

**NLWJC - Kagan**

**DPC - Box 007 - Folder 012**

**Consumer Safety - Food Safety  
Initiative [2]**

environmental protection -  
food safety



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Jerold R. Mande

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12/02/97 07:36:59 PM

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Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Thomas L. Freedman/OPD/EOP, Laura Emmett/WHO/EOP

Subject: Food Safety Budgets

Here is what I was able to learn about the FDA and USDA food safety passbacks. USDA and HHS together asked for a \$170M increase over the FY98 food safety level -- \$61M for USDA and \$109M for HHS. USDA received about half of its request in its passback. FDA received none in its passback. The reason for this disparity is the different situations the two PADs, TJ and Josh, were in. Josh, overall, had to dig himself out of an almost \$2B hole just to reach last year's level of spending, and then food safety had to compete against some heavyweight programs including NIH, CDC, and Ryan White. TJ had the flexibility to increase USDA's budget.

As you may know, the situation changes when the food safety budget is sent to Congress. At the White House, USDA and FDA compete for funds from different allocations. In Congress, USDA and FDA are in the same allocation -- the agriculture appropriations subcommittees. OMB, however, does expect the disparity will be straightened out before the budget is sent to the Hill through the Presidential priorities process.



National Performance Review  
750 Seventeenth Street, NW, Box 101  
Suite 200  
Washington, DC 20006  
voice: 202-632-0150  
fax: 202-632-0390

consumer protection -  
food safety -  
reorganization

## FAX COVER SHEET

To: Laura Emmett for Elena

Telephone Number: \_\_\_\_\_ Fax Number 456-2878

From: Susan Valstok

Direct Telephone Number or ext.: 632-0354

Date: \_\_\_\_\_ Number of Pages Including Cover: \_\_\_\_\_

Special Message or Comments:

As I mentioned this was current  
as of '93. The report was never  
published. You are welcome to the  
info; the recommendation on top is  
on our website.

Initiative: HHS03.01 -- Legislation should be enacted to create a single food safety agency responsible for administering a uniform set of scientifically based food safety laws. The President and Congress should work together to create a single food-safety agency.  
 Status Code: 96 - Overtaken by events - no further action expected.  
 Status Narrative: HHS has taken steps to improve food safety regulation; including issuing scientifically-based regulations on seafood. USDA has implemented HACCP regulations for meat and poultry.

456-2878  
 752 5584  
 LAUREA  
 EMMETT



# HHS03: DEVELOP A NATIONAL, UNIFORM INSPECTION SYSTEM TO ENSURE A SAFE FOOD SUPPLY

## BACKGROUND

The Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS) estimates that at least 9,000 Americans die from foodborne illness each year; another 6.5 million become sick from eating contaminated foods.<sup>1</sup> Because many of these cases go undiagnosed, the actual figure is probably much higher than the conservative estimate of 6.5 million. An estimate by the Food and Drug Administration (FDA) is in fact much higher, at a minimum of 24 million cases per year.<sup>2</sup>

Most cases of foodborne illness reported in the United States today can be traced to meat, poultry, eggs, milk, and shellfish.<sup>3</sup> Shellfish alone caused 21 percent of all reported food poisonings arising from meat, fish, or poultry between 1978 and 1987.<sup>4</sup> Foods can be contaminated with harmful microorganisms (such as bacteria, viruses, and fungi); parasites (such as tapeworms, roundworms, and flukes); chemicals (such as pesticides, animal drugs, flavor and color additives, or industrial chemicals); and natural poisons (such as the toxins in some shellfish). Since 1985, the United States has

witnessed significant and highly publicized outbreaks of foodborne illness caused by highly pathogenic bacteria, including cheese contaminated with *Listeria*, milk and cantaloupe contaminated with *Salmonella*, canned mushrooms contaminated with the toxin produced by *Staphylococcus*, and hamburger contaminated with *E. coli* O157:H7. In addition to these acute outbreaks, chemical contamination of foods with animal drugs and pesticide residues may contribute to unknown increases in cases of cancer and birth defects.

Some increases in reported foodborne illness may be attributable to improved detection and reporting methodologies. Others seem to be an outgrowth of modern food processing techniques and changing consumer habits.

Much of what Americans eat today is processed at centralized facilities geared to high-speed mass production, rather than in local shops and in the home. More food is transported across the country and imported from other countries.

In 1993, consumers rarely stay home and spend hours preparing food, but instead eat on the run. They buy from carry-outs, eat at fast-food chains, and cook in microwave ovens. Much more of our food is bought pre-prepared and pre-cooked.

## RECOMMENDATIONS AND ACTIONS

Also, consumers as a group are physiologically different than they were in the early 1900s, when most of our current food safety laws were written. The "baby boomers" are dominating an aging U.S. population. Lowered immunity is a natural part of the aging process, increasing susceptibility to various infectious diseases, including foodborne illness.<sup>5</sup> Due to modern medicine, today's consumers are living longer and are more likely to live with chronic illnesses, such as cancer and acquired immunodeficiency syndrome (AIDS), that also increase susceptibility to foodborne illness. Some foodborne bacteria, including *Salmonella*, have been associated with chronic diseases such as arthritis.<sup>6</sup> The parasite *Toxoplasma gondii* has been shown to cause dementia in individuals with compromised immune systems; more than half of all cases of dementia occurring in AIDS patients may be of foodborne origin.<sup>7</sup>

The prevention and control of foodborne illness is of great economic importance. Outbreaks are expensive, not only for those who become ill, but for society at large. An April 1985 *Journal of Food Protection* article estimated that foodborne illnesses cost the United States between \$1 billion and \$10 billion annually. This figure includes direct medical costs, lost wages and productivity, and industry losses through embargoes, voluntary destruction and recall. The article stated, "Any money spent on research, surveillance and public education would be only a small fraction of the cost otherwise borne by the economy when disease occurs. . . . In most instances food supplier losses in the form of recalls, lost business, legal fees, legal settlements and wages exceeded the medical costs and lost earnings of the victims, thus the indirect cost to the economy may equal or even double the patient-related cost estimates."<sup>8</sup> Several recent studies have reached similar conclusions.

The *New England Journal of Medicine* of August 1978 published a CDC study on the impact of one foodborne disease—salmonellosis. The study showed that "Salmonellosis

is much more than an inconvenience—it is responsible for complications, operations, and hospitalizations of five to six days for previously well persons in all age groups, not just infants and the elderly." The study also stated that "... the cost of public health programs to detect, control, and prevent salmonellosis must be measured against the unnecessary medical expenses and loss-of-productivity costs, which may be more than a billion dollars a year. [emphasis added]"<sup>9</sup>

The present food safety and inspection system has not kept up with the changing environment. It is a complex regulatory system consisting of as many as 35 different laws and involving 12 federal agencies. Of these agencies, five have primary responsibility for food safety inspections. The FDA is responsible for the safety of most foods. Within the U.S. Department of Agriculture (USDA), the Food Safety and Inspection Service (FSIS) is responsible for ensuring the safety of meat and poultry products; the Agricultural Marketing Service (AMS) for eggs and egg products; and the Federal Grain Inspection Service (FGIS) for exported grain products. The Department of Commerce's National Marine Fisheries Service (NMFS) is primarily responsible for grading seafood products, but also provides voluntary food safety inspections at the request of the seafood industries. The FDA and FSIS are responsible for about 95 percent of all food inspections mandated by law.<sup>10</sup>

However, inconsistencies among these agencies' policies, procedures, and enforcement authority weaken the system's effectiveness. The frequency with which food processing plants are inspected and the actions taken to enforce regulatory standards for safety are determined by the legislation that governs the inspecting agency and the current allocation of resources among the agencies, and not by the relative risk the products in question pose to public safety. An optimal inspection system would be based on consistent science-based standards to ensure safety and would have different levels of intensity of inspection, reflecting the degree of public health risk at various stages

## RECOMMENDATIONS AND ACTIONS

It is not enough, however, to simply implement a system such as HACCP. It is not a regulatory program; HACCP only assists the industry in taking responsibility for a safer product.

An optimal inspection system would link HACCP with varying levels of government inspection that reflect the degree of public health risk present at each of the various stages in the process and that ensures HACCP plans are being implemented. Such a system would include a reliable monitoring system and an accurate compliance history for each establishment in the food industry. Our present inspection system clearly does not meet these criteria; neither does HACCP alone. HACCP only addresses process control, concentrating on critical control points in the process that pose potential public health risks. It does not provide a reliable monitoring system or an accurate compliance history of food establishments.

The current U.S. food safety inspection system also is inconsistent in its intensity and frequency of inspection for foods posing similar risks. FDA inspectors responsible for inspecting the nation's food supply are also responsible for inspecting firms that produce medical devices, drug manufacturing facilities, and blood banks. Due to limited resources, these medical-support firms usually are assigned a higher priority than food processing plants producing high-risk foods (such as low-acid canned foods and infant formulas).

Although FDA attempts to assign a risk priority to foods by categorizing them as "high" or "low" risk, the assignment of inspection frequency is inconsistent and based too much on the availability of resources. Availability is often controlled by the existence of a perceived "crisis" in the drug or medical device industry or in the nation's blood supply. Such crises usually demand that FDA concentrate its limited resources on the crisis issue and reduce its inspection of food manufacturing firms.<sup>14</sup> A recent General Accounting Office (GAO) report indicated that, on average, FDA inspects food establishments only once every

three to five years.<sup>14</sup>

The Federal Meat Act of 1907 and the Poultry Products Inspection Act of 1957 require the Department of Agriculture to provide continuous inspections at slaughter establishments, examining every carcass. The acts also require that inspectors visit meat and poultry processing plants on a daily basis. These laws are inflexible and do not allow FSIS to vary its frequency of inspections to concentrate its resources on risk and issues significant to the public's health, as recommended in the National Academy of Sciences report of 1985.<sup>15</sup>

The same GAO report states, "... in fiscal year 1991, FSIS devoted about 9,000 staff years to oversee about 6,100 establishments, while FDA devoted about 255 staff years to oversee an estimated 53,000 food establishments."<sup>16</sup> (This statement referred to the inspection of domestic food establishments and did not include import inspections.) The two agencies also have different approaches for foods posing similar risks. For example, beef broth is inspected daily by FSIS, while plants manufacturing chicken broth may be inspected by FDA once every three to five years. Meat and poultry products are inspected daily by FSIS, while shellfish are normally inspected by a small number of state inspectors. These are only a few examples of inconsistencies in the present system.

As already indicated in this paper, most authorities believe that the frequency and intensity of inspection should be based on risk. Risk should be determined by a form of risk analysis that takes into account hazards associated with the food product, the process by which it is manufactured, and the compliance history of the establishment producing the product.<sup>17</sup> This could allow federal agencies responsible for food safety inspections to use their resources more efficiently.

The food safety inspection system also suffers from inconsistent enforcement authority. FDA lacks the necessary enforcement power to ensure a safe food supply. FDA must prove actual or potential

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in the processing of foods. It also would have a reliable monitoring system and an accurate compliance history for each establishment in the food industry. Our present inspection system does not meet these criteria. Different regulatory approaches, jurisdictional conflicts among agencies, and a persistent inability to allocate resources efficiently across agencies have hampered the federal government's inspection efforts.<sup>11</sup> Viewed in its entirety, the existing regulatory structure is inefficient, cumbersome, and costly.

The United States needs a scientific, risk-based system. FSIS inspectors continue to use a method developed in the early 1900s, when the Federal Meat Inspection Act, the Poultry Products Inspection Act, and other food safety statutes were enacted. This method, called "organoleptic inspection," simply means using the five senses to determine product wholesomeness. Such inspections are a critical step in the elimination of dead, dying, diseased, disabled, visibly contaminated, and otherwise unwholesome meat and poultry products from the food supply. For example, in 1989, organoleptic inspections eliminated about 70 million head of poultry, 140,000 cattle, and 181,000 pigs from the food chain.

However, public health experts now realize that the most serious outbreaks of foodborne illness in this decade are due to pathogenic microorganisms that may not be detected by the five senses during inspection. These experts are also concerned with potential risks from chemical residues—again, hazards that cannot be detected by organoleptic inspection alone. Scientific inspections, including chemical and microbiological testing or other appropriate verification steps, must be developed and implemented if regulatory agencies are to be successful in reducing foodborne illness. Rapid, on-site microbiological and chemical diagnostic tests are needed to keep pace with the daily food production volume. Process control must be a priority to prevent product contamination and ensure a safe product.

FDA's enforcement strategy, which is grounded in the Food, Drug, and Cosmetic

Act, emphasizes end-product testing. Periodic inspections provide only a snapshot of what is happening in a facility at the time of inspection. There is no way to tell whether the conditions observed at the time represent a norm. Given the agency's current resources and level of sampling, this strategy simply cannot adequately cover the expanding universe of food products and manufacturers. Again, process control must be a priority to ensure a safe product.

Viable models exist for effective process control. In 1971, the National Aeronautics and Space Administration (NASA), the U.S. Army Natick Laboratories, and the Pillsbury Company developed the Hazard Analysis Critical Control Point (HACCP) approach to process control for the production of food products. The program was intended to ensure that products produced by Pillsbury for use by astronauts were wholesome and essentially pathogen-free. Pillsbury demonstrated that adequate controls in the manufacturing process could produce a high degree of assurance that the end-products would be safe.

In 1985, a National Academy of Sciences Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program and the National Academy of Sciences Subcommittee on Microbiological Criteria of the Committee on Food Protection embraced the HACCP concept as an effective and efficient approach to manufacturing safer food products. FDA has successfully applied HACCP principles in controlling the safety of low-acid canned foods.<sup>12</sup>

HACCP principles are defined differently by different users, making it imperative that a clear and consistent definition be understood by the food industry. If regulatory agencies encourage HACCP implementation by food manufacturers, each manufacturer could develop its own specific HACCP plan for each category of products it produces. HACCP would allow the industry to take responsibility for identifying and controlling public health hazards under its control.

product contamination or establish that conditions are unsanitary. Most FDA findings of adulteration or unsanitary conditions or practices are resolved through voluntary compliance. FDA does not have direct authority to detain adulterated food products; its inspectors must take control of suspect products through federal court warrants, often a lengthy process. While an inspector is obtaining the warrant, the product may end up in the marketplace, unless the state uses its authority to seize or detain the product. FDA also lacks the authority to recall adulterated products from market and access company safety and quality-control records.<sup>18</sup>

FDA lacks a mandatory registration requirement. Establishments that are not identified by the agency go uninspected. FSIS, by contrast, requires the industry to prove safety before food products can be marketed. However, while it possesses many authorities that FDA lacks, FSIS cannot seize or prevent the shipment of known infected animals to market for slaughter.

The current food safety inspection system provides little incentive for food establishments to exceed minimum requirements. There should be a system of incentives for companies to regularly exceed standards for wholesomeness. These incentives can be positive or negative. A negative incentive would be an increased inspection cost for less than desirable compliance.

Food safety research is also duplicative and driven by the varying missions of some 21 agencies. A January 1993 report by the Committee on Food, Agricultural, and Forestry Research of the Federal Coordinating Council for Science, Engineering, and Technology reports that these agencies spend approximately \$200 million on food safety research under about 50 laws that directly or indirectly authorize such research. This research may be basic or applied, laboratory-based or social science research. It may be broadly or specifically focused and carried out in federal laboratories, through contracts, cooperative

programs, or grants to academia and the private sector. The areas of research include infectious disease agents and their toxins, drug and pesticide residues, food additives, environmental and industrial contaminants, food product processing, storage and packaging, diet and nutrition, and food production. Each area may address improved methods to identify hazards, prevention and control, mechanisms of action, risk assessment and risk management methods, or consumer behavior studies.<sup>19</sup>

The United States needs coordinated efforts for food safety research, driven by a single mission and accountable to a single authority. This would eliminate the duplication of expensive research projects and provide effective communications and information sharing among researchers.

The food safety inspection system also maintains overlapping and duplicative inspections. Inspection efforts are poorly coordinated. Coordination agreements under which agencies are required to notify other responsible agencies of plant problems or deficiencies found during inspection do not always work; a recent GAO report states such notifications do not always take place, and that problems referred to a responsible agency are not always promptly investigated.<sup>20</sup> The use of interagency agreements has been hindered by a lack of resources to follow up on referrals.

## ACTION

*Legislation should be enacted to create a single food safety agency responsible for administering a uniform set of scientifically based food safety laws. The President and Congress should establish a single food-safety agency within FDA responsible for food safety inspections and research. Authority for enforcing all federal food inspection laws and regulations, and all personnel, facilities, and equipment currently used by such programs, should be transferred to the new agency. (See Table 1 for a list of food safety responsibilities*

## RECOMMENDATIONS AND ACTIONS

*that should be transferred to this new agency).*

Current laws regulating federal food inspection should be reviewed immediately to identify areas in which changes in the laws are needed to base food inspections on sound science. The new agency also should begin a review of current regulations governing federal food inspection for the purpose of producing uniform regulatory requirements, taking into consideration inherent risk in products and production methods, and the unique nature of the foods and the industries that produce them.

An immediate study should be made by the new agency of current staff and resources and the policies governing their use, and the information obtained should be used to construct a new organizational structure, a management system, inspection procedures, and research programs capable of meeting public health-based objectives.

This new food safety agency must serve as a reinvention model. Its primary mission must be consumer protection and food safety. It should be customer-driven, meeting consumer needs within the boundaries of sound science. Consistent prevention of foodborne illness and poor sanitation and manufacturing practices should replace crisis management. There should be in place a management system for continuous improvement, concentrating on the continuous reduction of risks of foodborne illness. This will include continuous evaluation and reduction in the numerical regulatory standards for sanitation, microorganisms, and residues that assist in reducing risks. Empowering the front-line food inspector and eliminating cumbersome layering and complicated chains-of-command will simplify decisionmaking in the field and improve regulatory effectiveness.

The new agency should be given the authority to impose user fees for appropriate services to aid in the cost of improving inspection processes. User fees should be considered for food establishments that require additional inspections and enforce-

ment efforts due to repeated noncompliance. Laboratory testing conducted to release detained or recalled products in cases of known or potential contamination could be subjected to a user fee, as could other testing outside of normal monitoring or surveillance sampling. User fees also should be considered for overtime, additional shifts requiring inspection oversight, inspection of imported food products, certification of exported food products, agency responses to Freedom of Information Act (FOIA) requests, and other special services as appropriate.

The single food safety agency would eliminate the need for interagency agreements coordinating inspection activities between agencies, as well as duplicative inspections in establishments with similar products under the authority of different agencies.

The food safety agency should meet the following criteria:

- (1) The new agency should provide a scientifically sound, risk-based inspection system.

The agency must have an adequate food-borne disease outbreak reporting system. This system would provide the data needed to determine risks associated with different types of food products. This would be an integral part of the foundation of a scientifically based food safety inspection system. HACCP or an equivalent system could be another important component of a scientific risk-based inspection system, placing responsibility for safe products on the food industry. Each food processing firm would be encouraged to have a HACCP plan for each category of food products it produces. Appropriate verification testing would be an integral part of each HACCP program.

- (2) The agency would have an automated reporting system to aid in determining inspection frequencies.

An automated reporting system can assist in identifying food establishments that are consistently out of compliance with federal regulations. This system could be adjusted to determine inspection frequency for each establishment based on the type of product manufactured, its inherent safety risks, and

**RECOMMENDATIONS AND ACTIONS**

**Table 1  
Food Safety Responsibilities to be Transferred into the  
Food Safety Agency Within the Food and Drug Administration**

Agency	Responsibility	Legislation
<b>U.S. Department of Agriculture</b>		
Food Safety and Inspection Service	Meat and Poultry Safety	Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.) Poultry Products Inspection Act, as amended (21 U.S.C. 431 et seq.) Tulane-Aiken Act of 1962 (7 U.S.C. 430 et seq.)
Agricultural Marketing Service	Egg/Egg Product Safety	Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.)
<b>Department of Health and Human Services</b>		
Food and Drug Administration	Safety of All Foods, Except Meat, Poultry, and Eggs	The Federal Food Drug and Cosmetic Act (FFDCA), as amended (21 U.S.C. 301 et seq.)
	Safety of Animal Drugs and Feeds	Public Health Marketing Improvement Act of 1983 (21 U.S.C. 1401 et seq.) Egg Products Inspection Act, as amended (21 U.S.C. 1031 et seq.) Salt Detracting Water Act, as amended (21 U.S.C. 349) Infant Formula Act of 1980, as amended (21 U.S.C. 330c) Federal Anti-Tampering Act (18 U.S.C. 1365) Federal Import Milk Act, as amended (21 U.S.C. 141)
Center For Disease Control and Prevention	Investigation of Foodborne Illnesses and Foodborne Disease Outbreaks	Public Health Service Act, as amended (42 U.S.C. 201 et seq.)
<b>U.S. Department of Commerce</b>		
National Marine Fisheries Service	Voluntary Seafood Inspection Program	Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 et seq.) Fish and Wildlife Act of 1956 (16 U.S.C. 742a et seq.) Lacey Act, as amended (16 U.S.C. 3371 et seq.) Magnuson Fishery Conservation and Management Act, as amended (16 U.S.C. 1801 et seq.) National Ocean Pollution Research and Development and Monitoring Planning Act of 1978 (33 U.S.C. 1701 et seq.)

**Note:** The food safety component of the Environmental Protection Agency (EPA) that can determine the pesticide in foods could also be considered as a component of the single food safety agency. If the food safety agency deems this appropriate a recommendation to Congress to legislate such a change could be submitted.

functions and management positions would continue; many cost-cutting opportunities inherent in a single food safety agency would be missed.

**FISCAL IMPACT**

All funds appropriated for current food safety activities would be transferred into FDA. Savings associated with this consolidation might include those from consolidating FDA and FSIS field offices and inspection activities, administrative activities such as personnel offices and activities, resource

management, and duplicative management positions.

Additional one-time costs could arise in creating the new agency and retraining field inspectors who now may perform different food safety tasks. Specific savings or additional costs cannot be determined at this time; this report assumes that the savings and additional costs will balance, with a neutral budget impact.

The projected total budget authority for fiscal years 1995 for the FDA and the USDA (FSIS and the food safety components of AMS) is \$817 million.

**HHS03: DEVELOP A NATIONAL, UNIFORM INSPECTION SYSTEM TO ENSURE A SAFE FOOD SUPPLY**

- Endnotes**
1. Bennett, John V., et al., "Toxicosis and Periodic Diseases," *Chasing the Gipsy: The Maelstrom of Unconcocted Illness*, ed. Robert W. Archer and H. Bruce Dull (New York: Oxford University Press, 1987), pp. 102-114.
  2. Archer, Douglas L., and John E. Koenberg, "Toxicosis and Care of Foodborne Bacterial Diseases in the United States," *Journal of Food Protection*, 48 (1985), pp. 887-894.
  3. Bova, N.H., and P.M. Griffin, "Foodborne Disease Outbreaks in the U.S., 1973-1987: Pathogens, Vehicles, and Trends," *Journal of Food Protection* (September 1990), pp. 804-817.
  4. National Academy of Sciences, Institute of Medicine, *Food Safety* (Washington, D.C.: National Academy Press, 1991).
  5. Manning, Edmund L., "Danger Lurks in Your Supermarket Meats," *Journal of the American Veterinary Medical Association* (1988), pp. 494-497.
  6. Archer, Douglas L., "The Impact of Foodborne Infections," *Food Technology*, 42(7) (July 1988), pp. 53-58.
  7. Weira, Mike, Turyn Roberts, and Hal Linsenon, "Food Safety Law: Modernizing Meat Inspection," *Agricultural Outlook* (June 1993), p. 35.
  8. Archer and Koenberg, pp. 887-894.
  9. Cohen, Mitchell L., et al., "An Assessment of Pasture Related Economic Loss in An Outbreak of Salmonella," *New England Journal of Medicine* (August 1978), pp. 299-301.
  10. See U.S. General Accounting Office (GAO), *Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply*, Report to the Congress, RCED-92-152 (Washington, D.C.: U.S. General Accounting Office [GAO], June 1992).
  11. *Ibid.*
  12. National Research Council, *An Evaluation of the Role of Microbiological Criteria for Food and Food Ingredients* (Washington, D.C.: National Academy Press, 1985), pp. 50-54.
  13. See U.S. Department of Health and Human Services (HHS), Office of Inspector General, *FDA Food Safety Inspection*, Audit Report No. OIG-05-90-01070 (August 1991).
  14. See GAO.
  15. Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection, *Meat and Poultry Inspection: The Basis of the Nation's Program* (Washington, D.C.: National Academy Press, 1985), p. 10.
  16. See GAO.
  17. Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection.
  18. See HHS.
  19. See Federal Coordinating Council for Science, Engineering, and Technology, *Committee on Food, Agriculture, and Forestry Research of the Food, Agriculture, and Forestry Research of the Food, Agriculture, and Forestry Research* (Washington, D.C.: U.S. Office of Science and Technology Policy, January 1993).
  20. See GAO.

Consumer protection - food safety

AUGUST 22, 1997

UPDATE ON HUDSON FOODS RECALL

USDA is continuing its investigation of the Hudson Foods recall. The team of FSIS and OIG investigators is examining records of shipments from slaughter plant suppliers of raw product to the Hudson Foods' Columbus, Nebraska plant in an effort to determine the source of the *E. coli* O157:H7 bacterium. As a part of the investigation, FSIS is also checking the records of the slaughter plant suppliers to the Hudson Columbus, Nebraska plant. The review of records will be conducted by FSIS officials who are not regularly assigned to the plant.

The Hudson Foods' Columbus, Nebraska plant has suspended operation. Today, FSIS Field Operations officials contacted Hudson's corporate management to offer assistance to the company in developing a plan to institute new procedures to ensure the safety of product and to enable the company to reopen. Hudson officials expressed appreciation and are considering the offer.

FSIS is continuing to work with Centers for Disease Control and the Colorado State Department of Health to gather information on the illnesses associated with Hudson product. However, illness data available from the states indicate no widespread outbreak. In fact, CDC believes the problem has been pretty well contained.

A total of 4400 callers contacted the Meat and Poultry Hotline between 7:30 p.m., Thursday, August 21 and noon, today. Most callers inquired about the names of the fast food restaurants which received the Hudson product. Other callers stated that they had purchased Hudson product and had discarded the packaging, but still had hamburgers in their freezers. These callers were instructed to return the product to the point of purchase. A number of callers stated that they were experiencing illness and were referred to the Hotline's resident nurse for follow-up information.

Interviews conducted:

8/21/97

Dan Glickman, Catherine Woteki, and Thomas Billy were filmed during a press conference by CNN, NBC and CBS.

Catherine Woteki and Thomas Billy were interviewed by Newsweek, USA Today, Columbus, Nebraska Telegram and the Los Angeles Times.

8/22/97

Dan Glickman and Thomas Billy were interviewed by the New York Times.

Thomas Billy was interviewed by CNN on a live morning broadcast.

Consumer protection -  
food safety



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

ADMINISTRATOR  
OFFICE OF  
INFORMATION AND  
REGULATORY AFFAIRS

AUG 20 1997

MEMORANDUM FOR ERSKINE BOWLES

FROM: Sally Katzen *SK/NF*

SUBJECT: Heads-up on FDA's Notice on Unpasteurized Fruit and Vegetable Juice

We are about to conclude review of a Notice that sets forth FDA's plans to address several outbreaks of foodborne illnesses (primarily from e-coli bacteria) from consumption of certain unpasteurized fruit and vegetable juices. The Notice outlines FDA's intent to propose two rules -- a rule requiring certain producers of unpasteurized fruit juices to institute a HACCP (Hazard Analysis and Critical Control Points) program designed to control hazards that may occur during processing; and a rule requiring labels warning consumers of the risks associated with drinking unpasteurized juices. In addition, the Notice encourages unpasteurized fruit juice producers to voluntarily and immediately place warning labels on fresh juices such as apple cider in anticipation of the 1997 apple cider season (only a few weeks away).

This Notice is not binding at this time. It will nonetheless attract some attention. Consumer groups will applaud the plans, but may comment that FDA is not acting swiftly enough in this area; industry, including particularly small apple growers who specialize in unpasteurized juices, will likely be wary of new mandates that are perceived as costly and difficult to implement. If you have any questions, please call my Special Assistant, Michael Fitzpatrick (5-1247), as soon as possible.

cc: Maria Echaveste  
Rahm Emanuel  
Thurgood Marshall, Jr.  
John Hilley  
Ann Lewis  
Sylvia Mathews  
Bruce Reed  
Chris Jennings  
Elena Kagan  
Victoria Radd  
Barry Toiv  
Michael Waldman  
Josh Gotbaum  
Larry Haas

Cons. safety -  
Food safety

*"We have built a solid foundation for the health of America's families. But clearly we must do more. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during dinner out."*

*- President Bill Clinton, Radio Address, January 25, 1997*

Today, Vice President Al Gore accepted a major report -- "Food Safety From Farm to Table" -- on how to reduce the incidence of foodborne illnesses from Health and Human Services Secretary Donna E. Shalala, Department of Agriculture Secretary Dan Glickman, and Environmental Protection Agency Administrator Carol M. Browner. The report, requested by President Clinton in January, sets forth new steps the Administration will take this year to strengthen food safety and details how we will use \$43.2 in new funds the President has requested in his 1998 budget.

**Working with consumers, producers, industry, states, universities, and the public, the Administration has developed measures to reduce foodborne illness from microbial contaminants; the Administration will:**

- o **Improve inspections and expand preventive safety measures:** FDA will use \$8.5 million of the new funds, in part, to hire additional Food and Drug Administration (FDA) inspectors for seafood plants and to expand the Hazard Analysis and Critical Control Point (HACCP) approach to the fruit and vegetable juice industries. U.S. Department of Agriculture (USDA) will propose preventive measures, including HACCP, this year for egg products.
- o **Increase research to develop new tests to detect foodborne pathogens and to assess risks in the food supply:** The agencies will target \$16.5 million to critical research needs, such as giving federal, state and local food safety officials new tools to detect these pathogens, some of which -- like the Hepatitis A virus and cyclospora -- cannot now be detected in many foods.
- o **Build a national Early Warning System to detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks:** With \$13.7 million of the new funds, USDA, FDA, and Centers for Disease Control and Prevention will increase the number of active "sentinel sites" across the country from 5 to 8 (current sites are in Northern California, Oregon, Minnesota, Georgia and Connecticut; new sites added this year are in New York and Maryland, and the eighth will open next year) and will equip these sites with new technology to identify the diseases and their sources and to communicate these findings nationwide rapidly.
- o **Establish a national education campaign that will improve food handling in homes and retail outlets.** FDA, USDA, CDC, and the Department of Education will launch a new public-private partnership with industry,

producer and consumer groups, and states to raise public awareness of safe food practices. Using public and private funds, the partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. USDA and FDA will use \$4 million of the new 1998 funds to support this and other education activities.

- o **Strengthen coordination and improve efficiency:** USDA, CDC, FDA and EPA will form a new intergovernmental group to improve federal, state and local responses to outbreaks of foodborne illnesses. Working with all stakeholders, the agencies will develop a strategic plan to further improve coordination, use resources more efficiently, and measure progress toward our common goal of reducing foodborne.

#### **Building on Our Accomplishments**

Food safety is a major public health challenge: millions of foodborne illnesses and thousands of food-related deaths occur annually. From the beginning, the Clinton Administration has made improving the safety of the nation's food supply a top public health priority.

- o **Building on the recommendations of the Vice President's National Performance Review, the President put in place new science-based, hazard prevention systems for seafood, meat, and poultry.** In late 1995 the Administration issued new rules to ensure seafood safety. In July, 1996 President Clinton announced new regulations to modernize the nation's meat and poultry inspection system for the first time in 90 years. The new Early Warning System will gather critical scientific data to further improve these prevention systems
- o **In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overhaul of our laws that regulate pesticides in food** putting in place reforms that the Clinton Administration had urged since 1993. These reforms will ensure health and safety for American families through a more protective, more stringent health-based standard plus special new provisions to protect the health of infants and children from pesticide risks.
- o **Last August, President Clinton also signed a new safe drinking water law** that strengthens protections to ensure that American families have clean safe tap water -- improvements that the Clinton Administration has called for since September 1993.

May 7 draft 9 am VPOTUS PRESS RELEASE

## CLINTON ADMINISTRATION ANNOUNCES NEW FOOD SAFETY MEASURES

The Clinton Administration today announced new measures to increase the safety of the nation's food supply. Stricter safety precautions for fruit and vegetable juices, improved seafood inspections, increased investment in research, risk assessment and surveillance, and a new national public education campaign top the list of initiatives included in the Administration report, "Food Safety From Farm to Table."

"Our families must be able to sit down at mealtime without any worries about the safety of their food," President Clinton said. "We can give them that peace of mind, but we have to work harder and smarter using new technologies and educating people to ensure that food travels safely from the farm to the table."

In his January 25 radio address, the President announced he was requesting \$43.2 million for food safety in his FY 1998 budget and requested a report detailing recommendations on ways to further improve food safety. The Departments of Agriculture and Health and Human Services, and the Environmental Protection Agency, working with state and local officials, the food industry, scientists, consumer, and producer groups, developed the report, which calls for improved inspections, public education and greater use of the latest science to dramatically reduce foodborne illness.

"This Administration is using the most modern science and a common-sense approach to public health regulation to protect our families," said Vice President Al Gore. "Improving food safety has been a public health priority of the Clinton Administration from its beginning, and these recommendations will take our efforts to a whole new level."

A key element of the Administration's food safety efforts has been the Hazard Analysis and Critical Control Point (HACCP) approach that requires the food industry to use the most modern science to identify sources of potential contamination in food production and transportation and then put in place preventive measures. Already required by the Food and Drug Administration for seafood and by USDA for meat and poultry, FDA will propose preventive measures, including HACCP, for the manufacture of fruit and vegetable juice products, and USDA will propose HACCP and other appropriate regulatory and non-regulatory options for egg products.

In addition to moving toward a science-based, preventive approach to food safety, the Administration continues to improve the effectiveness of food safety inspections. Specifically, the additional funds requested for FY 1998 will allow the FDA to add inspectors to implement seafood HACCP and to expand its program

to develop additional mutual recognition agreements (MRAs) with trading partners ensuring that imported foods are produced and manufactured under systems that offer comparable safety measures to those used in the United States. With the new funds, FDA will also be able to provide technical assistance to foreign countries on safe growing and handling practices.

The Administration is already taking steps to put in place the new National Early Warning System President Clinton announced in January to track and combat outbreaks of foodborne illness. This fiscal year, two new FoodNet sentinel sites were added in New York and Maryland. With funds requested for the upcoming fiscal year, an eighth site will open. This surveillance system is supported by the CDC, FDA and USDA, working with state authorities. New funds included in the FY 1998 budget will also allow these sites to update technology and build a "fingerprinting" database of bacterial DNA. This will enable food safety experts to clear any geographic hurdle to their work by having a national resource that can help them quickly identify contaminated foods that are the sources of foodborne illness.

Under the Administration's plan, work will start immediately on a national public education campaign on safe food handling. Today, an unprecedented public-private partnership was established among government agencies and industry and consumer groups to develop a food safety education campaign aimed at consumers. Partners in the campaign, which will kick-off later this year, include USDA, FDA, the Centers for Disease Control and Prevention, the Department of Education, Food Marketing Institute, the American Meat Institute, National Restaurant Association, Grocery Manufacturers of America, Produce Marketing Association, the American Egg Board, National Cattlemen's Beef Association, Public Voice for Food and Health Policy, Safe Food Coalition, and Consumer Federation of America [verify against final MOU].

Research to develop quick, reliable scientific methods for detecting contamination -- like the Hepatitis A virus and cyclospora -- will ensure that public health agencies have the necessary tools to prevent and control outbreaks of foodborne illnesses. The latest research will also explore how pathogens become resistant to traditional food preservation techniques such as heat and refrigeration, and will support new pathogen control methods.

Also under the new initiative, EPA, FDA and the CDC will collaborate with state and local health departments on research to help health officials better predict and control outbreaks of waterborne microbial contaminants, such as cryptosporidium.

Elena/Bruce

-PFI  
Mostly accurate  
Trade press  
5/2/97  
This is same  
reporter  
broke the  
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-Elena

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Cms safety -  
food safety

### Food safety initiative final version carries provisions for enhanced seafood surveillance, food safety council, education partnership, manure regulation and more

The seafood industry will see increased government attention on *Vibrio vulnificus* and the Norwalk virus if Congress approves funding for the multi-agency food safety initiative, sources told *Food Chemical News*. The final version of that initiative calls for increased surveillance for *Vibrio vulnificus* by CDC, FDA and states through boosts in personnel and epidemiological and lab resources.

That effort, detailed in a final version of the initiative submitted to President Clinton, would comprise an enhancement of the Gulf Coast *Vibrio vulnificus* surveillance program. The report, which is about 50 pages long, calls for research to develop new decontamination methods for such contaminants as *Vibrio* and Norwalk on seafood, as well as for hepatitis A on strawberries. The entire report emphasizes the need for research to find and improve pathogen detection methods. The federal agencies involved in the initiative are CDC, FDA, USDA and EPA.

One source close to the initiative noted that even if the government had known ahead of time about the hepatitis A recently linked to Mexican strawberries, the hepatitis A could not have been detected because the government lacks reliable methodology for such detection. Pathogen detection in the food supply is complicated by the fact that detection is different for almost every type of food. That is, detection of pathogens in milk is different from detection in berries, which is different from detection in meat, etc.

The White House was scheduled to announce the final version of the initiative April 29, but that was postponed due to conflicts with other White House press events. At press time, sources said that an announcement of the initiative by Vice President Al Gore was scheduled for May 12, but that date — and Gore's availability for the event — could change again.

(See FSI, Page 37)

May 5, 1997

FOOD CHEMICAL NEWS 37

"If ... improved objective performance standards can be crafted through additional, scientifically based rulemaking," Boyle added, "AMI will support and participate in those efforts."

### Consumer groups not satisfied with spinal cord safety

On Monday, April 28, Billy and his colleagues in FSIS held another meeting focusing on AMR, this one with representatives from the consumer advocacy groups Public Voice, National Consumers League, Center for Science in the Public Interest, and the Safe Food Coalition.

The meeting was prefaced by an April 22 letter from NCL's Linda Golodner to Billy and Agriculture Secretary Dan Glickman. NCL appears to be backing off its earlier demands that back and neck bones be kept out of AMR systems altogether, an action taken by Britain more than a year ago. Instead, Golodner suggested that USDA impose bone scoring requirements, "an iron limitation of not more than 2 mg per 100 g," a calcium test performed "after separator and before the desinewer" for a maximum level of 20 mg per 100 g, and a prohibition on presizing.

"Resolving the spinal cord and marrow issues through lengthy rulemaking procedures is unnecessary legally and represents an unacceptable abdication of responsibility," Golodner wrote. "The British waited much too long to act decisively and have paid a very dear price." NCL and other consumer groups are concerned that spinal cord in AMR meat may expose many American citizens to a higher risk of transmissible spongiform encephalopathies, Britain's deadly "mad cow disease."

At their meeting, the consumer groups reiterated these issues, focusing on the BSE risk from spinal cord. They cited risk factors, including the imports of British cattle into the U.S. in the 1980s, the imports of Mexican cattle into the U.S. that continue every year, and the limited resources FDA will have to enforce its proposed mammalian-to-ruminant feed ban.

According to one of the consumer group participants, the spinal cord directive will be "closing the barn door after the horse is out." Since spinal cord is only an economic

adulterant, not a health hazard, suspect product would go into distribution even if some of it is sent off for tests.

"We're not convinced that the directive itself will provide a complete assurance that spinal cord won't get into end products," one consumer advocate explained. The advocate noted, however, that the directive may be useful in putting pressure on industry to keep spinal cord out of AMR systems. "The next step is for us to meet with industry," the advocate said.

Under the terms of USDA's 1994 reorganization, FSIS cannot propose a "major regulation" dealing with human health or safety (changing the definition of meat to exclude spinal cord would qualify) without performing a risk assessment and cost-benefit analysis, which would take a minimum of six months to complete. The entire rulemaking process would last for one to two years. "They're doing the best that they can," the consumer advocate admitted.

On the bone marrow issue, the consumer groups requested that FSIS propose a rule aimed against "unacceptably high" marrow levels in AMR product. Bone scoring requirements might be used, as in NCL's proposal. But the performance standards proposed in Billy's letter to AMI may fulfill this request, one source said. "We'll wait to see what they come up with." (7FCN 1102, 3 pages, \$5, and 7FCN 1103, 2 pages, \$5)

— Wendy Love Anderson

(FSI, continued from Page 3)

The initiative is structurally the same as its draft predecessor, i.e., presented in seven sections, and most of the concepts from the draft survived in the final report (See *Food Chemical News*, April 7, Page 38).

### Regulation of manure likely

Regulation of manure is likely in the near future, as the report cites the need to control the various ways that manure can contaminate the food supply. The report does not detail any manure regulations, but emphasizes that controls are needed.

The report also calls for the establishment of a National Council on Food Safety, which would include an independent scientific board to review food safety messages. The board would include representation from the scientific and academic communities and would use a risk-based methodology for prioritizing its work.

A public/private partnership for food safety education also would be established by the initiative, but details on that effort were sketchy. The report places new emphasis on education of health care professionals, a goal that was accentuated repeatedly by participants in a March 31-April 2 public meeting on the draft initiative. Health care professionals need to recognize foodborne illness, test for it and report it, the source said. The agencies will try to be "appropriately multilingual" in all public and educational efforts, the source said.

#### **Egg and produce HACCP appear imminent**

Egg HACCP and produce HACCP appear imminent, as the report indicates that regulatory options will be proposed for controlling pathogens in eggs and in fresh fruits and vegetables.

Federal outreach to states and cooperation with states are linchpins of the plan, and that strategy is in line with the federal government's need to share the resource burden for implementing the initiative.

Federal agencies must maintain a dialogue with all parties who have a stake in the initiative, in order to establish and follow a strategic plan for developing, implementing and reviewing the initiative's components, the report said.

It remains uncertain whether Congress will give the agencies the \$43 million requested for the initiative. While it is tough for any congressional members to argue against the concept of a safer food supply, Congress will be very wary in the current budgetary climate to approve new funding for projects.

— John Briley

## **Performance standards featured in FSIS regulatory agenda**

The switch from requirements to performance standards, part of the "Reinventing Government" effort, dominates the semiannual regulatory agenda of USDA's Food Safety and Inspection Service, published in the April 25 *Federal Register*.

No fewer than six proposed rules explicitly establish performance standards. In June, FSIS plans to give notice that it is establishing performance standards "for the production of certain meat and poultry products with established standards of identity. ... Performance standards spell out the objective level of performance establishments must meet during their operations to produce safe products, but allow the use of customized, plant-specific processing procedures."

In this case, FSIS plans to establish food safety performance standards specific to the standards-of-identity products instead of relying on "statutory authorities, general regulations, regulations for similar products, or FSIS directives." Similarly, FSIS is developing new performance standards "to limit the amount of water absorbed and retained by single-ingredient raw meat and poultry products to the amount that is unavoidable in carrying out washing or chilling procedures." Water-added raw products may have to bear a label attesting to their absorbed water content, according to the proposal, which was scheduled for publication in April 1997.

In other cases, however, the agency is replacing its own specific regulations. For instance, proposed performance standards will replace "command-and-control" procedures for thermal processing of meat and poultry products; irradiation of poultry to control foodborne pathogens; handling, chilling and freezing of poultry; cutting carcasses into primal parts within an establishment; and preventing physical or chemical contamination of meat and poultry products and product ingredients.

Consumer Safety -  
Food safety



Elizabeth Drye

04/28/97 06:29:45 PM



Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:

Subject: Food Safety Report

Agencies are wrapping the report to us this week. You had asked that we leak it Sunday for Monday -- without an event, however, it will be tough to get meaningful press coverage so I don't think release date is critical. Shalala and Glickman will both be out of town Monday as well. I'd like to cut the agencies loose to release to press when they send the final over here later this week or early next week. Is that o.k.? Do you still care what date it gets out or can I defer to agencies?

Consumer Safety -  
Food safety



Elizabeth Drye

04/17/97 06:27:08 PM



Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc: Christa Robinson/OPD/EOP

Subject: Food Safety Report Potential Event Options

When does this need to be ready? We're on track to get a document drafted and cleared by 4/25, but not ready to release it at an event earlier in the week. Good (long) meeting w/OMB staff today but still need to work through some details on pieces we would highlight. Is that o.k. given a press conference next week is unlikely? Any chance we could do an event in the following 1-2 weeks? Given the extensive public participation in/anticipation of the report and the need to get moving on actions in it, I don't think we'll be able to sit on it for long.

Cons safety - food safety



Elizabeth Drye

04/09/97 03:43:59 PM

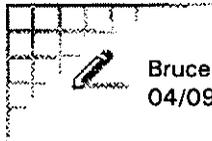


Record Type: Record

To: Michael A. Fitzpatrick/OMB/EOP  
cc: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
Subject: Customs Service Food Safety Rule

Mike -- can you check on the status of this rule? Is it possible for Customs to get it out the door in the next two weeks? My understanding is that the comment period has closed and those supporting it -- e.g. domestic produce growers -- were asleep at the wheel and missed the comment period. Given that, is Customs in a position to go forward with the labeling requirement? Does OMB have a position on it?

----- Forwarded by Elizabeth Drye/OPD/EOP on 04/09/97 03:42 PM -----

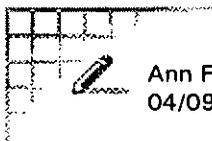


Bruce N. Reed  
04/09/97 03:26:02 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP  
cc:  
Subject: Food Safety

----- Forwarded by Bruce N. Reed/OPD/EOP on 04/09/97 03:31 PM -----



Ann F. Lewis  
04/09/97 08:48:31 AM

Record Type: Record

To: Kathryn O. Higgins/WHO/EOP, Bruce N. Reed/OPD/EOP, Rahm I. Emanuel/WHO/EOP, Sylvia M. Mathews/WHO/EOP  
cc:  
Subject: Food Safety

According to today's NY Times, page c8, Customs is considering a rule to put country of origin labels on the front of frozen foods. (As in frozen strawberries ) The industry is objecting. Marcy Kaptur and the Teamsters have now sent a letter to Rubin supporting the rule.

Is this something that should be addressed at the same time as the April 25 food safety report ? Sooner ?



Elizabeth Drye

04/04/97 04:02:17 PM



Record Type: Record

To: Rahm I. Emanuel/WHO/EOP, Michelle Crisci/WHO/EOP, Kris M Balderston/WHO/EOP  
cc: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Anne E. McGuire/WHO/EOP  
Subject: Food Safety Report

We're on track to finish the food safety report -- and clear it through OMB -- by April 25th as directed by the President. This week the agencies held a large 2 1/2 day public meeting with industry and consumer groups to build consensus on specific policies. We expect to have ready for the final report, among other things, a public-private food safety education campaign (industry, consumers, and all agencies support and industry is interested in contributing funds) and a new government-wide outbreak response group that assures CDC/USDA/FDA will work as a team. Much of the report will be technical, but there will be gems -- similar to the early warning system we announced in January -- that we can highlight if we choose to do so. No way we can be done before April 25th.

----- Forwarded by Elizabeth Drye/OPD/EOP on 04/04/97 03:54 PM -----



Kris M Balderston

04/04/97 02:14:29 PM

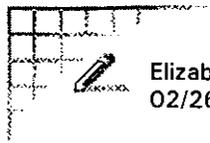


Record Type: Record

To: Michelle Crisci/WHO/EOP, Rahm I. Emanuel/WHO/EOP  
cc: Anne E. McGuire/WHO/EOP, Elizabeth Drye/OPD/EOP  
Subject: Food Safety Report

Kitty is out for the afternoon but she wanted me to get you an update on the USDA/HHS food safety initiative draft report. USDA informs me that the working group has been in town for a technical meeting and the draft report is not anywhere near ready to release. Accdg to them the report is in its infant stages.

*Can safety:  
food  
safety  
initiative*



Elizabeth Drye  
02/26/97 12:29:20 PM

Record Type: Record

To: Patricia F. Lewis/WHO/EOP, Mary E. Glynn/WHO/EOP, Lori L. Anderson/WHO/EOP  
cc: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP  
Subject: Trade reporter call re. food safety meetings

Lori -- please forward to Lorrie McHugh who's not showing up on e-mail. Thanks.

John Briley of Food Chemical News (544-1980) called to talk to me about a series of meetings I am hosting this week on the President's food safety initiative. Below are background and talking points. Pat -- do you want to return the call as we discussed? I'd be happy to talk to him on background if that's appropriate. Let me know what you suggest.

**Background** On January 25th the President announced a food safety budget initiative, including a new national early warning system for foodborne illness. He also directed the Secretaries of HHS and Agriculture, and the Administrator of the EPA, to work with consumers, producers, industry, states universities, and the public to identify ways to further improve the safety of our food supply through government and private sector actions, including public-private partnerships.

I am hosting 8-10 White House meetings this week with White House and agency staff as described below. The meetings are with 5-10 organizations at a time. The organizations were recommended to me by the agencies. In addition to DPC, staff from OMB and VP's office are participating in some meetings.

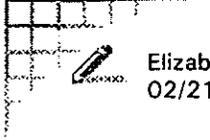
#### **Talking Points about White House Meetings**

In January the President asked the Secretaries of HHS and Ag, and EPA Administrator Browner, to work with consumers, industry, producers, states and scientists to find ways to further improve the safety of our food supply. The President asked for a report in 90 days.

The agencies have started a process of consultation with interested groups.  
We are reaching out to groups in a number of ways.

Last Thursday the agencies made a discussion draft of the report available, and announced in the Federal Register that they will host two public meetings to discuss the report (March 5th and early April). The agencies are also setting up a docket for written comments.

This week White House staff along with FDA, USDA, and CDC are meeting with a cross-section of organizations (e.g. consumer, industry, producer, and science organizations) to hear their initial thoughts about the initiative and the report. These smaller meetings provide an opportunity for White House and agency staff to listen to stakeholders ideas and concerns in a smaller setting. They are one way we're reaching out to the public as we implement the initiative.



Elizabeth Drye  
02/21/97 03:14:40 PM

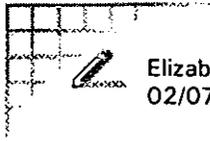
Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

cc:

Subject: Release of Food Safety Report

You should know that yesterday we published a Federal Register notice announcing the availability of an (OMB-cleared) USDA/FDA/CDC discussion draft of the food safety report the President's requested. The report is due to POTUS April 24, and over the next two months we will consult extensively with stakeholders on its content. I'm hosting 10 short meetings here next week with WH offices and agencies to hear from key industry and consumer players, and the agencies are hosting two public meetings in March. Just wanted you to know in case any of the many players on the issue feel they need to bend your ear as we go forward. I'm working closely w/OMB (particularly Katzen) to keep us all on the same page. So far so good.



Elizabeth Drye  
02/07/97 04:40:38 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc:

Subject: Monday's event, radio address, and food safety

We are on for child safety seat radio address next Saturday and in good shape. Rahm has asked DOT to put together necessary materials and get to me by Tuesday a.m. Christa Robinson is helping Mike and me do invites for Monday event-- she's following through since I am going to be gone this weekend and Monday.

Also, I'd like to talk to one or both of you briefly about food safety follow-up Tuesday. As you know, POTUS asked agencies to report back in 90 days with additional measures. USDA and FDA want and need the WH to coordinate the 90-day effort. I'd like to get your signoff on (1) my taking the lead in this effort for WH (OMB and VP's office should be fine with that) and (2) my proposed approach. Can I schedule 10-15 min w/one or both of you Tuesday?

THE WHITE HOUSE  
WASHINGTON

Elaina -

File -  
Food  
Safety

Attached are

- ① Shalala/Glickman memo to POTUS on 98 budget request, for background and context.
- ② Previously cleared radio address (never delivered).
- ③ Early warning system description (will change).
- ④ Previous directive.



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

*FY I - As  
we discussed  
only 1/3 of  
the requested  
funds are in  
budget, so  
DEC 13 1996 numbers  
don't hold, and  
scope has  
been  
narrowed.*

**MEMORANDUM FOR THE PRESIDENT**

**SUBJECT: New Initiative to Protect Americans' Food Supply**

**PURPOSE**

We wanted to let you know about a joint initiative we are proposing, to reduce death and disease caused by food poisoning. This food safety initiative, which is now under consideration as part of the FY 1998 budget process, would affect every American but would involve only a modest amount of new funding (about \$100 million).

**BACKGROUND**

Last month's outbreak of E. coli-contaminated apple juice sickened dozens and killed one child. There was a similar outbreak involving hamburger in the northwest during the early days of your Administration. Although those outbreaks received nationwide publicity, the reality is that every year millions of Americans are sickened, and an estimated 9,000 die, from E. coli, Salmonella, Cryptosporidium and other foodborne "pathogens."

Hospitalization costs alone for these illnesses are over \$3 billion a year, and costs for lost productivity have been estimated to range, for seven specific pathogens, between \$6 and \$9 billion; total costs for all food poisonings are likely to be much higher. In August, you announced that USDA was adopting modern requirements to make meat and poultry safer. Last year, HHS adopted similar requirements for seafood. This initiative would strengthen those programs and implement important measures to make the rest of the food supply safer.

Today, our understanding of many pathogens is limited; for some, we do not even know how much must be present in food to cause illness. The public health system has limited means to identify and track the causes of foodborne illness; and Federal, State, and local food safety agencies need to improve coordination for more effective response to outbreaks of illness. Years go by before most non-meat plants receive an FDA or State inspection, and increasing quantities of imported foods flow into this country daily with little scrutiny by FDA inspectors. And food processors, restauranteurs, supermarket managers, and consumers often lack basic understanding of the threat of foodborne contaminants and how to protect against them.

Page 2

During the past three months, experts at our two departments and the EPA have worked intensively to develop a highly targeted initiative to address this issue; a summary has been shared with your staff. OSTP and State health officials have also been involved in the development of this plan, which addresses one of the initiatives identified in your recent report, "Meeting the Challenge: A Research Agenda for America's Health, Safety, and Food (1996)."

### PROPOSAL

The good news is that we have the scientific talent and wherewithal to reduce the number of illnesses that do occur and to ensure that the United States will have a safer food supply. We believe that this Administration should launch a major new initiative next year that will positively affect the lives of all Americans. We would work through this initiative to reinvent the currently inadequate system devised by Theodore Roosevelt at the turn of the century into one that incorporates the science and technology of the 21st Century. Moreover, these gains can be achieved with a relatively small investment in new resources--around \$100 million--that can yield enormous benefits in health and public confidence in the food supply. Indeed, it is estimated that we can prevent 2 to 9 million illnesses, head-off up to 3,000 deaths, and save society billions of dollars in preventable health care costs each year.

The proposed interagency food safety initiative includes the following actions:

- o Build up the "early warning" and surveillance systems for foodborne illnesses and track them to their cause.
- o Increase FDA's inspections of food processors and imported foods, and improve collaboration with States in that area.
- o Better coordinate when disease outbreaks occur, including electronic communication among Federal, State, and local health authorities.
- o Expand education of food processors, retailers, restauranteurs, and consumers about the latest safe food processing, storage, and handling techniques.
- o Improve risk assessment for food pathogens, so that regulators can make the most cost-effective decisions.
- o Expand and better coordinate Federal research efforts on pathogens that pose the highest risk to the public.

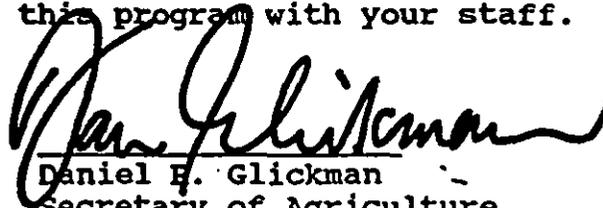
In addition, we recognize that fundamental change of the food safety system is necessary, and we propose the development of a comprehensive, strategic plan to improve the food safety infrastructure through broad-based discussions involving all stakeholders.

Page 3

A number of industry, academic, and other reports, such as those of GAO and NAS, have indicated that such reforms are necessary. We believe, therefore, that this initiative will be well received by the food industry and the general public. This interagency food safety initiative can be a significant feature of your domestic agenda for the coming year, and will accomplish an historic advance in public health. If you concur, we will coordinate further preparation of this program with your staff.



Donna E. Shalala  
Secretary of  
Health and Human Services



Daniel H. Glickman  
Secretary of Agriculture

**DRAFT 10/28 6pm**

**Fighting Foodborne Disease: A New "Early Warning System"**

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better, particularly in our efforts to reduce or eliminate disease caused by microorganisms and other contaminants carried by food. The Council for Agricultural Science and Technology, a private non-profit organization, estimated in its 1994 report *Foodborne Pathogens: Risks and Consequences* that as many as 9,000 deaths and 6.5 to 33 million illnesses in the U.S. each year are food-related; other studies have found similar results.

We also face special challenges as we enter the 21st Century. Novel pathogens are emerging. Long-understood pathogens are growing resistant to the treatments we have relied upon. Lowering of trade barriers has led to record levels of food imports. Companies now routinely move food from the furthest reaches of the world to the American dinner table overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention and control, research, and education.

Today, President Clinton announced a new national early-warning system for outbreaks of foodborne disease. The Administration will double the number of food safety surveillance sites around the country from 5 to 10, enhance their technology, and link them together to create a powerful new national network to detect, respond to, and prevent outbreaks of foodborne illness. In collaboration with state and local health departments, we will look intensively for cases of foodborne disease, and will make every effort to understand how the food came to be contaminated, and how contaminated food is being passed into our kitchens. At the ten "sentinel" sites, we will fund more scientists to investigate food-related disease outbreaks -- new "disease detectives." We will also fund enhanced lab capabilities and use the latest science to develop DNA "fingerprints" of harmful microorganisms. And we will link the sites electronically with the latest computer technology so that we can identify related outbreaks that occur in different areas of the country.

This new national early warning system will help us catch outbreaks early, preventing illness and possibly deaths. The ten sentinel sites will also gather data that will advance our understanding of foodborne illness and further our efforts to identify and prevent harmful contamination in our food.

This initiative builds on the steps the Administration has taken to date to strengthen our food safety system. This summer the President issued new meat and poultry regulations. He replaced a century old system that still relied on touch and smell with a hazard analysis and critical control points (HACCP) system -- a new science-based approach geared toward today's microbiological threats. Data gathered by the ten sentinel sites will help us implement this new approach by helping us understand where food is most likely to become contaminated. This Administration has also modernized our seafood safety programs using the HACCP

approach. And in August the President signed the Food Quality Protection Act to protect Americans, and especially our children, from unsafe levels of pesticides in foods.

These steps, taken together, will help keep our food supply safe as we enter the 21st Century. But there is more to do. The new circumstances we face require strengthened systems of prevention, surveillance, research, and education. The President today asked Secretaries Shalala and Glickman, and Administrator Browner, to recommend to him within 60 days additional measures the Administration should take to further improve the safety of the nation's food supply.

**Initiative:** The Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), and the Department of Agriculture (USDA), in cooperation with state and local health departments, are taking the following steps to establish the new early warning system:

**1. Increase the number of food safety "sentinel" sites from 5 to 10.**

CDC, FDA, and USDA currently support 5 sentinel sites run by state and local governments to track foodborne illness (Northern California, Connecticut, Minnesota, Oregon, and metropolitan Atlanta). These sites do not adequately cover the U.S. population; in particular, there is underrepresentation of the mid-Atlantic, south, and south-west regions. Under this initiative, we will expand the number of sites from 5 to 10.

*[Cost: including enhancements outlined below, \$600,000/site, for a total of \$3,000,000 for five additional sites]*

**2. Create foodborne disease electronic communication network.**

A key element in any early warning system is the ability to communicate unusual findings, and to be able to swiftly recognize patterns of illness within and among sites that may indicate larger outbreaks. The need for rapid communication applies to both epidemiologic data and laboratory data. For epidemiologic data, there is a need for swift electronic reporting of cases to health departments in sentinel sites, as well as rapid reporting from sentinel sites to CDC and rapid communication to FDA and USDA for appropriate follow-up to prevent further illness. Laboratory data also need to be quickly communicated both back to the physician and laboratory sending the sample and to CDC. Currently available technology also permits the transmission of DNA "fingerprints" from bacteria and other microorganisms; there is the potential to create large databases containing these fingerprints much like the fingerprint libraries maintained by law enforcement agencies so that there can be immediate recognition of relationships among isolates (samples isolated and identified from individual disease cases).

To respond to these opportunities and meet these needs CDC, FDA, and USDA will fund a new computer network and database system that will capture bacterial fingerprints in a centralized database and will electronically link the sentinel sites and the three government agencies. This technology will, for example, permit immediate

recognition that an *E. coli* O157:H7 isolate from a patient in Oregon was identical to an isolate from a patient in Minnesota -- which, in turn, may allow public health investigators to determine that a product distributed to both Oregon and Minnesota was contaminated with the organism.

*[Cost: for computer hardware and software purchase and development, \$100,000/site for 5 sites, \$450,000 for CDC, \$350,000 for FDA. Total for 5 existing sites, CDC, and FDA, \$1,300,000.]*

### **3. Modernize Laboratories at Sentinel Sites.**

Upgrade laboratory capability so that sites can utilize DNA fingerprinting and other highly sophisticated techniques to identify infectious agents or other causes of illness. Reinforce the existing Salmonella serotyping system. This new capacity will allow us to identify the same fingerprint on bacteria from two widely separated cases. It will also provide a basis for subsequent epidemiologic investigation and development of strategies to prevent future outbreaks.

*[Cost: at each site, purchase of equipment and supplies necessary for DNA probe, PCR, and pulsed field gel electrophoresis analysis of specimens (\$50,000), and hiring of additional technicians for work in enteric diseases (\$100,000). Total for 5 existing sites: \$150,000/site times 5 sites = \$750,000. CDC will also need to have enhanced capabilities and additional personnel to provide technical back-up to the states -- cost to CDC, \$150,000, and \$650,000 to produce laboratory serotyping reagents. Total for 5 sites and CDC, \$1,550,000.]*

### **4. Increase "Disease Detectives" to Investigate Outbreaks**

CDC, FDA, and USDA will fund additional experts to investigate and control foodborne disease outbreaks. While sophisticated laboratory studies can identify causes of illness and show relationships among isolates, there is still a need for people to make certain samples are collected correctly, and to do the investigative work (i.e., to trace back and try to find out why outbreaks of illness occurred, so that preventive measures can be put in place).

*[Cost: at each site, hiring of additional persons to assist with epidemiologic investigations/data management (\$150,000). For 5 existing sites, total of \$750,000. At CDC, additional 2 epidemiologists, to help in coordination of activities at a national level, \$140,000. FDA \$150,000 Total for 5 sites, CDC, and FDA \$1,040,000.]*

Here's our previous directive.

We will amend to ask

Secretaries to work

w/ industries and consumer  
groups and report back  
in 90-days.

Received 11-1-96

6:12 p.m.

MEMORANDUM TO: Bruce Reed  
Jack Quinn  
T.J. Glauthier  
Nancy Ann Min  
Sally Katzen

FROM: Elizabeth Drye, 456-5573

SUBJECT: Draft Presidential Directive on Food Safety

FOR YOUR IMMEDIATE REVIEW

----- DRAFT 10/31/96 -----

Memorandum on Improving the Safety of the Nation's Food Supply  
November 2, 1996  
Memorandum for the Secretary of Agriculture, the Secretary of  
Health and Human Services, and the Administrator of the  
Environmental Protection Agency.

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better in our efforts to eliminate disease caused by microorganisms and other contaminants. Americans still suffer thousands of food-related deaths and millions of food-related illnesses.

The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to treatment. Americans consume record-levels of imported food, some of which moves across the globe overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention, research, and education.

My Administration has already taken a number of steps to improve food safety. We modernized the meat, poultry, and seafood safety systems. I signed into law new legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. Earlier today I announced a new national early warning system for foodborne illness. The system will allow us to respond more quickly to disease outbreaks and to better prevent them in the future. But we need to do more.

I hereby direct that you report back to me within 60 days and recommend additional measures to improve the safety of our food. Your recommendations should include ways to improve surveillance, inspections, research, education and coordination among local, state, and federal health authorities. In particular, I direct you to consider ways to: increase the number of experts investigating food-borne disease outbreaks; give health experts state-of-the-art technology to trace infectious agents to their source; and use advanced communications networks to speed outbreak information to health authorities across the country.

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11/1/96 FINAL

PRESIDENT WILLIAM J. CLINTON  
RADIO ADDRESS TO THE NATION  
NOVEMBER 2, 1996

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

I believe this is a positive and hopeful time...an age of enormous possibility...a chance for us to build a country and a world that is stronger and safer and full of more possibility than any that existed before.

The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. Several children, some as young as 2, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria.

I imagine just about every parent in America remembers what E Coli can do. In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Food and Drug Administration, we stopped this week's outbreak of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. The Centers for Disease Control and Prevention notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get its juice off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. Now, of the 5 children who were hospitalized in Seattle, all are recovering.

This quick response is part of our larger effort to protect the health and safety of all our people. Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us. We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90 years. I signed into law legislation to keep harmful pesticides off our fruits and vegetables --

*Elaine -  
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and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

**Today, we add to the solid foundation of food safety we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.**

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the CDC sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of "disease detectives" to investigate and control food-borne disease outbreaks...to give health experts state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

**With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will do everything in our power to make sure that the world's most bountiful food supply is also the safest.**

By protecting the public health, by bringing our people together around our basic values of opportunity, responsibility, and community, we will surely make this an age of possibility for all Americans.

Thanks for listening.

Here's what we'd like to be able to say  
on early warning system

years. I signed into law legislation that protects our fruits and vegetables from harmful pesticides -- and legislation that keeps our drinking water safe and pure.

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

**Today, we add to the solid foundation of health security we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria.**

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the Centers for Disease Control sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, we will use state-of-the-art technology to keep our food safe. We will increase the number of expert disease detectives to investigate and control food borne disease outbreaks. We will give these experts the technology to use revolutionary new DNA fingerprinting methods to trace infectious agents to their source, and create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use cutting-edge communications networks to speed outbreak information from these centers to hospitals and public health agencies all across the country.

Third, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to ensure the safety of our food.

**With these initiatives we say, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children.**

Today, in America, no parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.

Key  
Page 3/4



DRYE\_E @ A1  
01/22/97 12:32:00 PM

*Larry Haas*

Record Type: Record

To: Bruce N. Reed  
cc: Elena Kagan  
Subject: Need help w/Raines and Food Safety

Raines staff won't clear or advise on final event materials until you bring the event up at 7:30 and get a specific group decision to unveil food safety budget numbers before budget goes to Hill. Again, no policy disagreement here from PADS or OIRA, just Raines insistence that this consultation take place at 7:30. A phone call to Raines might suffice.

It would help to get closure on this today as Departments need to work w/OMB on how and at what level of detail we present budget request numbers. Right now they're planning to give total request (\$42 million) and total for early warning system (\$11.5 million), and indicate remainder goes to seafood inspectors, education, and research, but not break it out further.

We are otherwise on track and I am working w/David Shipley on remarks. He will have a draft for you in the a.m.

Paper

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- remarks
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Dept will want to  
do press releases  
to amplify.

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FLR -

Food Safety amendment

leaked to trade press -

nothing terrible here, and  
some positive feedback  
from industry on early warning  
system (negative remarks on  
user fees). Bruce is  
not alarmed  
- Elizabeth

OPTIONAL FORM 99 (7-90)

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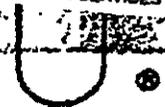
# FOOD CHEMICAL NEWS

To: *Sue Darcey*  
 NSN 7540-01-317-7368

From: *Sally Fernandez*  
 Phone # *202-7025*  
 Fax # *202-7025*

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## WHITE HOUSE POISED TO RELEASE DETAILS OF INTERAGENCY FOOD SAFETY PLAN

The Clinton administration may be planning to unveil its interagency food safety initiative as early as this week, but details of the final document were still being hammered out late last week and an initial release date of Jan. 21 was scrapped on Friday, Jan. 17.

The package of food safety efforts, some already being implemented at the Food and Drug Administration and USDA's Food Safety and Inspection Service, are being pitched as an item in the administration's budget request for fiscal year 1998 (Oct. 1, 1997 through Sept. 30, 1998). As of press time, the amount of the budget request was in flux, with some estimates as high as \$90 million and some as low as \$50 million.

The initiative, which lays out steps to combat foodborne illness in the near term and gives details of future plans for food safety research and other measures, is the administration's blueprint for responding to food safety concerns for the next four years and a means to beef up FDA's shrinking funding pool.

One Washington insider said Clinton's announcement of the plan will be "very general and lacking in substance, and will address the need for early-warning networks and the need for strengthening [food safety] agencies." That source echoed others' comments that government has made a concerted effort to meet with the industries and consumers affected by the initiative.

Industry sources said the initiative likely will contain a range of safety reforms following on the success of USDA's much-touted meat and poultry HACCP rule and the recently enacted Food Quality Protection Act. Measures to guard against contamination of fresh-cut produce and eggs reportedly are in the initiative, and are believed to be HACCP-based. "In general, it covers all the things they wanted to do but haven't done so far," one source said.

An FDA official confirmed that consumer education is a key part of the initiative and that "industry will have a role in that, just as they wanted to." On-farm food safety measures, included in an earlier draft, have been dropped from the final document, a source said (See FOOD CHEMICAL NEWS, Dec. 9, Page 20).

A HACCP program is under development at FSIS for non-shell eggs, but is not tied to the food safety initiative, a USDA staffer said. That program, which will not address shell eggs, "will be a proposed rule in and of itself," but will not be released any time soon, that staffer commented.

(See FOOD SAFETY INITIATIVE, Page 32)

(FOOD SAFETY INITIATIVE, continued from Page 3)

### Food Safety Initiative Details Have Been Kept Close to the Vest

Details of the food safety initiative have been closely guarded. Federal food regulators have yet to brief House Agriculture Committee staff on the measure despite two requests to do so, said a committee staffer. But since the initiative is tied to President Clinton's budget request, the administration has leeway not to reveal details until the spending plan is released to Congress, the staffer added.

FDA and USDA officials are reluctant to discuss the initiative prior to an official announcement by the White House because of the unusual chain of command for the project. FDA has been the lead agency on the initiative, acting as a clearinghouse for input from USDA, the Centers for Disease Control and Prevention and the Environmental Protection Agency.

But because the initiative was ordered by Health and Human Services Secretary Donna Shalala, FDA is in the unusual position of having to defer to a higher power, the agency is usually given a long leash to carry out its mission. So FDA officials are hesitant to release details of this project for fear of stepping on bigger toes, and are even reluctant to confirm or deny hearsay. "I will only confirm that this [project] is unique," one FDA food official said, in reference to the secrecy of the initiative.

FDA did confirm that the initiative is "very HACCP-like," in that it relies on government cooperation with industry and consumer groups — as opposed to straight regulatory missives — to advance food safety. The inclusion of non-government factions in the initiative's development illuminates HHS' awareness that a heavy-handed set of policies would be unlikely to survive congressional scrutiny.

### Sentinel Site Surveillance Program Could Expand; CDC Could Boost Laboratory Capabilities under Initiative

According to a Nov. 2 draft of comments prepared for President Clinton to announce the

initiative, the measure would establish a nationwide early-warning system for foodborne illness by expanding the joint CDC-FDA-USDA sentinel site program. Some industry sources touted the move toward investing in surveillance and disease reporting as an important tool for measuring success with USDA's HACCP program for meat and poultry.

According to the earlier draft, the administration plans to double the five "sentinel sites" to 10 to identify and track contaminants in foods to prevent future outbreaks. The five sites currently are located in Northern California, Oregon, Connecticut, Minnesota and Atlanta. "However, these sites do not adequately cover the United States — there is underrepresentation of the mid-Atlantic, south and southwest regions," said the draft document. The administration plans to request applications from interested states, and CDC would consider which additional five sites would be included in the two-year-old program.

Among other initiatives, the draft document said the administration would: create new electronic and computer networks to allow for rapid dissemination of epidemiologic and laboratory data; introduce state-of-the-art laboratory capabilities like "DNA fingerprinting" to rapidly identify diseases and sources; and increase the number of "disease detectives" who investigate and control foodborne disease outbreaks. It appears the White House was poised to announce the interagency food safety initiative on the heels of a recent outbreak of *E. coli* O157:H7 linked to unpasteurized apple juice, but then opted to delay the announcement.

The November draft document said Clinton would ask USDA, HHS and EPA officials to find ways to step up food safety protections by improving inspection, research, education and coordination among local, state and federal health authorities; it appears federal regulators have been working on that part of the initiative for several months.

The draft noted the administration's view that "the complex system of delivering food from the farm to the tables of American consumers offers

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January 20, 1997

FOOD CHEMICAL NEWS

opportunities along the route for contamination and mishandling." But the U.S. food supply is among the safest in the world, the announcement said. The administration estimates that between 6.6 and 33 million cases of foodborne illness occur each year, with up to 9,000 deaths.

### Congressional Critics Already Taking Aim at User Fee Provisions

Because the initiative is budgetary — i.e., FDA is asking Congress for money to implement the plan — the program must be cleared by Congress. The initiative is likely to move forward in Congress regardless of when President Clinton announces it publicly, an FDA source said, but it probably will not be given priority over other budgetary initiatives in Congress. As for congressional action on the initiative, the source said: "Who knows what they will do?"

Critics in Congress already are taking aim at the reported user fees that are slated to help fund the food safety measure, a congressional official noted. The Clinton administration wants to fund the new package through new user fees on food additives, animal drugs and meat plant inspections, the official said.

Such tolls are likely to be unpopular in Congress and among powerful regulated industries. The official branded the measure "dead on arrival," since new user fees for the food industry have failed in the congressional budget review process in past years.

However, others in Congress may take a softer stance toward user fees because such fees have brought quick and dramatic improvements in relations between FDA and the pharmaceutical industry. Through organizational realignments and revised application review programs — largely funded with user fees — FDA's Center for Drug Evaluation and Research slashed review times and approved 53 new molecular entities (NMEs) in calendar year 1996.

That approval total, one of the major yardsticks of the agency's drug review performance, shattered the prior modern record of 35 NMEs for one year. Support for a continuation of user fees is fairly strong in the drug industry.

For the remaining chunk of funding for the food safety initiative, FDA may include a far-reaching user fee on FDA-regulated food establishments and distribution facilities.

### INSPECTOR LEHMAN RESIGNS, CONTINUES LEGAL FIGHT AGAINST CANADIAN IMPORT INSPECTION PRACTICES

After 34 years as an inspector and four months of fighting reassignment by the Food Safety and Inspection Service, whistleblowing import inspector Bill Lehman is resigning effective Feb. 1.

Lehman has spoken out against FSIS' Canadian meat inspection practices since the 1989 U.S.-Canada Free Trade Agreement altered them. Under the new procedures, and even under their 1992 "streamlining," Lehman said that he might easily be giving contaminated meat his inspection stamp. "You've got to realize that this isn't standard operating procedure for a meat inspection program," Lehman told FOOD CHEMICAL NEWS last year. "We actually notified the Canadian shippers of which truck we wanted to inspect, and asked them to put the samples at the rear of the truck" (See FOOD CHEMICAL NEWS, Dec. 2, Page 26).

Lehman withstood a suit from his Sweetgrass, Mont., station's owners in 1992, but last September FSIS itself told him to move. "Over the past several years," the agency wrote to Lehman, "your conflicts with the management of Establishment I-264, as well as other incidents, have required unacceptable amounts of supervisory time and effort to resolve." Lehman was also charged with two infractions, leading the agency to offer him a choice of five urban locations where he would be under "closer supervision."

Lehman declined to choose, then refused to leave. FSIS selected Detroit and instructed Lehman to move there by Jan. 18 or face dismissal. Several days before the allotted deadline, Lehman took matters into his own hands and announced his resignation. "I saw no let-up in the animosity that exists between me

1/23/97

**PRESIDENT WILLIAM J. CLINTON  
WEEKLY RADIO ADDRESS  
THE WHITE HOUSE  
JANUARY 25, 1997**

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

Almost a week ago, in my inaugural address, I told the American people in broad terms what our vision must be -- to lead this country into the 21st century with the American Dream alive for all our children; with the American promise of a more perfect union a reality for all our people; with America's bright flame of freedom illuminating the world.

I believe we will make real this vision by doing what we have always done in moments of great change: By holding fast to our enduring values. Central among these is the belief that Americans are entitled to clean air, safe food, pure water. Hard-working American parents deserve the peace of mind that comes from knowing that the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State and in 6 other Western states this fall. Apple juice contaminated with a deadly strain of E Coli bacteria reached supermarket shelves. Several children -- some as young as 2 -- were hospitalized. One child died. *✓ starts*

I imagine just about every parent in America remembers what E Coli can do. Four years ago this very week, tragedy struck hundreds of families in the Western United States when they took their children to fast-food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children lost their lives.

*no numbers?* There's simply no excuse for this. Though America has the world's safest food supply, as many as 33 million Americans are made sick by food-borne diseases every year. As many as 9,000 people die. *✓*

That's why my administration has made it a top priority to protect the health and safety of all Americans. We strengthened the Community Right to Know law, which requires industries to tell our citizens what chemicals are being released into our neighborhoods. I signed into law legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. We put in place strong new protections to ensure that seafood is safe. And we announced steps to modernize our meat and poultry inspection system for the first time in 90 years. Those new safety rules will begin to take effect next week. From now on,

[ all meat and poultry plants will be required to test for E Coli. ]



**We have built a solid foundation of health security for our families. But, clearly, we must do more. (No parent should have to think twice about the juice they pour their children at breakfast or a hamburger ordered during a dinner out.) That is why today I am announcing new steps to keep our food safe and to protect our children from deadly bacteria.**



First, we will put in place a nationwide early-warning <sup>burden spots</sup> system for food-borne illness. Right now, the Centers for Disease Control sponsors 5 centers across the country whose mission is to post a look-out for food-borne diseases -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will increase the number of these sites from 5 to 8. And we will link them to other state health agencies. This full-scale early-warning system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, we will use state-of-the-art technology to keep our food safe. We will increase the number of expert disease detectives to investigate and control food-borne disease outbreaks. We will give these experts the technology to use sophisticated new DNA fingerprinting methods to trace infectious agents to their source. We will create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use advanced communications networks to speed outbreak information to hospitals and public health agencies around the country.

Third, I am directing the Secretaries of Agriculture and Health and Human Services, as well as the Administrator of the Environmental Protection Agency, to work with communities, businesses, consumer protection groups, and all levels of government to come up with additional measures to improve food safety. I want them to focus on what sort of public-private partnerships we can develop to meet this goal. And I want them to report back to me with their findings within 90 days.

Finally, let me add that all these new investments are paid for line-by-line, dime-by-dime in the balanced budget I will officially send to Congress next month.

**With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children. Together, with steps like these, we will see to it that our people find a land of new promise in the 21st century.**

Thanks for listening.

NOTE TO BRUCE AND ELENA

FROM: Elizabeth Drye

SUBJECT: 7:30 Meeting / Food Safety

Frank is expecting DPC to raise at 7:30 whether and how to discuss 98 budget numbers in the food safety radio address and accompanying materials. He may just want a straight decision on whether to give any numbers, but his staff tell me he may want to discuss details. Here is my quick assessment of the options:

1. Give no numbers. Simply say we'll give numbers when we release budget. Pros: consistent with general policy. Cons: event is less newsworthy, invites speculation, wrong numbers have already been in trade press.
2. Give total number for initiative, \$42 million. Pros: better information. Cons. Not much better.
3. State that we'll request \$42 million total -- \$11.5 million for early warning system and the remainder for seafood safety inspectors, research, education, and training. (Current draft fact sheet). Don't elaborate on allocation. Pros -- much more concrete, leaves HHS room to make further adjustments, keeps focus on early warning system. Cons -- still ambiguous.
4. Spell how USDA/FDA/CDC will allocate \$42 million among early warning system, inspectors, education, research and training. Pros: more detail for reporters. Cons: HHS may need to adjust allocation later.

I like option 3.

Thanks for your help.

*Glenn / Bruce  
FZI*

NOTE TO DAVID SHIPLEY --

FROM: Elizabeth Drye

SUBJECT: Radio Address

Attached are fact sheet, directive, and my edits to your previous food safety radio address. Bruce has not had time to review. I suggest you do a first redraft and then we'll share with him in the a.m. Have a nice flight.

**President Clinton Announces new Measures to  
Reduce Foodborne Illness**

January xx, 1997

-- DRAFT --

**Announcement**

- o President Clinton announced a new Early Warning System to help catch and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. The Administration will:
  - o increase the number of active food safety surveillance sites across the country from 5 to 8;
  - o equip these "sentinel" sites and other state health departments with state-of-the-art technology, including DNA "fingerprinting" to identify infectious agents and additional expert disease detectives to trace outbreaks to their source;
  - o link the sites, other state health departments, and Federal public health agencies electronically to allow rapid sharing of lab data -- including digitized fingerprinting data -- nationwide; and
  - o at the sentinel sites, investigate foodborne illnesses in depth to strengthen the scientific basis for our hazard prevention programs.
  
- o Second, President Clinton directed the Secretaries of Health and Human Services and Agriculture, and the Administrator of the Environmental Protection Agency -- working with consumers, producers, industry, states, and the public -- to identify new ways to advance food safety through government and private sector actions, including public-private partnerships. The President asked for recommendations in 90 days.
  
- o Third, President Clinton announced he will request \$42 million in his 1998 budget to fund the Early Warning System, increase seafood safety inspections, and expand food safety research and education. (41.5 million)

**Background**

- o Although America's food supply is unmatched in quality and quantity, we can do more to eliminate disease caused by foodborne microorganisms. As many as 9,000 deaths and 33 million illnesses each year are food related, imposing an estimated \$3 billion in hospital costs.
  
- o We face new challenges involving food safety as we enter the 21st Century. Novel pathogens are emerging. Familiar ones are growing resistant to treatment. Americans eat in restaurants more. And we eat more imported foods, some of which comes from across the globe overnight. These changes require strengthened systems of coordination, surveillance, prevention, inspections, research, risk assessment and education.

### **Building on Our Accomplishments**

- o President Clinton took a number of steps to modernize food safety programs in his first four years and prevent foodborne illnesses.
  
- o The President put in place new science-based, hazard prevention systems for seafood, meat, and poultry. In 1995, President Clinton issued strong protections to ensure seafood safety. In July, 1996 President Clinton announced new rules -- that begin to take effect next week -- to modernize the nation's meat and poultry inspection system for the first time in 90 years. The new Early Warning System will gather critical scientific data to further improve these prevention systems.
  
- o In August, 1996 President Clinton signed the Food Quality Protection Act -- a comprehensive overall of our food safety laws that regulate pesticides in food. The new law establishes a single, strong health-based standard, creates special safeguards for children, protects public health and safety by using the best science available, and, for the first time, provides Americans with the "right-to-know" about health risks from pesticides. Last August, President Clinton also signed a new safe drinking water law that strengthens protections to ensure that American families have clean, safe tap water to drink.

SUBJECT: Draft Presidential Directive on Food Safety

FOR YOUR IMMEDIATE REVIEW

---- DRAFT 01/16/97 ----

Memorandum on Improving the Safety of the Nation's Food Supply  
January 25, 1996  
*Memorandum for the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency.*

Americans rightly expect to have the world's safest food supply. Although our food is unmatched in quantity and quality, we can do better in our efforts to eliminate disease caused by microorganisms and other contaminants. Americans still suffer thousands of food-related deaths and millions of food-related illnesses.

The 21st century will present new and greater challenges. Novel pathogens are emerging. Long-understood pathogens are growing resistant to treatment. Americans eat more foods prepared outside the home, and we consume record levels of imported food - some of which moves across the globe overnight. These changing circumstances require greatly strengthened systems of coordination, surveillance, prevention, research, and education.

My Administration has already taken a number of steps to improve food safety. We modernized the meat, poultry, and seafood safety systems. I signed into law new legislation to keep harmful pesticides off our fruits and vegetables -- and legislation that keeps our drinking water safe and pure. Today I announced a new national early warning system for foodborne illness. The system will allow us to respond more quickly to disease outbreaks and to better prevent them in the future.

But we need to do more. Government, consumers and industry must work together to further reduce foodborne disease, and to ensure our food supply is the safest in the world.

I hereby direct that you work with consumers, producers, industry, states and the public to identify additional ways to improve the safety of our food supply through government and private sector action, including public-private partnerships. Your recommendations should identify steps to further improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities. You should report back to me with in 90 days with your recommendations.

11/1/96 FINAL

PRESIDENT WILLIAM J. CLINTON  
RADIO ADDRESS TO THE NATION  
NOVEMBER 2, 1996

Good morning.

Today, I am pleased to announce a major new step toward protecting the health and safety of all Americans -- especially our children.

I believe this is a positive and hopeful time...an age of enormous possibility...a chance for us to build a country and a world that is stronger and safer and full of more possibility than any that existed before.

The way we will master this moment of change is the way we always have: By holding fast to our enduring values. Central among these is the belief that Americans are owed the basic security of knowing that the food we eat, the air we breathe, the water we drink will not make us sick. Hard-working American parents deserve the peace of mind that comes from knowing the wholesome meal they set before their children is safe.

That's why I was so concerned by what happened in Washington State earlier this week. Several children, some as young as 2, got very sick from drinking apple juice contaminated with a deadly strain of E Coli bacteria. *State and 6 other western states this fall.* *reached supermarket shelves.*

*all recovery facts*

*[Several children, some as young as 2, were hospitalized, and one died]*  
I imagine just about every parent in America remembers what E Coli can do. *Four years ago [this week]* In 1993, tragedy struck hundreds of families in the Western United States when they took their kids to fast food restaurants that served them hamburgers tainted by the E Coli bacteria. 500 people became ill -- some of them, severely ill; and 4 children died.

*Cap? or nd add*

Fortunately, we have made progress since 1993. Because of the careful work of state and local health authorities, and the swift and efficient action of the Food and Drug Administration, we stopped ~~the week's outbreak~~ *the recent* of E Coli in its tracks. As soon as we got the news, we went on an around-the-clock alert. The Centers for Disease Control and Prevention notified health officials in all 7 states where the juice was available. We worked with the manufacturer to get its juice off supermarket shelves. And we put doctors and hospitals across the country on watch for symptoms of E Coli infection. Now, ~~of the 5 children who were hospitalized in Seattle, all are recovering.~~

This quick response is part of our larger effort to protect the health and safety of all our people. ~~Under my administration, we strengthened the Community Right to Know law, which requires industries to tell our citizens what substances are being released into the world around us.~~ We put in place strong new protections to ensure that seafood is safe. We announced steps to modernize our meat and poultry inspection system for the first time in 90 years. I signed into law legislation to keep harmful pesticides off our fruits and vegetables --

*meat and poultry*  
Next week these rules begin to take effect -- plants must have in place new sanitation procedures and all slaughter

and legislation that keeps our drinking water safe and pure.]

And, just a year ago, I stood with America's families to fight off efforts to weaken our most basic safeguards for clean air, clean water, and clean food.

**Today, we add to the solid foundation of food safety we've built for our families. I am announcing new steps to keep our food safe and to protect our children from deadly bacteria. No parent should have to think twice about the juice they pour their children at breakfast, or a hamburger ordered during a dinner out.**

First, we will put in place a nationwide early-warning system for food-borne illness. Right now, the CDC sponsors 5 centers across the country whose mission is to post a look-out for food-borne illnesses -- like E Coli and Salmonella. Working with state and local governments, these "sentinel sites" stand watch over our public health. Today, I am announcing that we will double the number of these sites from 5 to 10. This national system will enable us to catch outbreaks sooner, and give us the data we need to prevent outbreaks from happening in the first place.

Second, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within 60 days with additional measures to further improve the safety of our food.

These recommendations should tell us how we can further improve inspections, research, education, and coordination among local, state, and federal health authorities. I want the agencies to look at ways to increase the number of "disease detectives" to investigate and control food-borne disease outbreaks...to give health experts state-of-the-art technology to trace infectious agents to their source...to use advanced communications networks to speed outbreak information to health authorities across the country.

**With this new early-warning system to track food-borne illness, we are saying, loud and clear, that we will do everything in our power to make sure that the world's most bountiful food supply is also the safest.**

By protecting the public health, by bringing our people together around our basic values of opportunity, responsibility, and community, we will surely make this an age of possibility for all Americans.

Thanks for listening.

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Drop

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Second, <sup>W</sup> we will use state-of-the-art technology <sup>at the sentinel sites and in other states</sup> to keep our food safe. We will increase the number of expert disease detectives to investigate and control food-borne disease outbreaks. We will give these experts the technology to use sophisticated new DNA fingerprinting methods to trace infectious agents to their source, and create a permanent fingerprint library, so we can immediately recognize an illness if it reappears. And we will use advanced communications networks to speed outbreak information from these centers to hospitals and public health agencies all across the country.

<sup>Second</sup> Third, I am directing the Secretary of Health and Human Services, the Secretary of Agriculture, and the Administrator of the Environmental Protection Agency to report back to me within ~~60~~ <sup>90</sup> days with additional measures to further improve the safety of our food.

<sup>these investments</sup> With ~~this new early warning system to track food-borne illness~~, we are saying, loud and clear, that we will use the world's best science to make the world's most bountiful food supply safer than ever before for our families and our children.

Thanks for listening.

and will link them together with other state health agencies, to create a national early warning system. The new

work with consumers, producers, industry, states and the public -- to suggest new ways to improve food safety, and to explore 2 public-private partnerships.

Third, <sup>my 1998 budget</sup> ~~I will~~ asks Congress for \$42 million in additional funds to pay for the early-warning system →

additional seafood safety inspectors, and further research and education.

(A)

~~We can never eliminate all~~

But we can and must do better. My Administration has already put in place new laws that use the best science to protect our food.

Elann -  
Draft Final version - pls  
review first pp -  
This is the  
Thanks.

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Reduce Foodborne Illness

January xx, 1997

-- DRAFT --

Announcement

- modified  
by  
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- o In August, 1996 President Clinton signed the Food Quality Protection Act which streamlines pesticide regulations while strengthening health protections for all Americans, especially children.