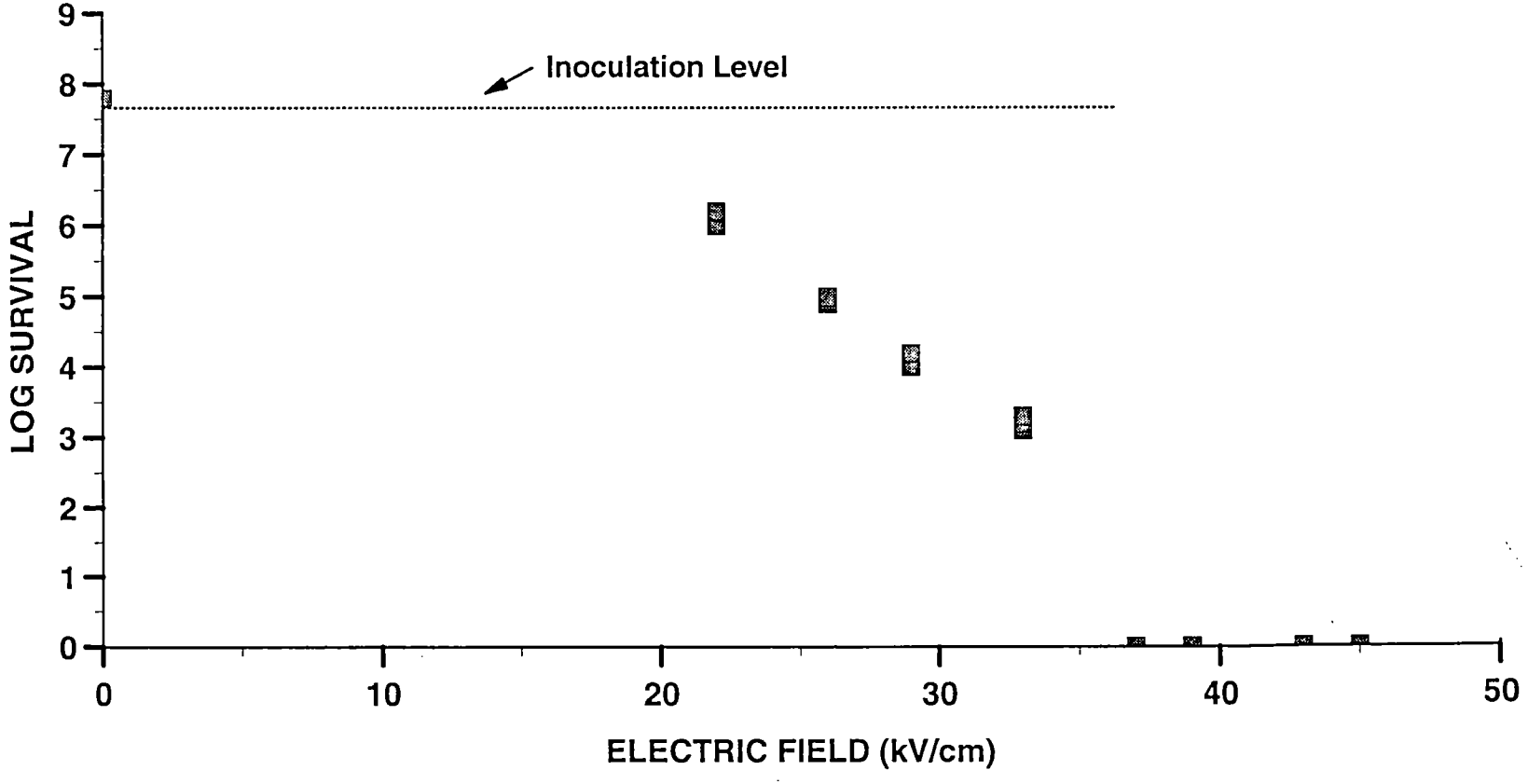
CoolPure Equipment



300 liter to 6000 liter per hr. systems in operation

PUREPULSE TECHNOLOGIES

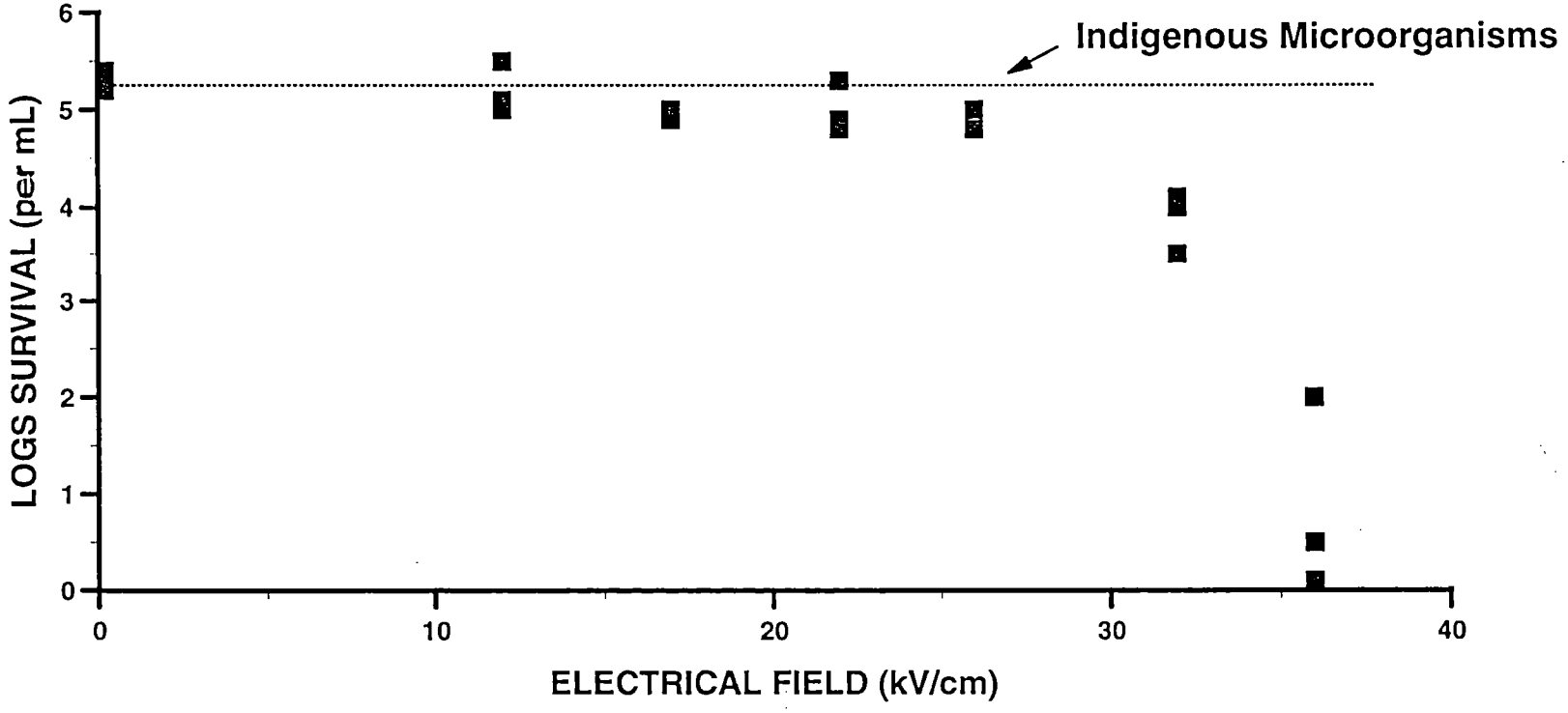
CoolPure Kills E. Coli in Buffer Solution



PUREPULSE TECHNOLOGIES

CoolPure Kills Microorganisms in Fresh Orange Juice

Treated juice tastes like fresh squeezed



PUREPULSE TECHNOLOGIES

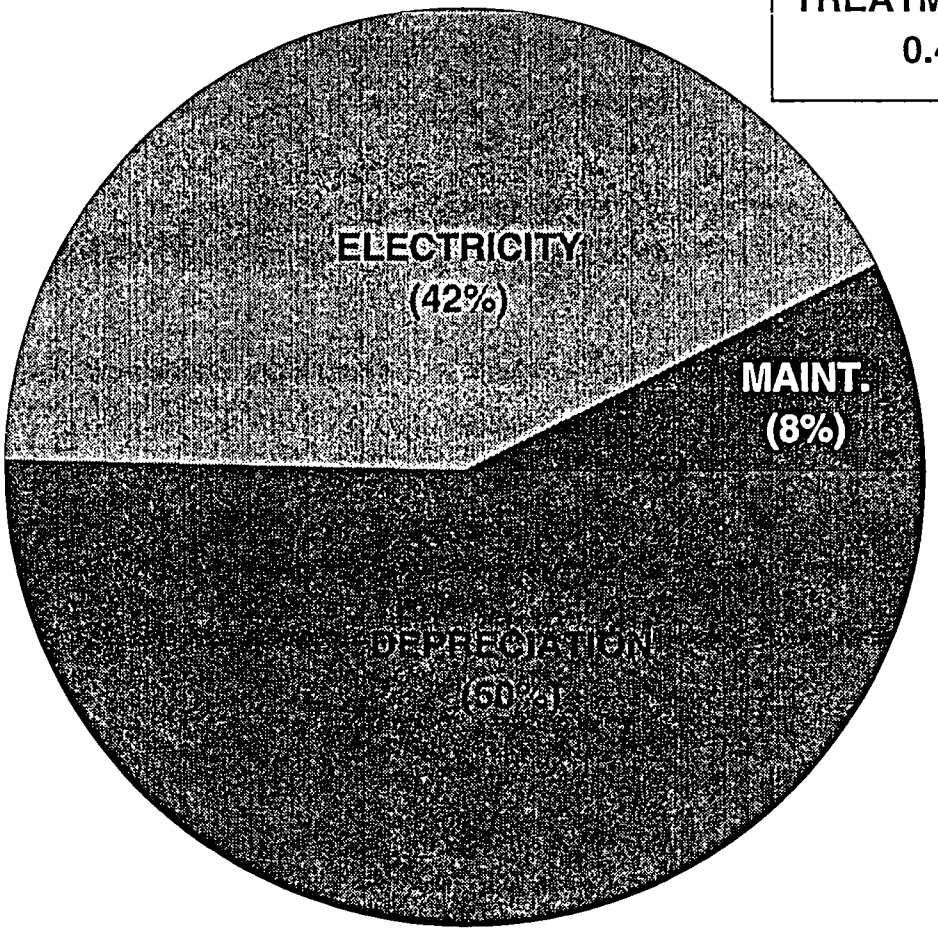
No Product Changes

- No Vitamin C change in orange juice
- No effects on complex composition of milk
- No change in enzyme activity
- Taste panelists unable to distinguish treated from fresh apple and orange juices
- Review by FDA -- "Letter of No Objection" received

PUREPULSE TECHNOLOGIES

CoolPure ECONOMICS ARE FAVORABLE

TREATMENT COST IS LESS THAN 0.4 CENTS PER LITER



PUREPULSE TECHNOLOGIES

CoolPure Produces Safe, Fresh Quality Juices

- Fresh juice taste and nutrients
- High microbial kill
- Safe juice products
- Better shelf life than fresh juice
- Economics are favorable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 12, 1991

SEAFOOD SAFETY

The purpose of this paper is to briefly summarize what is known and not known about the safety of seafood. Overall, seafood is a very safe source of muscle protein. The primary exception is molluscan shellfish when consumed raw or partially cooked, and the risk of illness dissipates when these products are adequately cooked. Other known health risks with seafood tend to focus on a limited number of species and geographic regions.

No food will ever be completely risk free. Fortunately, for seafood, the overwhelming majority of illnesses that are known to occur are mild and of short duration. As with most foods, however, a small fraction of illnesses can be severe, especially among individuals with severe liver disease such as cirrhosis, or severe iron metabolism disorders such as hemochromatosis.

The Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition, in close cooperation with the Centers for Disease Control (CDC), has recently updated an assessment of risk for seafood it performed last year, based on the latest available data. The updated assessment shows the following: (a) one illness per approximately 1,000 servings for molluscan shellfish when eaten raw or partially cooked; (b) one illness per approximately 2,000,000 servings for seafood minus molluscan shellfish when eaten raw or partially cooked; (c) for comparison purposes, one illness per approximately 25,000 servings for chicken. (The original assessment of risk also estimated one illness per 250,000 servings for all seafood, including molluscan shellfish when eaten raw or partially cooked; this figure is currently being recalculated but is not expected to change significantly.)

FDA's assessment of risk is one of the two primary sources of data on the safety of seafood. The other is the reporting system on foodborne illnesses maintained by CDC. CDC's system collects reports submitted to it by state and local health authorities. Many foodborne illnesses, however, go unreported to CDC. Moreover, the rates of underreporting vary depending on the type of food and the nature of the disease symptoms. For these and other reasons relating to the fact that "outbreaks" of illness, rather than individual illnesses, are primarily reported to CDC, (as discussed briefly below), the Director of CDC has publicly stated that CDC data alone cannot provide a true picture of relative risk among different types of foods and that an assessment of risk such as that performed by FDA must be relied upon to fill in the gaps.

This is an important point, because the picture provided by the CDC data alone is in startling contrast to that provided by the assessment of risk. Without the necessary compensation provided by the assessment of risk, the CDC data appears to show seafood as being "25 times riskier than beef and 16 times riskier than poultry." The use of these figures in this manner has no scientific basis. Nonetheless, these figures continue to be reported in the media and elsewhere even though they are not supported by CDC or by the recent report of the National Academy of Sciences on seafood safety.

As indicated above, another reason why the CDC data appears to show an extreme risk for seafood compared to those for beef and poultry is the fact that "outbreak," rather than individual cases, tend to be reported. An "outbreak" is two or more illnesses from a single source. Because the number of actual illnesses within an "outbreak" can vary significantly, a comparison of CDC's outbreak data for different types of foods can produce a highly misleading picture about the actual number of individual illnesses that are attributable to each food. Comparing numbers of individual illnesses within the outbreaks can provide a more accurate picture, as CDC has itself pointed out, but such a comparison still does not compensate for variations in rates of underreporting and certain other factors that require an assessment of risk to sort out. Most importantly, CDC data alone cannot account for sporadic illnesses, which CDC and the public health community feel comprise that vast majority of foodborne illness.

Approximately 85 percent of seafood related illnesses are estimated to derive from the consumption of raw molluscan shellfish, even though these products represent a very small fraction of seafood consumed in this country. Of the remaining 15 percent, the most frequent source of illness appears to be from ciguatoxins and scombrotoxins, both of which are unique to seafood. Fortunately, these toxins occur in relatively few types of fish that are consumed in the United States. Ciguatera is caused by certain microorganisms unique to the tropical marine environment that can impart toxins into the flesh of certain reef dwelling, predatory fish, such as barracuda, red snapper, amberjack and grouper. The overwhelming preponderance of cases reported as ciguatera poisoning (roughly 80 reported cases per year but FDA estimates that the real number is somewhere around 3,000) occur in home settings on lands adjacent to waters with tropical reefs, strongly suggesting that sport and subsistence fishing play a major role in the transmission of ciguatoxins to humans.

Scombroid poisoning (again, FDA estimates that the actual number of cases per year is approximately 5-6,000) derives from certain species of fish, primarily tuna, mahi-mahi and bluefish, that

have not been sufficiently iced somewhere between catch and table. It is completely preventable.

The three principal problems with seafood discussed here--raw molluscan shellfish, ciguatoxins and scombrotoxins--continue to be a major focus of attention within FDA's seafood safety program. The key to safe shellfish is water quality. FDA's research program into better "indicators" of water quality is state-of-the-art, and the National Oceanic and Atmospheric Administration of the Department of Commerce is funding a "National Indicator Study" being conducted by a consortium of universities. FDA also hopes to be able to field test an advanced detection test for ciguatoxins in the near future. The eradication of scombrotoxins through adequate icing from catch to home or restaurant is an FDA priority.

It is true, as the National Academy of Sciences recently noted, that there are some knowledge gaps relating to seafood safety, especially with regard to whether low levels of various chemicals are accumulating in some seafoods and whether there are long term health consequences as a result. The NAS is correct that further research is needed in these areas.

THE VICTIMS THAT GOT AWAY: INEFFECTIVE FEDERAL SURVEILLANCE OF SEAFOOD-BORNE ILLNESS

The exact number of seafood victims nationwide continues to remain a mystery as a result of the inadequacy of the federal disease surveillance system. At least half of the individual victims documented in this report, for example, were never reported as having seafood illnesses to the Centers for Disease Control.

Underreporting of seafood-borne illness is widespread throughout the country's state public health agencies. Since federal public health agencies, such as CDC and FDA, base their assessments of the extent of seafood-borne illness on officially reported cases from state or local health departments, such reporting failures inevitably lead to massive underestimates of the actual incidence of seafood illnesses. This serious deficiency in public health surveillance and risk assessment was confirmed by Public Voice's recent survey of 49 state health departments and the District of Columbia.

Specifically, Public Voice found the following barriers to the reporting of seafood-borne illnesses:

- The food source causing a food-borne illness usually is not defined. Health officials in 66 percent of the states said that the food responsible for an illness could not be detected at least half the time.

- Most illnesses that are primarily seafood-borne are not required to be reported. Only two states have ciguatera on their list of reportable illnesses; two listed scombroid poisoning; 14 list vibrio-related illnesses; and none list Norwalk viruses. None of these illnesses are on the Center for Disease Control's list of nationally notifiable diseases.

- Doctors often don't diagnose or report seafood-borne illness to state health departments. Nearly 70 percent of state health departments said that doctors do not realize that seafood-borne illnesses should be reported. Eighty-three percent said that doctors do not diagnose seafood-borne illnesses.

- Forty-two pereent of state health departments identified lack of enforcement of reporting requirements and 51 percent identified underfunding of their departments as barriers to complete reporting of food-borne illnesses.

The absence of a comprehensive, reliable surveillance system for seafood-borne illness leaves consumers at greater risk of being victimized by contaminated seafood. Without complete information about the actual incidence of seafood-borne illnesses, federal regulators are unable to accurately assess the risk to consumers and they cannot effectively target their consumer protection activities. Moreover, the federal government's failure to account for the victims of seafood-borne illnesses invariably leaves the public in the dark about the extent of the problem and prevents federal regulators from being held fully accountable for the inadequacies of their public health programs.

Example of a label for an unpasteurized apple juice product:

UNPASTEURIZED

Caution: This product is unpasteurized and may contain harmful bacteria known to cause illness and death. Children, the elderly, and persons with weakened immune systems should avoid this product. Consumers can protect themselves by heating this product to 160°F before serving it.

---

* *Another word could be substituted for "unpasteurized" if FDA determines the word conveys the risk of the product to consumers more effectively.*

AMERICAN SOCIETY FOR MICROBIOLOGY

Public and Scientific Affairs Board
1325 MASSACHUSETTS AVE., N.W.
WASHINGTON, D.C. 20005-4171
TEL: (202) 737-3600
FAX: (202) 942-9335

▸▸FACSIMILE TRANSMISSION◂◂

To: Elizabeth Drye

Date: 3/31/97

From: Janet Shoemaker
Office of Public Affairs
Phone: (202) 942-9294
Fax: (202) 942-9335
e-mail: jshoemaker@asmusa.org

4 page(s) follow(s) this one.

Comments:

AMERICAN SOCIETY FOR MICROBIOLOGY

Public and Scientific Affairs Board
1325 MASSACHUSETTS AVE., N.W.
WASHINGTON, D.C. 20005-4171
TEL. (202) 737-3600
FAX: (202) 942-9335

Statement of the American Society for Microbiology
on the National Food Safety Initiative
March 28, 1997

Thank you for the opportunity to provide comments on the National Food Safety Initiative and to participate in the process to identify issues and approaches that will lead to the development of a comprehensive food safety plan to protect the public against foodborne disease. The American Society for Microbiology (ASM) is the largest single life science society in the world with over 42,000 members. ASM members include individuals working in academe, public health, clinical laboratories, industry, veterinary medicine, agriculture and government. Many of our members are engaged in the research, detection, diagnosis, prevention and surveillance of foodborne disease.

The ASM would like to commend the Administration for focusing on the problem of microbial foodborne disease and emerging pathogens as outlined in the National Food Safety Initiative. Overall, the ASM concurs with the principles and strategy outlined in the Initiative. However, there are issues within the key areas that have not been adequately addressed. We would like to focus our comments on issues which we believe are in need of further attention. One of our key areas of concern is the omission of the National Institutes of Health (NIH) and, specifically, the National Institute of Allergy and Infectious Diseases (NIAID), from involvement in the early planning of the Initiative. We urge that the NIH and the NIAID, which is the federal government's lead agency for sponsoring scientific research on the causes of infectious disease, pathogenic mechanisms, host defense mechanisms, vaccines and antibiotics, be included in the future development of the food safety plan to ensure that their expertise is brought to bear on this growing threat to public health.

RESOURCES FOR THE FOOD SAFETY INITIATIVE:

First, we congratulate the Administration for allocation of resources in the FY 1998 budget specifically for the implementation of the Food Safety Initiative. We also commend the Centers for Disease Control (CDC), the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) for protecting the nation's food supply even with limited resources. Research and the public health infrastructure related to food safety have been very underfunded for the past decade. We would like to bring to the attention of the Administration and Congress that the proposed funding in FY 1998 is not adequate to address the complexity and magnitude of the problems associated with food safety. Additional new and sustained resources will be needed to achieve the goals of a comprehensive plan that still needs to be developed to ensure food safety, not only in the short term but over the long term.

COORDINATION:

To be effective it is absolutely essential that the Food Safety Initiative be coordinated across the federal government agencies and with local and state government health authorities. The FDA, CDC, NIH, USDA and the Environmental Protection Agency (EPA) need to work collaboratively on foodborne disease research and prevention activities. However, the Food

Safety Initiative does not clearly state how interagency coordination will be achieved. One approach would be to designate a lead federal agency and establish an interagency coordinating committee. We strongly support the Foodborne Outbreak Response Coordinating Group and recommend the participation of the public in the deliberations of this group, including representatives from industry and the scientific community. There should be clearly delineated lines of authority and jurisdiction for this group. The ASM recommends that the risk assessment consortium involve all government agencies conducting research in this area and include industry and academic representatives as part of the group.

SURVEILLANCE:

The new National Early Warning System for public health surveillance is a key element of the Food Safety Initiative. An effective national and global surveillance system is critical to maintaining a strong defense against infectious diseases, including foodborne diseases, that affect, or threaten to affect, the public's health. We applaud the allocation of $10 million in the Centers for Disease Control and Prevention's FY 1998 budget which will enable CDC to implement a number of activities related to food safety surveillance and about $3 million in the Food and Drug Administration's budget for surveillance efforts. We believe this effort should enhance the capacity of the current seven FoodNet sites located at state health departments to serve as centers of excellence that define the needs for foodborne disease surveillance for the entire country. In turn, it will be necessary to take the findings from the FoodNet effort and implement appropriate surveillance in state and local health departments nationwide. New resources are needed for information technology which is vital for sharing information on organism typing collected by surveillance sites throughout the country with other laboratories and facilities. Public health laboratories are in need of additional resources and expertise to produce and share surveillance data.

The Food Safety Initiative should encourage the participation of the private health care delivery system in national surveillance. The managed care industry and the physician community should become partners with their state health departments and with the CDC to ensure that foodborne disease continues to be diagnosed accurately and reported. For example, stool cultures need to be collected and laboratory diagnosis performed on a patient presenting with diarrheal illness in order to detect, isolate and diagnose the infecting pathogen and to treat it with the correct antimicrobial therapy.

Managed care organizations and insurance companies should be educated about the impacts their decisions and practices are having on foodborne disease surveillance and prevention in this country. They should be full fledged participants in the Food Safety Initiative. Another essential component to an effective surveillance system is the need to have trained and qualified clinical microbiologists available to perform critical laboratory diagnoses and to recognize the emergence of new pathogens.

Foodborne surveillance data should be communicated to industry in a cooperative, efficient and timely manner. Scientific experts from industry should also provide expertise on processing and distribution issues in outbreak investigations to assure that assumptions made in epidemiological investigation are valid. With complete information, industry and public agencies can effectively respond to outbreaks and implement new strategies for more effective control. It is important

that scientific data be carefully subjected to thorough analysis, review and interpretation prior to public communication and dissemination.

Animal population and disease surveillance is also critical to solving the food safety problem. Animal to human disease transmission is an emerging public health threat that needs to be examined further. Risks associated with the public acquiring antimicrobial resistant pathogens from food animals are also of great concern. The ASM supports the FDA Center for Veterinary Medicine in its efforts to establish an Antimicrobial Susceptibility Monitoring Program using both human and animal isolates and recommends that this program be considered for increased funding in the fiscal year 1999 budget and include the CDC and the USDA.

RESEARCH:

Additional research is urgently needed so that changes in current food safety practices will be guided by valid scientific data. The Food Safety Initiative correctly identifies research as a high priority. However, the FY 1998 resources allocated for infectious disease research and for specific areas of needed research outlined in the Initiative are insufficient. It is essential to develop a research agenda that will effectively develop methods and technologies to prevent foodborne disease. For instance, such an agenda could include the following research areas: microbiological hazards in water used to irrigate produce fields; the use of antibiotics in livestock to control infection and the use of probiotics in livestock to control pathogens; the safety of food products imported from other countries; processing and slaughter practices; and food formulation and handling practices that can prevent illness such as new preservatives and antimicrobials, safety testing of modified products (e.g. reduced fat, reduced sodium foods that may allow enhanced growth of pathogens), terminal pasteurization processes (e.g. pulsed electric fields, irradiation, high pressure, etc.) that could inactivate organisms in foods, and identifying innovative control methods to kill acid-tolerant pathogens such as *E. coli* O157:H7 in acidic foods that until recently had a history of being safe.

A serious omission of the Initiative is the need for basic and clinical research. Surveillance tells us when and where a disease appears unexpectedly or dramatically increases in incidence. However, surveillance is only as good as the methods used for detection. A sustained basic and clinical research program in foodborne pathogens is necessary to provide the tools needed to detect and control these diseases. Clinical research is needed to determine health risks from foodborne pathogens and subsequently to establish meaningful risk management programs. Basic research in microbial physiology and genetics is needed not only for development of rapid, sensitive, and cost effective diagnostic tests but also to provide better understanding of an organism's ability to respond to environmental stress and to survive in food products. New foodborne pathogens have emerged over the past decade and established pathogens have developed increased virulence and antimicrobial resistance. We need to know the agents responsible for enteric infection and research will help define the scope and etiology of the problem. Thus, the need for a sustained research program.

For example, we know little about the mechanism of colonization, pathogenesis and importance of strain variation of *Campylobacter jejuni*. Furthermore, enhanced detection methods are needed for this fastidious organism. Another needed area in research is the role of strains of *E. coli* other than O157:H7 in foodborne disease and the potential need for inclusion of these strains

in surveillance programs. Research is also needed to determine the role of astrovirus and caliciviruses in foodborne disease. In short, there is a great need to determine the overall microbial content of different food products, especially fresh fruits and vegetables, and then to assess their health risks. Only limited data are available concerning the presence of fastidious bacterial, viral and parasitic pathogens in food and the resulting health risks. The latter is particularly important because in at least 50 percent of cases of diarrhea the etiology remains unknown.

Given the critical role of basic and clinical research in the area of food safety, it is unclear why the Food Safety Initiative does not include the National Institutes of Health, specifically the National Institute of Allergy and Infectious Diseases. Research supported by NIH has provided much of our basic knowledge about many of the major foodborne pathogens, including *Salmonella*, *Shigella*, *Campylobacter*, *E. coli* O157:H7, *Clostridium botulinum*, *Listeria monocytogenes*, and *Vibrio*. Also, regarding the potential role of other important federal programs in Food Safety Initiative, the Department of Defense and NASA have invested heavily in development of large scale, sensitive detection methods for viral and bacterial pathogens in environmental specimens. The Food Safety Initiative should take advantage of this existing infrastructure. In addition, the Food Safety Initiative should emphasize the critical role that the academic and industry research communities play in providing solutions to problems associated with foodborne diseases.

EDUCATION:

Education efforts should be given high priority in the Food Safety Initiative. The federal government should assume responsibility for the coordination and funding of educational programs relating to foodborne disease as soon as possible. The United States Department of Agriculture and the Centers for Disease Control and Prevention should be charged with developing and managing public/consumer education campaigns and given the appropriate resources to do so. Targeted campaigns to particular populations (elderly, children, immunocompromised) should also be developed and funded. In addition, targeted campaigns to industry (food service, retail, and food handlers) should be conducted.

INSPECTIONS:

Federal oversight must assure uniform understanding and administration of regulatory requirements that are shared with state and local agencies. Finally, while the ASM believes that, overall, Hazard Analysis Critical Control Point (HACCP) is the best approach for enhancing our nation's food supply, the imposition of mandatory HACCP is not necessary for all foods. Provisions must be made for alternative approaches to ensuring safety as long as they are demonstrated to be effective.

We appreciate the opportunity to provide comments and recommendation on the National Food Safety Initiative. The ASM would be pleased to respond to any questions or to provide additional information.

Food Safeguards Council, Inc.

1925 North Lynn Street, Suite 725
Arlington, VA 22209 USA
703-276-8444 ❀ 703-276-8447/Fax
safefood@aol.com

April 8, 1997

Mr. Thomas J. Billy
Food Safety and Inspection Service
U.S. Department of Agriculture
14th and Independence Avenues, SW
Washington, DC 20250

Dear Mr. Billy:

I want to thank you and the organizers of the President's National Food Safety Initiative for allowing me an opportunity to express our views. You are to be commended for marshaling the resources of our major government agencies to discuss ways to help control this serious problem and I wish you success.

In my remarks on March 31, I expressed concern that most of the information and material discussed at the meeting dealt with detection of food-borne diseases; inspection of food to determine if it is safe; and instructions, regulations, and recommendations on handling food to avoid contacting food-borne diseases. While this is important and should be supported to the fullest extent, I believe significantly more progress can be made through the development of technologies that will prevent these diseases from occurring in the first place.

I suggested that food irradiation, an available and proven technology, could eliminate a significantly large portion of the pathogens that cause food diseases. This process is overwhelming supported by scientific and medical organizations and most of us are totally convinced it will save lives. It is not in widespread use primarily because of the effective use of scare tactics and misinformation by opponents of "all things nuclear" as well as lack of support by the federal government. As I stated in my remarks, this is an ideal time for you and the Initiative to assume a leadership role and determine if this process can be used effectively to safeguard our food. Medical treatments using radionuclides, industrial applications of radiation, and food irradiation are beneficial applications that save lives. In the case of food irradiation, this process is no more harmful than microwaving or canning and freezing and if the public understands its benefits, I feel certain there would be a demand for this process.

I was pleased that at least five other presenters favored food irradiation and two companies indicated they were prepared to use this technology. At the end of my discussion, I suggested the Initiative form a special committee or group to examine food irradiation. I hereby restate my interest in such a group and would be glad to volunteered my services and I know of others who would also be interested. Please let me know if I can help in any way.

Very truly yours,

R. W. Durante

R. W. Durante
Food Safeguards Council
American Nuclear Society

cc: Elizabeth Drye, Associate Director
Domestic Policy Council
White House

Food Safeguards Council, Inc.

1925 North Lynn Street, Suite 725
Arlington, VA 22209 USA
703-276-8444 ❀ 703-276-8447/Fax
safefood@aol.com

August 11, 1997

Mr. Thomas J. Billy
Food Safety and Inspection Service
U.S. Department of Agriculture
14th and Independence Avenues, SW
Washington, DC 20250

Dear Mr. Billy:

I have reviewed the report to the President on the National Food Safety Initiative entitled, ***Food Safety From Farm to Table***, May 1997. I was deeply disappointed that no where in this 50 page report was there any meaningful discussion of the application of ionizing radiation as a way to eliminate food-borne diseases.

During the public hearings held by the Departments of Health and Agriculture, and EPA, I had an opportunity to comment on behalf of the Food Safeguards Council and presented what I thought was a compelling case for the application of this process to help prevent food from becoming diseased. Representatives of the American Nuclear Society and the Eagle Alliance, and several other leading industrial companies also testified on the benefits and availability of this proven technology. We all agreed that while the Initiative's focus on increased inspection services, additional regulations, and public education were commendable and should be encouraged, there was little or no discussion of methods to prevent food from becoming diseased in the first place. I do not believe it is necessary for me to try to convince you in this letter that food irradiation is a technically proven, safe, effective, and economical process and already in use in more than 40 countries throughout the world. These are established facts and can be substantiated by any number of leading scientists and engineers. This process could be effectively employed in the United States and with the proper educational/information program, the public would not only accept this treatment of foods but demand it. I have always felt this is an important role for the government to play and the National Food Safety Initiative would have been an excellent forum to thoroughly review this process. By deliberately avoiding any mention of this technology as a possible method of food disease prevention, you are supporting those opponents who feel we do not know enough about food irradiation and therefore should not allow its use.

At the presentations made in March and in following correspondence, I suggested a small committee be formed as part of your study to look specifically at ionizing radiation and other **preventative** processes. I volunteered my services and others from the scientific community to work, at no cost if necessary, on such a committee. While it is clear the Administration has a strong anti-nuclear bias, scientists such as yourself should transcend these political viewpoints and look for the best solution to help prevent Americans from getting sick and our children from dying from food-borne diseases. The process of irradiating food is really no more harmful than microwaving, freezing, canning, or steaming foods to destroy deadly pathogens and we believe that with the proper presentation, the public and the food industry would gladly choose it as a lifesaving process.

Very truly yours,

R. W. Durante

cc: Elizabeth Drye

1000 North Oak Avenue
Marshfield, WI 54449-5790
715-387-9137
FAX. 715-389-3131

Department of
Health Systems Research

Gregory Nycz
Director

MARSHFIELD MEDICAL RESEARCH FOUNDATION

June 19, 1997

Elizabeth Drye, Associate Director
Domestic Policy Council
222 Old Executive Office Building
17th Street and Pennsylvania Avenue, NW
Washington, DC 20502

Dear Ms. Drye:

I'm writing to express my gratitude for your participation in the White House briefing conducted for the Public Health Service Primary Care Policy Fellows on Tuesday, June 10, 1997. I thoroughly enjoyed the briefing and wish we had had more time to get to the issues surrounding the Cloning Prohibition Act of 1997. I'm writing to follow-up on the suggestion I made regarding possible linkages between the President's initiatives regarding a more safe food system and the Kellogg Foundation's Food Systems Professions Education Initiative. The attached folder provides information on the Wisconsin Food System Partnership as well as a brochure discussing the overall Kellogg initiative. At a minimum, I believe it would be helpful to the land grant universities to receive information on the President's initiatives as it appears a significant overlap exists in the underlying goals and objectives.

Thanks again for the time you spent with the Primary Care Policy Fellows last week.

Sincerely,

Greg Nycz, Director
Health Systems Research

H:\FAM_H\JOHNSONP\DRYE0619.DOC 06/19/97 1:00 PM