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ABSTRACT

Accurate estimates of disease burden are the foundation of sound public health policy. To better quantify the morbidity and mortality associated with foodborne diseases in the United States, we compiled and analyzed information from a wide variety of surveillance systems, including data from the recently developed Foodborne Diseases Active Surveillance Network. Overall, foodborne diseases cause 76 million illnesses, 350,799 hospitalizations and 4,981 deaths in the United States each year. Known pathogens account for 67 million foodborne illness, 67,614 hospitalizations and 1,854 deaths. Three pathogens, *Salmonella*, *Listeria*, and *Toxoplasma*, are responsible for 51% of deaths caused by foodborne transmission of known pathogens. A large proportion of foodborne illness is caused by agents which have not yet been identified.

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IV. Overall Burden of Foodborne Illness

To determine the total burden of foodborne illness, we summed the burden of illness attributable to foodborne gastroenteritis caused by known pathogens and unknown agents, yielding an estimate of 76 million illnesses, 345,910 hospitalizations, and 4,103 deaths due foodborne gastroenteritis (Figure 1). Adding to these figures the burden associated with non-gastrointestinal illness caused by *Listeria*, *Toxoplasma*, and Hepatitis A (Table 5), we arrived at a final national estimate of 76 million illnesses, 345,910 hospitalizations, and 4,981 deaths each year.

DISCUSSION

Previous estimates of foodborne illness in the United States have varied widely. Since 1985, different authors have estimated the annual burden of foodborne illness at 24-81 million illnesses (1), 6.5 million illnesses with 9,000 deaths (3), 12.5 million illnesses with 11 deaths (4), and 33 million illnesses (5) nationwide. Although often overlooked, part of the disparity among these figures stems from differences in the entity being estimated. For example, the estimate of 6.5 million illnesses derived by Bennett et al. refers only to those illnesses caused by known infectious agents, whereas the estimate of 33 million illnesses by the Council for Agricultural Science and Technology (6) refers to gastrointestinal illnesses caused by all agents, known and unknown, infectious and noninfectious.

Our estimates for the burden of foodborne illness differ from previously published figures in several respects. For known pathogens, our estimate of 12.5 million illnesses is nearly threefold higher than the previous estimate

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of 6 million illnesses per year derived by Bennett et al. (3). Most of this difference is due to our inclusion of foodborne illness caused by Norwalk-like viruses. Similarly, for foodborne illness of all etiologies, our estimate of 76 million cases is considerably higher than the 33 million cases estimated in the CAST report (5). Notably, the CAST estimate assumes that 35% of all gastroenteritis cases resulted from foodborne transmission, a percentage that is similar to the one developed here. The disparity between these two estimates reflects differences in the estimated frequency of acute gastroenteritis overall: 99 million cases annually for the CAST estimate, 211 million for our estimate.

In contrast to our figures for total illnesses, our mortality estimates are generally lower than previous studies. We estimated that foodborne illness causes 4,981 deaths annually (1,850 deaths due to known infectious agents and 3,127 deaths of unknown etiology), a total that is slightly over half of the 9,000 deaths estimated by Bennett et al. (3). This previous estimate included 2,100 deaths due to campylobacteriosis, 1,200 deaths due to staphylococcal food poisoning, and 1,000 deaths due to trichinosis; our total for all three of these diseases is 4,377 deaths. Our estimated case-fatality rates for several other diseases are also lower than those used in the Bennett report, either because better data are available, or perhaps because treatment has improved.

Differences between our estimates and previously published figures are generally the result of better information and new analyses rather than real changes in disease frequency over time. For example, *E. coli* O157:H7 was previously estimated to cause 10,000 to 20,000 illnesses annually. This

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estimate was based principally on studies of patients visiting a physician for diarrhea. Recent FoodNet data have allowed a more detailed estimation of mild illnesses not resulting in physician consultation. Our estimate of nearly 74,000 illnesses each year incorporates these milder illnesses and should not be misconstrued as demonstrating a sudden surge in *E. coli* O157:H7 infections.

With respect to the overall frequency of diarrheal illness, differences in methodology make it difficult to compare recent FoodNet data with earlier data from the Tecumseh and Cleveland studies. Nevertheless, markers of disease severity suggest that episodes of diarrheal illness reported in the FoodNet and the Tecumseh studies were comparable with regard to duration, activity restriction and the presence of fever (H. Markstedt, manuscript in preparation). Age-adjusted rates of diarrhea were somewhat higher in the FoodNet survey population, but the rate of diarrhea with vomiting, arguably a more robust measure of gastrointestinal illness, was slightly lower (Table 2). While it is difficult to conclude with certainty that rates of diarrheal illness have increased since the late 1960's when the Tecumseh study was conducted, there is no evidence to suggest that they have decreased significantly. Consequently, our continued reliance on data from the Tecumseh study is unlikely to have falsely elevated our estimates of gastrointestinal illness.

The pathogen-specific estimates developed here harbor several notable findings. Norwalk-like viruses (NLV) account for over 75% of all cases of foodborne illnesses and 42% of related hospitalizations, but only 8% of fatalities. *Campylobacter* and *Salmonella* are other important causes of hospitalization, and *Listeria*, *Salmonella*, and *Toxoplasma* are the leading

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causes of mortality. It should be noted that a large number of deaths due to toxoplasmosis occur among patients infected with the human immunodeficiency virus (HIV). In this respect, advances in HIV treatment are likely to have greater impact on mortality due to toxoplasmosis than are efforts to prevent toxoplasmosis infection.

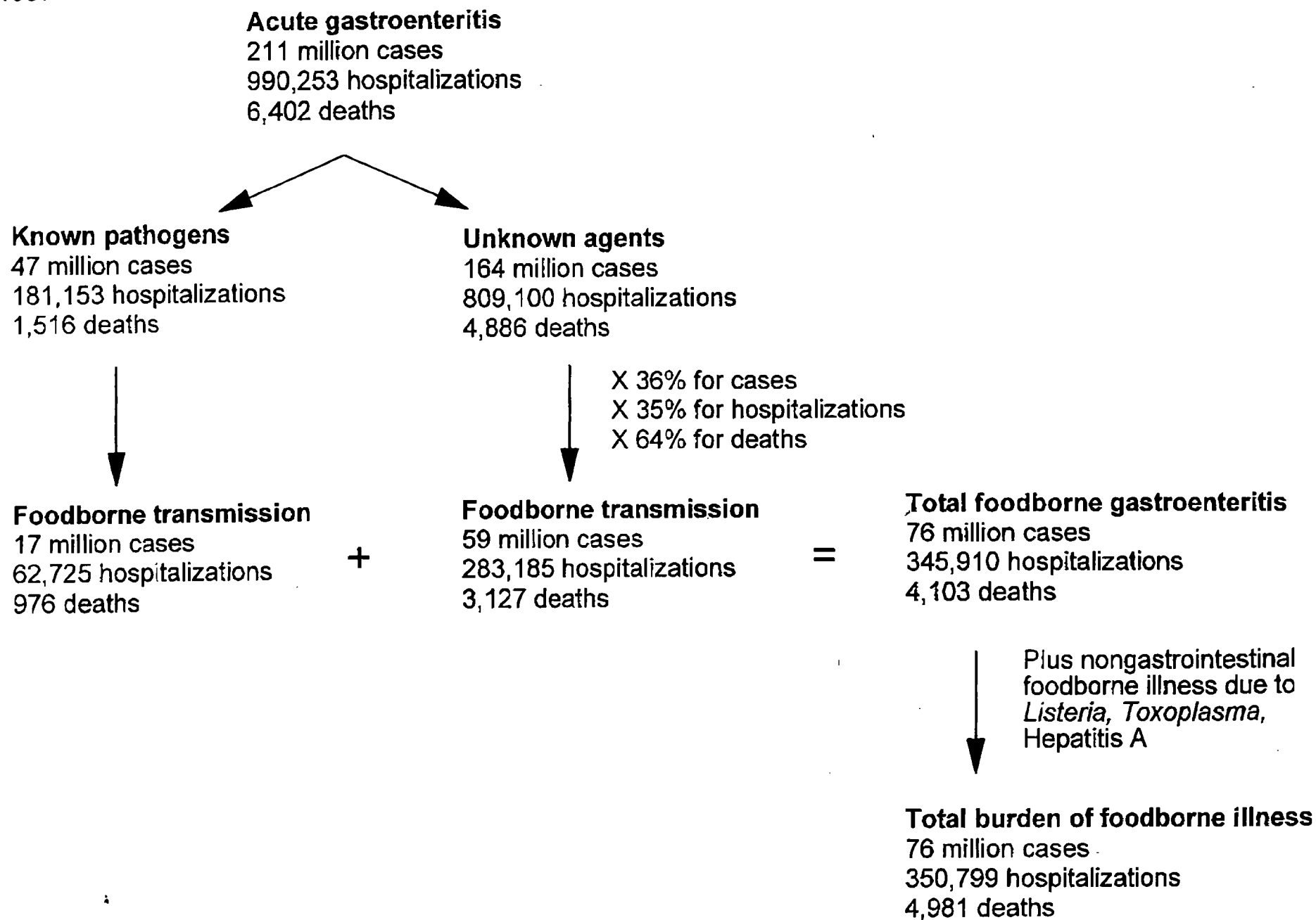
Our analysis has several limitations. First, with the exception of a few pathogens (see appendix), we have not estimated the burden of chronic sequela, although this may be an important part of the overall burden. Second, because of a paucity of surveillance information, we did not have specific estimates for some known, occasionally foodborne pathogens (*Plesiomonas*, *Aeromonas*, or *Edwardsiella*), nor did we develop specific estimates for known noninfectious agents such as mushroom or marine biotoxins, metals and other inorganic toxins. Many of these agents cause gastroenteritis and are therefore captured in our overall estimate of gastrointestinal illness. Third, differences in surveillance information prevented us from using the same method for estimating the burden of all bacterial, parasitic, viral pathogens. Fourth, few data are available on the relative frequency of foodborne transmission for individual pathogens, and well documented estimates for the degree of underreporting are not available for most pathogens. We were therefore forced to rely on multipliers derived for *Salmonella* other diseases. Fifth, the generation of mortality estimates is based on somewhat arbitrary assumptions, although we believe our assumptions to be reasonable or even conservative. Future research may refine these assumptions and allow for more precise estimates. Finally, because a very large number of illnesses are attributed to Norwalk-like viruses (NLV), the data for these agents have a

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major effect on our overall estimates. For example, if the actual number of cases of NLV infections due to foodborne transmission is 30% rather than 40%, our overall estimate would decrease from 76 million cases per year to 62 million cases per year.

Addressing these limitations will require continued and refined active surveillance activities. Beginning in 1998, the FoodNet population survey was modified to capture cases of vomiting not associated with diarrhea, and further adjustment to capture concomitant respiratory symptoms should enhance the utility of the FoodNet survey data. With additional clinical diagnostic capacity, surveillance efforts should be able to estimate the degree of underreporting for additional diseases, and to refine estimates for the proportion of specific diseases that are transmitted through food. Heightened surveillance for acute, noninfectious foodborne diseases such as mushroom poisoning and other illnesses caused by toxins could further improve estimates of the burden of foodborne illness. Emergency department-based surveillance systems (30) or poison control center-based surveillance may provide a way of obtaining this type of information. Finally, our estimates suggest that a substantial proportion of foodborne illness is of unknown or unrecognized etiology. Expanded efforts are needed to identify new causes of enteric illness and to define the public health significance of known agents (e.g., enteric agent *E. coli*) whose role as pathogens in this country is currently uncertain.

Figure 1. Estimated frequency of foodborne gastroenteritis in the United States, 1997



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OASPA NEWS DIV.

DRAFT**RAFT**Food Safety
#206 99-00**U.S. Food Safety Team: A Winner**

*Secretary Donna E. Shalala, U.S. Department of Health and Human Services
Secretary Dan Glickman, U.S. Department of Agriculture*

In his recent criticism of the Clinton Administration's food safety efforts, *Chicago Tribune* columnist James Warren claimed that the segmenting of responsibilities has weakened our food safety system. This simply is not the case. In fact, the very key to our successful science-based food safety is seamless collaboration with clear responsibility. It has made our food supply one of the safest in the world, and without it, we will not be able to meet the food safety challenges of the next century.

Food safety has been an administration priority since day one, and we have adopted a successful approach that looks at food safety as an integrated, interdependent system, all the way from the farm to consumers' kitchens. But controlling the safety of the American food supply has grown increasingly complex. American consumers eat out more and cook for themselves less. They also eat more processed food than ever before, as well as more imported food. Additionally, new pathogens have evolved. To adequately continue addressing these challenges, we need a strong science base that cuts across agency lines and departmental barriers -- a science base that draws on government-wide expertise.

Under the current structure, two federal agencies have primary responsibility for assuring the safety of our food supply: the Food and Drug Administration and USDA's Food Safety and Inspection Service. But, the Environmental Protection Agency (EPA), the Centers for Disease Control (CDC), and state and local partners also play key roles.

For example, CDC takes the lead on gathering data about food-borne disease in the same way it collects data on other diseases. EPA, the expert agency in tackling pollution issues, protects our water supply by setting appropriate drinking water standards. Food safety can only be effective if it has this strong underpinning in scientific research and risk assessment.

In May 1997, the President announced a national food safety initiative that proposed specific steps to improve the safety of the food supply. A year later, he established the Council on Food Safety. Its goal is to make the food supply even safer through a food safety system based on public health and supported by well-coordinated surveillance, standards, inspection, enforcement, research, risk assessment, education and strategic planning.

In just two years, with support from Congress, the vast majority of recommendations laid out in the report have been implemented and already are leading to important improvements in our food safety system.

Last year, our new national electronic network for bacterial DNA fingerprinting, known as PulseNet, connected two seemingly independent *E. coli* outbreaks in Michigan

New York

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to a common source: alfalfa sprouts. PulseNet also helped confirm that approximately 50 cases of *E. coli* in Wisconsin were attributable to cheese curds from a single facility, and it connected *E. coli* outbreaks from ground beef to specific processors.

This new DNA fingerprinting enables epidemiologists to move up to five times faster than previously feasible in identifying serious, widespread food contamination problems.

As we've continued to tackle food-borne illness, we've also developed new approaches for inspecting seafood, meat and poultry plants. We made significant amendments to the Safe Drinking Water Act in 1996. We've sought to improve interagency coordination at every point in our food safety system. And we aren't stopping there.

Our Food Safety Council has established a task force that is working with the private sector to reassess the U.S. food safety system, even the structural and organizational options that could strengthen the system. We're carefully working with all of our partners, and a final recommendation is due to the President in July 2000.

It's so easy to say, "let's start all over again and create a better food safety system." While there is always room for improvement, it is shortsighted to think that a safer food supply is as simple as just naming a single food agency and ignoring what we have already learned.

In fact, such a plan could create more problems than it would solve. Attempting to combine hundreds of regulators from the various agencies involved in our food safety system would take years to complete with unclear benefits to the system already set in place.

Take it from two "bureaucrats," the last thing we need is to create a new bureaucracy.

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ABSTRACT

Accurate estimates of disease burden are the foundation of sound public health policy. To better quantify the morbidity and mortality associated with foodborne diseases in the United States, we compiled and analyzed information from a wide variety of surveillance systems, including data from the recently developed Foodborne Diseases Active Surveillance Network. Overall, foodborne diseases cause 76 million illnesses, 350,799 hospitalizations and 4,981 deaths in the United States each year. Known pathogens account for 17 million foodborne illness, 67,614 hospitalizations and 1,854 deaths. Three pathogens, *Salmonella*, *Listeria*, and *Toxoplasma*, are responsible for 25% of deaths caused by foodborne transmission of known pathogens. A large proportion of foodborne illness is caused by agents which have not yet been identified.

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IV. Overall Burden of Foodborne Illness

To determine the total burden of foodborne illness, we summed the burden of illness attributable to foodborne gastroenteritis caused by known pathogens and unknown agents, yielding an estimate of 76 million illnesses, 345,910 hospitalizations, and 4,103 deaths due foodborne gastroenteritis (Figure 1). Adding to these figures the burden associated with non-gastrointestinal illness caused by *Listeria*, *Toxoplasma*, and Hepatitis A (Table 5), we arrived at a final national estimate of 76 million illnesses, 340,790 hospitalizations, and 4,981 deaths each year.

DISCUSSION

Previous estimates of foodborne illness in the United States have varied widely. Since 1985, different authors have estimated the annual burden of foodborne illness at 24-81 million illnesses (1), 6.5 million illnesses with 9,000 deaths (3), 12.5 million illnesses with 31 deaths (4), and 33 million illnesses (5) nationwide. Although often overlooked, part of the disparity among these figures stems from differences in the entity being estimated. For example, the estimate of 6.5 million illnesses derived by Bennett et al. refers only to illnesses caused by known infectious agents, whereas the estimate of 33 million illnesses derived by the Council for Agricultural Science and Technology refers to gastrointestinal illnesses caused by all agents, known and unknown, infectious and noninfectious.

Our estimates for the burden of foodborne illness differ from previously published figures in several respects. For known pathogens, our estimate of 14.5 million illnesses is nearly threefold higher than the previous estimate

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of 6 million illnesses per year derived by Bennett et al. (3). Most of this difference is due to our inclusion of foodborne illness caused by Norwalk-like viruses. Similarly, for foodborne illness of all etiologies, our estimate of 76 million cases is considerably higher than the 33 million cases estimated in the CAST report (5). Notably, the CAST estimate assumes that 35% of all gastroenteritis cases resulted from foodborne transmission, a percentage that is similar to the one developed here. The disparity between these two estimates reflects differences in the estimated frequency of acute gastroenteritis overall: 99 million cases annually for the CAST estimate, 211 million for our estimate.

In contrast to our figures for total illnesses, our mortality estimates are generally lower than previous studies. We estimated that foodborne illness causes 4,981 deaths annually (1,854 deaths due to known infectious agents and 3,127 deaths of unknown etiology), a total that is slightly over half of the 9,000 deaths estimated by Bennett et al. (3). This previous estimate included 2,100 deaths due to campylobacteriosis, 1,200 deaths due to staphylococcal food poisoning, and 1,000 deaths due to trichinosis; our total for all three of these diseases is 3,354 deaths. Our estimated case-fatality rates for several other diseases are also lower than those used in the Bennett report, either because better data are available, or perhaps because treatment has improved.

Differences between our estimates and previously published figures are generally the result of better information and new analyses rather than real changes in disease frequency over time. For example, *E. coli* O157:H7 was previously estimated to cause 10,000 to 20,000 illnesses annually. This

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estimate was based principally on studies of patients visiting a physician for diarrhea. Recent FoodNet data have allowed a more detailed estimation of mild illnesses not resulting in physician consultation. Our estimate of nearly 74,000 illnesses each year incorporates these milder illnesses and should not be misconstrued as demonstrating a sudden surge in *E. coli* O157:H7 infections.

With respect to the overall frequency of diarrheal illness, differences in methodology make it difficult to compare recent FoodNet data with earlier data from the Tecumseh and Cleveland studies. Nevertheless, markers of disease severity suggest that episodes of diarrheal illness reported in the FoodNet and the Tecumseh studies were comparable with regard to duration, activity restriction and the presence of fever (H. Hensley, manuscript in preparation). Age-adjusted rates of diarrhea were somewhat higher in the FoodNet survey population, but the rate of diarrhea with vomiting, arguably a more robust measure of gastrointestinal illness, was slightly lower (Table 2). While it is difficult to conclude with certainty that rates of diarrheal illness have increased since the late 1960's when the Tecumseh study was conducted, there is no evidence to suggest that they have decreased significantly. Consequently, our previous reliance on data from the Tecumseh study is unlikely to have falsely elevated our estimates of gastrointestinal illness.

The pathogen-specific estimates developed here harbor several notable findings. Norwalk-like viruses (NLV) account for over 75% of all cases of foodborne illnesses and 42% of related hospitalizations, but only 8% of fatalities. *Campylobacter* and *Salmonella* are other important causes of hospitalization, and *Listeria*, *Salmonella*, and *Toxoplasma* are the leading

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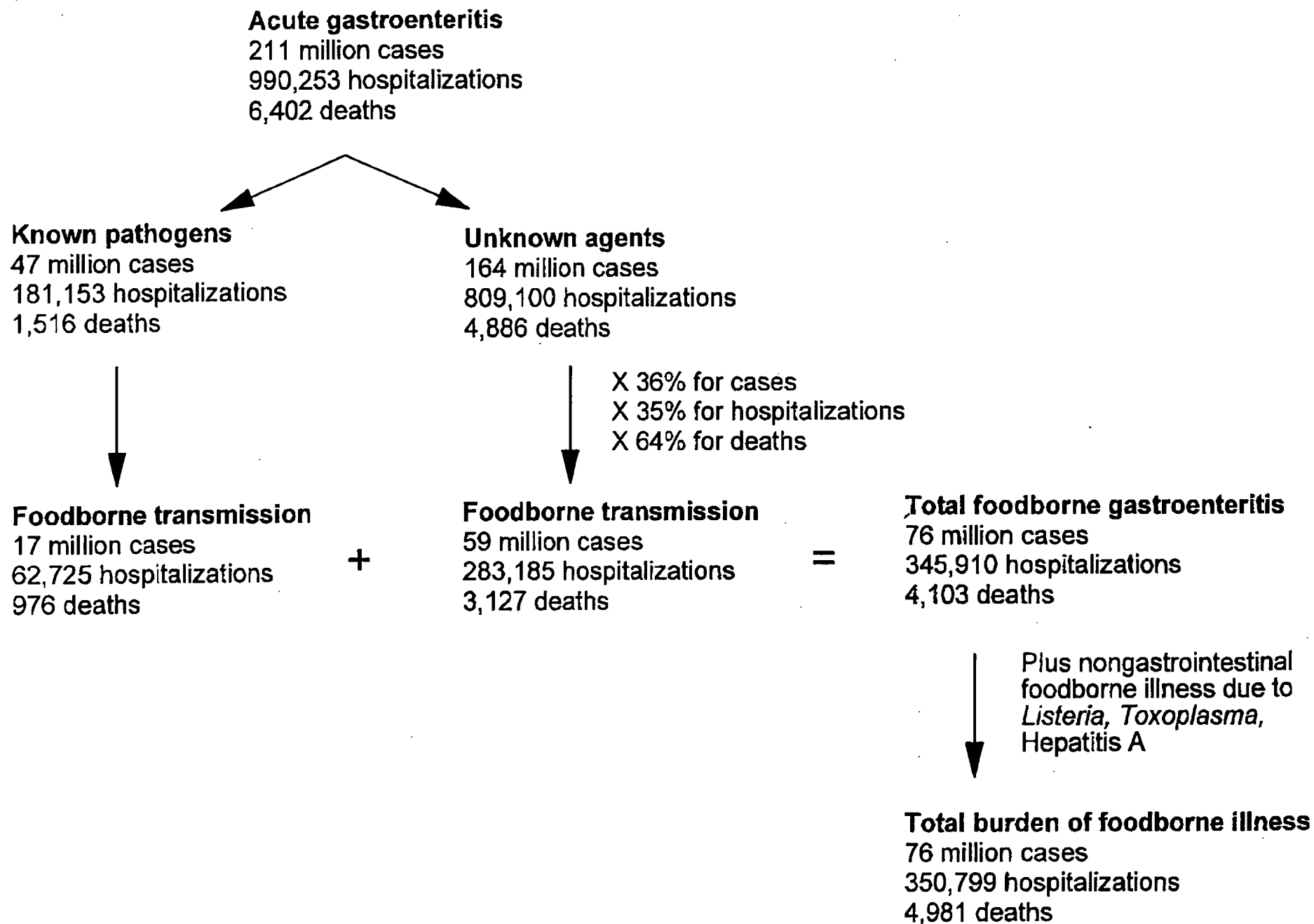
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major effect on our overall estimates. For example, if the actual number of cases of NLV infections due to foodborne transmission is 30% rather than 40%, our overall estimate would decrease from 76 million cases per year to 62 million cases per year.

Addressing these limitations will require continued and refined active surveillance activities. Beginning in 1998, the FoodNet population survey was modified to capture cases of vomiting not associated with diarrhea, and further adjustment to capture concomitant respiratory symptoms should enhance the utility of the FoodNet survey data. With additional clinical diagnostic capacity, surveillance efforts should be able to estimate the degree of underreporting for additional diseases, and to refine estimates of the proportion of specific diseases that are transmitted through food. Heightened surveillance for acute, noninfectious foodborne diseases such as mushroom poisoning and other illnesses caused by toxins could further improve estimates of the burden of foodborne illness. Emergency department-based surveillance systems (30) or poison control center-based surveillance may provide a way of obtaining this type of information. Finally, our estimates suggest that a substantial proportion of foodborne illness is of unknown or unrecognized etiology. Expanded efforts are needed to identify new causes of enteric illness and to define the public health significance of known agents (e.g., enterococci and *E. coli*) whose role as pathogens in this country is currently uncertain.

Figure 1. Estimated frequency of foodborne gastroenteritis in the United States, 1997



Eating safely

Hungering for an American food czar

Liberals and conservatives can get into great quarrels over the proper role of government. But on a few things they agree: When a fire breaks out, firefighters should show up. When bullets fly, cops should rush in. And when tainted food is headed for market, food-safety inspectors should stop it. These are things government should do: Shield people from dangers they can't fight off on their own.

For the most part government delivers on this proposition — except when it comes to food. While other public-safety officials rely on state-of-the-art techniques, the folks charged with keeping food safe are stuck with antiquated methods and hamstrung by a baffling bureaucratic tangle. That's the conclusion of a report delivered to Congress last week by the Institute of Medicine, a government-appointed group of science advisers.

The report zeroes in on the food-safety system's biggest flaw: It isn't a system. About a dozen U.S. agencies bear responsibility for assuring that food is fit to eat; each lives by its own rules. Some agencies use embarrassingly outmoded techniques — like the "poke and sniff" practice that still prevails for meat and poultry.

So the U.S. government has been wielding a food-safety sieve instead of a shield, and the upshot has been dire: Every week brings new episodes of food contamination, causing an annual toll of 9,000 deaths and 81 million illnesses. These food-borne illnesses are dreadful for those who suffer them, of course, and they're expensive as well. The scientists found that food poisoning costs the nation up to \$37 billion a year in medical treatment

and lost work time.

This would be merely lamentable if it were unavoidable. But as the report emphasized, most food-borne illness could readily be prevented simply by thoughtful strategy. What it will take, say the scientists, is a federal food czar — a single official charged with guaranteeing food safety.

This czar needs more than a title. He or she also needs power, a palace and modern weaponry. Thus the scientists urge creation of a centralized agency to manage all food-safety programs. They recommend changes in law to ensure that inspection, research and enforcement are based on solid science and tested prevention tactics. They favor development of a national food safety plan to fight the special perils that accompany Americans' increasing reliance on imported foods.

In short, the scientists recommend just what the country's food-safety critics have long been urging: Create a system. Apply sound science. Develop rational safety standards. Inspect and enforce. In fact, this advice is so practical that the Clinton administration has already taken it to heart. While the advisers were still writing their report, the White House was seeking \$101 million to reform the food-safety program. But so far Congress has been reluctant to go along: Just before the August recess, the Senate approved just \$68 million — and the House a paltry \$16.8 million — of the administration request.

It's a pity, because food safety isn't a partisan issue. After all, even Newt Gingrich has to eat now and then. He shouldn't have to worry that the food on his plate may be out to get him. Neither should his fellow Americans.

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Food and Drug Law Journal

Food Safety

*Analyzing the Laws, Regulations, and Policies Affecting
FDA-Regulated Products*

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Clinton to Press for Money and Import Controls for Food Safety

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tration has requested to expand inspections, increase research and surveillance of food-borne illness and educate consumers. Before the Fourth of July recess, the House voted to provide only \$16.8 million of the requested money, and the Senate bill, which has not been voted on, provides just \$2.6 million.

"Until the day the agencies can quantitatively answer how much it would cost to reduce food-borne illness," said John Zioikowski, a member of the staff of the House Appropriations Committee, "they won't get any more money. If they can say we will cut food-borne illness by so much, I'm sure the members would say that is a serious proposal. Did we provide enough money? No. I'm sure we didn't for a lot of people."

The chairman of the Senate Appropriations subcommittee on agriculture, Thad Cochran, Republican of Mississippi, said that even though some of the new programs proposed by the Administration had merit, the committee did not have the money for them. So it provided nothing. Instead, Mr. Cochran suggested that some of the Food and Drug Administration's duties be delegated to states and local governments.

But Government officials say more action is needed.

"Food-borne diseases are a continuing problem that have not yet been resolved," said Dr. Robert Tauxe, chief of the food-borne and diarrheal diseases branch of the Centers for Disease Control and Prevention. This fact has been underscored recently by two unexpected outbreaks of food-borne illnesses: travelers' diarrhea, or enterotoxigenic E. coli, from potato salad, which sickened thousands of people in Illinois, and salmonella in cereal, which made 200 people ill in 11 states.

"Salmonella in breakfast cereal is basically a first for us in this country," Dr. Tauxe said. "We cannot have a breakfast-cereal plant having failures like that, and that's an inspection problem."

The potato salad outbreak is equally worrisome, he said. "We used to believe you had to travel overseas to get travelers' diarrhea. It's a classic example of emerging infections common in Latin America becoming a problem here."

Congress is unlikely to budge until the cost of reducing illness is proved.

Despite what Dr. Tauxe described as "extraordinary efforts" to prevent E. coli O157:H7 from contaminating meat, it continues to be a problem. "I don't feel that recalls are the answer," he said, "because we don't want E. coli in the meat to begin with. That's a sign that additional efforts are needed."

Since 1988, the number of products recalled for life-threatening microbial contamination has increased, almost fivefold, according to the Food and Drug Administration. But in a report issued in May, the General Accounting Office, an investigative arm of Congress, said, "Federal agencies cannot insure that the growing volume of imported food is safe for consumers," and recommended greater authority for the agencies to control imports.

The Food and Drug Administration can stop food at the borders but has no authority to prevent a country with an inferior food-safety system from exporting the food in the first place. The Agriculture Department does have that power, called equivalence, but only for meat and poultry.

The Food and Drug Administration now deals with imported fruits, vegetables, grains, fish and other food only after it arrives. It inspects slightly more than 1.5 percent of foreign shipments, and among imported produce items, a source for some extremely serious outbreaks of food-borne illness, only 0.2 percent were sampled last year. The number of shipments of food for which the F.D.A. is responsible has increased to 2.2 million from 1.5 million five years ago. The number of people who inspect the food has remained the same. And domestically, the agency inspects food plants only every 10 years, on average.

When Congress returns from its recess, Senator Tom Harkin, Democrat of Iowa, will offer an amendment to restore all of the original \$101 million for the President's food safety initiative.

And in his radio address, the President will announce what the Administration can do without Congressional approval. One measure is an F.D.A. rule requiring warning labels on all packaged juice that has not been pasteurized or processed to kill harmful bacteria. A second measure is the creation of a national institute for food safety research to coordinate public and private research.

Unpasteurized apple juice, contaminated with E. coli O157:H7, caused the death of a 16-month-old child last year and led to the hospitalization of a dozen other children. The new labeling rule will take effect in time for the apple cider season.

Congress is sitting on its hands while we watch all these outbreaks occur around this country," said Caroline Smith deWaal, director of food safety for the Center for Science in the Public Interest, an advocacy

group, "and things are not going to get better without resources and authority to regulate food."

Deli Cited Before Illness

ORLAND PARK, Ill., July 3 (AP) — The delicatessen that is the suspected source of an E. coli outbreak in June that officials now say sickened up to 6,500 people had been cited for 15 health violations just before the illnesses were reported.

Investigators are awaiting more test results but suspect that the potato salad from Iwan's Deli and Catering near Chicago caused the illnesses.

Iwan's got a below-average score in a surprise health inspection less than 24 hours before the City Health Department began receiving calls from people who became ill after eating food catered by Iwan's.

PRESIDENT TO PUSH FOR FOOD SAFETY

Seeks More Money and Power to Tighten Import Controls

By MARIAN BURROS

President Clinton plans to press Congress today to provide all \$101 million he has sought to insure the safety of the nation's food supply. But Congress seems unlikely to cooperate.

Mr. Clinton also plans to announce two steps the Administration can take without Congressional authority to protect food safety. Administration officials said.

According to an advance text of his Saturday radio address, the President will also ask Congress to give the Food and Drug Administration greater authority to halt imports of fruits, vegetables and other food products that are produced under safety conditions that do not match our own strict standards, and to give the Department of Agriculture new authority to impose tough fines on businesses who violate those standards and to issue mandatory recall of unsafe meat and poultry.

The Government has no reliable tracking system, but health officials say food-borne diseases account for up to 30 million cases of illness and 9,000 deaths a year. There have been many large outbreaks of food-borne illness in the last year, including one just last week that made a New York woman ill and resulted in the recall of 172,000 pounds of ground beef patties contaminated with the potentially deadly bacteria E. coli O157:H7.

But Congress has failed to address legislation proposed by the Administration to give the food agencies greater authority, and it appears unlikely that Congress will provide the full amount of the Adminis-

Total Pages: 15

LRM ID: MDH213

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Wednesday, July 1, 1998

LEGISLATIVE REFERRAL MEMORANDUM

URGENT

TO: Legislative Liaison Officer - See Distribution below
FROM: *Janet R. Forsgren* Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Melinda D. Haskins
PHONE: (202)395-3923 FAX: (202)395-6148
SUBJECT: HHS Testimony on Foodborne Illnesses in the United States
DEADLINE: 10 AM Thursday, July 2, 1998

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: HHS (CDC) will deliver the attached testimony at a July 9th hearing on foodborne illnesses before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations. HHS has asked for expedited clearance of this testimony.

IF WE DO NOT HEAR FROM YOU BY THE COMMENT DEADLINE, WE WILL ASSUME THAT YOU HAVE NO OBJECTION.

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June 30, 1998

STATEMENT OF

STEPHEN M. OSTROFF, M.D.

ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCE

NATIONAL CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL AND PREVENTION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

U.S. SENATE

JULY 9, 1998

Good morning. I am Dr. Stephen M. Ostroff, Associate Director for Epidemiologic Science at the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Barbara Herwaldt, also of the National Center for Infectious Diseases. I am pleased to be here this morning to discuss CDC's programs to monitor, prevent, and control foodborne diseases in the United States. I will provide an overview of CDC's foodborne disease surveillance systems and describe cyclosporiasis associated with imported raspberries as an example of our role in outbreak response.

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne diseases is still substantial. It is estimated that millions of persons become ill and thousands die from foodborne diseases each year; foodborne disease costs the U.S. economy several billion dollars annually. A variety of pathogens and toxins have been described as causes of foodborne disease, and new ones continue to be identified.

Foodborne diseases are common and, in principle, preventable. Some of the causes of foodborne diseases that were formerly problematic are now well controlled by standard prevention strategies, such as pasteurizing raw milk, appropriately managing the canning of food, and ensuring that restaurants and other food preparation areas are clean and well maintained. However, new challenges continue to arise, including the increasing globalization of our food supply, larger scale production and distribution networks, and changing dietary habits; and new efforts are required to address these issues.

Preventing foodborne disease requires a coordinated program of risk assessment and risk

management involving Federal, State, and local agencies and non-governmental partners. CDC's primary role in this coordinated effort is to identify foodborne hazards, characterize the risk of foodborne disease, and identify strategies that will prevent additional cases. In 1994, CDC issued a strategic plan, *Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States*, which emphasized surveillance, applied research, and prevention activities. An updated version of this plan will be published later this year. As in the 1994 plan, many aspects of the new version of the plan deal with emerging infectious foodborne diseases. The plan complements sections of the Food and Drug Administration's (FDA) 1997 Food Code and the Hazard Analysis and Critical Control Point (HACCP) food safety programs being implemented by FDA and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and provides a platform from which CDC's role in the National Food Safety Initiative, which was launched in 1997, can be instituted.

Identification of Foodborne Diseases Problems

A person who becomes ill with a foodborne disease may be part of an outbreak or cluster (a group of patients who all have the same illness after consuming the same food) or may have a sporadic illness (an illness that may be an isolated occurrence and not part of a recognized cluster). Usually, investigations of outbreaks can rapidly determine the source and nature of the illness and identify the control measures needed to prevent additional cases. However, sporadic illnesses are often not diagnosed or considered to be foodborne. Even if they are recognized as being foodborne, it is usually impossible, for single cases, to determine which food is the source of the infection. Because individual sporadic cases are far more common than outbreaks, they are a prime target for prevention efforts.

Effective public health surveillance is key to identifying and monitoring the prevalence of foodborne disease. CDC is typically notified of a potential foodborne disease problem by a State or local health department or by an astute clinician or laboratorian who notices an unusually large number of cases of a certain disease. Physician-based surveillance is useful for public health emergencies that require rapid response, such as potentially lethal botulism, where one case could herald an outbreak and immediate public health action is necessary. Clinical laboratories help detect foodborne diseases by tracking the number of times they identify a specific pathogen. Clinical laboratory-based surveillance has identified multiple outbreaks, including a recent multistate outbreak of *Salmonella* Agona infection linked to cereal. State public health laboratories play an important role in further characterizing the strains isolated from ill people, to see whether there are groups of similar pathogens. Taking advantage of recent advances in computer technology and molecular biology, CDC has developed PulseNet, a network of molecular subtyping (fingerprinting) laboratories at State health departments, FDA, USDA, and CDC, which enhances the ability of laboratory-based surveillance to rapidly identify clusters of related foodborne infections of certain pathogens, sometimes scattered over large geographic areas.

Another source of data is CDC's active foodborne disease surveillance system, FoodNet, which is conducted in CDC's seven Emerging Infections Program sites developed as part of the 1994 emerging infections plan. The FDA and the Food Safety and Inspection Service (FSIS) of USDA are providing financial assistance and are important collaborators with CDC in this system. The seven active surveillance sites cover about 7.7% of the U.S. population. These sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect

information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. As data are collected, this surveillance system provides important information about changes over time in the burden of foodborne diseases and will help the agencies evaluate current food safety initiatives and develop future food safety activities.

For these surveillance systems to be effective and for an illness to be identified as caused by a foodborne pathogen, several things must occur. A person who eats contaminated food and becomes ill must seek medical attention or contact the health department. The patient's clinicians must obtain appropriate diagnostic tests. The laboratory results must be reported to the health department. Information must be assessed to recognize a potential outbreak. Often, not all of these steps occur, and sporadic illnesses and outbreaks are not recognized or reported.

Outbreak Investigations

Once an outbreak is detected, the first response is usually from the State or local health department. When necessary, the State or local health department conducts an outbreak investigation. Due to limited resources at State and local levels, not all outbreaks can be investigated and reported. If an outbreak is very large or significant, is thought to involve an unusual pathogen or unexpected food vehicle, affects multiple states or countries, or when preliminary investigations do not reveal a source, CDC will often be invited by the State health departments to participate in the investigation.

When investigating an outbreak of a foodborne illness, public health officials must combine laboratory diagnostic techniques and epidemiologic investigative methods to determine both the

causative agent of the illness and the vehicle for its transmission. This involves interviews with patients and comparison of their responses to those of non-ill persons (control subjects) to determine which foods are implicated. If a food is identified as the source of illness, CDC collaborates with FDA or USDA on the investigation and control of the outbreak, based upon which agency regulates the food suspected.

Approximately 400-500 foodborne outbreaks are reported by State health departments to CDC each year, accounting for 10,000 to 12,000 persons with foodborne illness. CDC summarizes the information in these reports through its Foodborne Disease Outbreak Surveillance System. The reports provide useful, detailed information on particular diseases and on the type and severity of outbreaks that occur in various settings, such as nursing homes or schools. Outbreak investigations can lead to effective prevention strategies, as they are often critical in identifying contaminated foods that can then be removed from the marketplace and in elucidating the problems in food production that lead to disease.

Case Study: *Cyclospora cayentanensis*

CDC's role in outbreak investigation is well illustrated by the 1996 and 1997 outbreaks of infection caused by *Cyclospora cayentanensis*, a recently characterized parasite that causes a gastrointestinal illness called cyclosporiasis. This illness is typically characterized by watery diarrhea and other symptoms, such as nausea, abdominal cramps, weight loss, and fatigue. If not treated, the illness can be severe and prolonged. Before 1996, most of the small number of cases of cyclosporiasis in the United States occurred in travelers who had been in developing countries, and only three small U.S. outbreaks had been reported.

When the pattern of *Cyclospora* infections changed in 1996 and health departments noted cases of cyclosporiasis in people who had not traveled overseas, CDC was notified promptly. In mid-May of 1996, health departments in Florida and New York informed CDC that sporadic cases of cyclosporiasis had been identified in their states. At the end of May, health departments in Texas and Canada informed CDC that some people who had attended specific events, such as a party, had become ill with cyclosporiasis. Thus, CDC was notified of "clusters" of cases, which indicated that an outbreak might be occurring. In June, CDC learned of additional sporadic cases and clusters in the eastern United States and Canada.

Ultimately, 55 clusters with a total of 725 cases of cyclosporiasis were reported to CDC by 14 States, the District of Columbia, and two Canadian provinces. The 55 clusters were associated with events that occurred May 3 through June 14, 1996. In addition, 740 sporadic cases that were not associated with identified events or overseas travel were reported, for an overall total of 1,465 cases from 20 States, the District of Columbia, and two provinces. Twenty-two people are known to have been hospitalized, but no deaths are known to have occurred. Because in most foodborne outbreaks, particularly those that involve more than one locality, many affected cases are unrecognized or unreported, the total number of cases of cyclosporiasis that occurred in this outbreak may have been much larger than the officially reported number.

CDC played many roles in the outbreak investigation, including serving as the national reference laboratory for identifying *Cyclospora* in stool specimens and thus confirming that this parasite caused the outbreak. This role was particularly important because many laboratorians had not had experience identifying *Cyclospora*.

Another role CDC played was to help State and local health departments conduct the studies that ultimately implicated raspberries as the food item that had made people sick. This aspect of the outbreak investigation focused on the clusters of cases that were associated with specific events. Health departments interviewed the people who had attended the respective events about what they had consumed and compared the responses of the sick and the well people to see how they differed. CDC assisted in various ways — for example, by helping to design questionnaires, conduct data analysis, and identify important issues that needed to be addressed in the investigations. CDC also assisted some health departments on site with their local investigations.

As more and more clusters of cases were identified, CDC's coordinating role at the national level became increasingly important. CDC sponsored frequent conference calls and a meeting in July 1996 to discuss the findings to date and to help establish priorities for the investigation and future research. Whereas the investigators from individual States and localities focused on their own jurisdictions, staff at CDC repeatedly looked for the patterns that emerged as data from the individual clusters were compiled and analyzed. Fresh raspberries were found to have been served at virtually all the events, and a strong statistical association was found between illness and consumption of raspberries. Although the investigation focused on the clusters of cases, some studies that compared the exposures of sporadic cases and control subjects were also conducted and implicated raspberries.

Another important role played by CDC was that of coordinating public communications as the investigation progressed. CDC helped improve the consistency of the messages that State and

local health departments gave to local media. CDC provided a national perspective about the outbreak when interviewed by the national media and published articles in CDC's *Morbidity and Mortality Weekly Report* to rapidly communicate important findings about the investigation to the public health and medical communities.

Once it was determined that raspberries were the food item responsible for illness, the next step was to determine where they had been grown. This traceback process required close coordination with FDA, State and local agencies, and industry. The first steps of the tracebacks entailed determining where the various events took place and where the raspberries that were served had been bought. The raspberries were then tracked from suppliers and distributors back to importers, exporters, and farms of origin, looking for common themes at each step. The available traceback data implicated Guatemala as the common source for the raspberries. By the time Guatemalan raspberries were implicated, Guatemala's spring export season had essentially ended.

Investigators next tried to determine how the raspberries became contaminated. CDC and FDA sent investigators to Guatemala and to Miami, a major port of entry for imported raspberries, to explore possible modes of contamination. We were able to observe how raspberries were grown, picked, sorted, packed, cooled, transported, and inspected. Because no single packing or storage facility in Guatemala, exporter, type of shipping container, shipment, airline carrier, U.S. port of entry or cargo clearance area, importer, distributor, retailer, or food handler was linked to all events for which we had adequate data about the source of the implicated raspberries, we concluded that some practice or attribute common to multiple farms was the most likely

explanation for the outbreak.

Although the mode of contamination was not determined, one hypothesis under consideration is that contaminated water may have been used to mix the insecticides, fungicides, and fertilizers that were sprayed on raspberries. Good laboratory methods for detecting low levels of the *Cyclospora* parasite on produce such as raspberries or in water and other environmental samples are not yet available. By the time the clusters of cases were detected, leftover raspberries from the events were not available for testing.

Although the precise mechanism by which raspberries became contaminated was unclear, FDA and CDC provided suggestions to the Guatemalan Berry Commission (GBC) about possible ways to reduce the risk for contamination. The GBC voluntarily implemented various prudent measures to improve water quality and sanitary conditions on farms that were going to export to the United States in subsequent export seasons.

Despite these control measures, another multistate outbreak linked to Guatemalan raspberries occurred in North America in the spring of 1997. CDC learned of this outbreak in early May 1997, when several health departments informed CDC of clusters of cases that were associated with April events. Ultimately, 41 clusters with a total of 762 cases were reported, which were associated with events that occurred April 1 through May 26, 1997, in 13 states, the District of Columbia, and one Canadian province. In addition, 250 sporadic cases were reported for the outbreak period, for an overall total of 1,012 cases in 17 states, the District of Columbia, and two provinces.

Once again, the investigation, which focused on the clusters of cases, implicated fresh raspberries, and Guatemala was found to be the major source of the implicated berries. The outbreak ended shortly after Guatemala voluntarily suspended exportation of fresh raspberries to the United States at the end of May 1997. The fact that another outbreak occurred despite the implementation of various control measures suggests either that the control measures may not have been fully implemented by some farms or that the measures may not have addressed the true source of contamination of the raspberries.

These outbreaks in 1996 and 1997 highlighted challenges related to the investigation of outbreaks of foodborne diseases. Many State and local health departments do not have the necessary infrastructure to conduct outbreak investigations. Also, because *Cyclospora* is an emerging pathogen, most laboratorians lacked the experience and expertise to identify *Cyclospora* in stool specimens, particularly during the 1996 investigation. CDC is developing the capacity to use the Internet to assist laboratories in identifying parasites such as *Cyclospora* in patient specimens. However, many laboratories do not yet have the necessary equipment to take advantage of this technology.

New Challenges--New Opportunities

As we draw to the close of the 20th century, we face new paradigms for foodborne disease due to the globalization of the food supply, the large-scale nature of food production and distribution, and the continuing recognition of new foodborne pathogens. CDC addresses these issues by harnessing the technology of electronic telecommunications and computer systems, developing state of the art molecular fingerprinting techniques, integrating its disease prevention and control

activities with food safety programs in FDA and USDA, and building active epidemiologic and laboratory-based surveillance programs in collaboration with our State and local partners. However, much work needs to be done to build the necessary architecture for a truly sensitive and responsive early warning network. Building investigative and laboratory capacity in all of our State partners, enhancing our collaborative activities with international partners where, increasingly, some of our food supplies originate, and improving the qualitative and quantitative understanding of critical food safety problems are important components of CDC's response. CDC has been working with the Council of State and Territorial Epidemiologists and the Association of State and Territorial Public Health Laboratory Directors to enhance core surveillance capacity and to assure that the appropriate architecture exists. A 21st century system is needed to confront 21st century challenges.

In 1997, in response to the growing concern about food safety, the President announced the National Food Safety Initiative. CDC's collaborative involvement with FDA, USDA, and the Environmental Protection Agency in the ongoing expansion of this initiative responds to the new challenges by building a national early warning system for hazards in the food supply through enhanced capacity for surveillance and outbreak investigations at the State and federal levels. Specific activities of the Initiative include expanding the scope of FoodNet, using it to define the true incidence of many diagnosed foodborne infections and to assess their sources and potential for control; developing and standardizing new and rapid diagnostic techniques and molecular subtyping, or fingerprinting, for foodborne pathogens; and designing and delivering training programs for epidemiologists, laboratorians, and health professionals.

Conclusions

In conclusion, strong Federal, State, and local public health surveillance networks are the foundation for rapid identification and investigation of infectious disease threats, including those illnesses that are caused by foodborne pathogens. Foodborne diseases remain a challenge for public health. To address this challenge will require continued investments in our public health infrastructure and strong partnerships among State and local health departments and Federal agencies.

Thank you for the opportunity to discuss the surveillance of foodborne disease. We will be happy to answer questions you or other members of the Subcommittee may have.

MAY-08-1998 18:30

Talking Points on GAO Food Safety Report
Friday, May 8, 1998

* While our food supply remains among the world's safest, Americans are increasingly eating more food from around the world and we need to do all we can to ensure the safety of our food supply from whatever source.

* Since taking office, the President recognized the importance of protecting the wholesomeness and safety of our food supply and launched a major cross-Department initiative. The President has also called for an additional \$50 million in his FY'99 budget for food safety. (\$25 M would be for imports.)

* The GAO report echoes the Administration's call to Congress to promptly pass legislation giving FDA greater authority to ensure the safety of imported foods.

* With the volume of imports having doubled in the past five years and anticipated to double again by the end of the decade, the Agency has long recognized that it needs greater authority and more resources and hopes this report is a catalyst for Congressional action. Moreover, many of GAO's recommendations mirror solutions FDA has championed for more than a year.

(Quote given to the AP on 5/8: "Although the Agency has not seen the final report, it appears to echo the Administration's call to Congress to promptly pass legislation giving FDA greater authority to ensure the safety of imported foods. With the volume of food imports having doubled in the past five years, the Agency has long recognized that it needs greater authority and more resources and hopes this report is a catalyst for Congressional action. Moreover, many of GAO's recommendations mirror solutions FDA has championed for more than a year")

---- We are also sending you draft Qs and As. On Monday morning, you will receive a one page statement from FDA and most likely a backgrounder that gets into more of the specifics.

Q: What safety problems have been associated with imported foods?

A: The same kinds of problems we see with domestic foods--occasional contamination with microbiological, physical or chemical contaminants. Some problems, such as last year's outbreak from raspberries containing the pathogen *cyclospora*, have caused major outbreaks of foodborne disease and have been difficult to trace and contain.

Q: How does FDA inspect imported foods?

A: Under current law, which was originally enacted at the turn of the century, FDA is empowered to inspect foods at the border or port of entry and refuse entry to foods the agency believes may be risky. That system worked well earlier in the century, when food imports were relatively few. However, today the agency's ability to examine such imports is overwhelmed by the volume of imports.

Q: How many imports come into the U.S. each year?

A: Since 1990, the volume of imports of FDA-regulated products has increased from about 1.2 million entries to almost 4 million in 1997. That volume is expected to double again (to over 8 million) by the year 2000. The majority of those imports are foods.

Q: What does FDA inspect imported food for?

A: A variety of things related to safety--pesticides and other chemical contaminants; microbiological contamination; natural toxins (such as molds); unapproved food and color additives. Inspectors also look for inaccurate labeling or other things less directly related to safety.

Q: How many inspectors does FDA have at the borders to examine these imports?

A: There are over 300 ports of entry at which imported foods arrive from other countries, including seaports, border entry points, and airports. In 1997, FDA assigned 222 inspectors to review imports entering the U.S.; about 1/2 of that effort was focused on food imports. Another 240 staff in FDA laboratories analyzed imports for their safety (202 focused on foods).

May 8, 1998

Qs and As on GAO Report on Imported Foods

Q: What are the GAO's findings re: imported foods?

A: The GAO has affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report recommends that Congress give FDA the authority to require foreign countries to have a safety system in place equivalent to the U.S. system before those countries can export food to the U.S. The Administration submitted such legislation to Congress earlier this year.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A: No hearings have been scheduled and this issue does not appear to be on the Congressional agenda for this year.

Q: Does FDA agree with the conclusions reached by GAO on the imported food issue?

A: Yes. The major conclusion that FDA needs additional authority is consistent with FDA's (and the Administration's) past pronouncements about how to strengthen protection against unsafe foods imported into the United States.

Q: Are there some findings and recommendations that FDA disagrees with?

A: Only relatively minor points. For example, the report notes that each year FDA plans to conduct a certain number of import inspections yet falls short of those plans. The "workplan" is merely a way of targeting resources, not a mandatory exercise whose failure to carry out to the letter will result in a threat to the public health. FDA does not expect to carry out 100% of the plan, as emergencies arise that pull staff off of routine duties.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent that. Do you agree with their recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes. FDA agrees with that recommendation, that CMPs would be an effective tool.

Q: Are imported foods safe?

A: In general, yes. However, recent outbreaks of illness associated with imported and domestic foods demonstrate that there is a problem and that the government needs to improve food safety. Current statistics on foodborne illness do not show conclusively that imported foods are riskier than domestic foods.

Interagency Strategic Planning Session
July 2, 1998
Minutes



Attendees: Tom Billy, Karen Carson, Phil Derfler, Gary Dykstra, Elaine Francis, Margaret Glavin, Lynn Goldman, Caren Wilcox, Karen Hulebak, Bill Jordan, Eileen Kennedy, Joe Levitt, Joan Mondschein, Judy Nelson, Jim O'Hara, Janice Oliver, Dalton Paxman, Bill Raub, Steve Schaub, and Cathy Woteki. Facilitator: Len Killkelley.

The session led off with discussion of which approach to take to planning: problem analysis (identify problem, determine cause, and construct plan to resolve) or "visioning". Tom Billy provided a short discussion of how he applied "visioning" successfully, the advantages, and how it had been used by FSIS to devise a new perspective on ensuring meat and poultry safety.

- Start with a vision where want to be at some time in the future. Should be a "stretch" without regard to constrictions imposed by current conditions.
- Set general goals toward that vision.

There was some discussion of the goal of Tom's plan (no one gets sick):

- Does it cover all potential contaminants and affects (acute and chronic)?
- You get a different type of research when posing questions from different perspective. Food safety is a good goal where we need to invest in research with potential spin-offs.
- Might it adversely affect consumers' choice of healthy diets, thereby having another, different adverse affect - negative impact on nutrition? Not only preventing risks but promoting nutrition.
- Concerns might be remedied by stating the goal more narrowly - "no one gets sick from *Cyclospora* on raspberries."
- Need to get away from "numericalness" that bogs us down. Use of reasonable vs absolute certainty. Make a big dent in food safety.

Decision was to use the "visioning" approach to planning. There were questions as to scope of planning: Just food safety or inter-program relationships of the agencies? The consensus was to treat food safety broadly.

Breakout groups conducted 3 exercises:

1. In broadly defined food safety area, describe a stunning success on the part of interagency action or in a single agency. Specifically, what did you do to make the success happen? What did others do that made it happen? What in the organization worked so that the success happened?

-Various successes described resulted in delineation of characteristics that promoted the success:

- Commitment of top management to accomplishing the task and to providing resources (e.g., funding and staffing).
- Positive attitude of top management and conveying that to those involved.
- Everyone understands that the task is a high priority.
- Hands-on work from top management down.
- Real-time decisions made, particularly about managing the risk, and an overall willingness to act on the part of management.
- Ownership of the project - those involved have something at stake in terms of outcome. - win/win.
- Perceived time for change.
- Strong working relationship among agencies, cross-agency trust and willingness to use other agency's (including states') data.
- Clearly defined goals.
- Early brainstorming and preliminary risk analysis to refine focus.
- Importance of the public process in achieving the success.
- Engagement of internal and external stakeholders (stakeholder meetings, early OMB and White House involvement etc.)
- Honest and open communication and outreach.
- Highly committed and competent staff.
- Willingness to listen and compromise.
- Genuine spirit of cooperation.

2. Describe a) agency strengths including cultural characteristics, technical skills, anything else that lead to accomplishments, and b) strengths stakeholders bring to the success process.

Agency Strengths:

- Strong sense of mission, motivation and commitment.
- Task and action oriented.
- Leadership and crisis management skills.
- Scientific expertise and Public Health Orientation.
- Commitment to public involvement.
- Availability and leveraging of resources.
- Commitment to public information, outreach, and education.
- Stable workforce.
- Research strengths and data rich.

Stakeholders' contributions:

- Provide diversity of views. They ask hard questions and bring in fresh ideas.
- Assist in obtaining resources.
- Provide criticism - constructive and keep us on track.

- Economic interest in safe foods.
- Source of assistance in developing new technologies and methods.
- Market our views to the public.
- Support of regulations and new approaches.

- Consumers Groups: grassroots network to bring problems up and get information from agencies disseminated. They bring passion to the cause.
- Congress: oversight and critical review, funding.
- Trade assn: bring agencies a single voice from many divergent views of industry represented.
- Industries: have practical experience and data. Volunteer to test new programs under consideration (e.g., HACCP pilots)
- Other countries: provide experiences.

3. Provocative future vision - reaches for dramatic improvements

-Characteristics:

- Future oriented.
- Idealistic/ambitious, yet manifestly desirable.
- Clarifies purpose, guides strategy and actions across agencies.
- Inspires enthusiasm.
- Compelling and important to people of the U.S.

-Focus on one component of food safety.

-Group choices:

- Seamless national (international?) food safety inspection system that is deployed based on risk, promotes sound food safety practices by industry, and assures safe food for consumers.
- Prevention.
- Seamless system of delivering safe food to consumers.

-This exercise continues on July 9 with an analysis of each group's product after which revisions can be made. Additional components of food safety will be dealt with in a similar manner, with the refinement that candidates for future vision will be chosen in the large group in order to get the widest breadth of coverage of the various aspects of food safety (i.e., no duplication).

RADIO ADDRESS OF THE PRESIDENT TO THE NATION

Hong Kong

THE PRESIDENT: Good morning. I've just returned from my trip to China, a great and ancient nation that is undergoing historic change -- change I could see in new private businesses that are helping China's economy to grow, in people free for the first time to work in jobs of their own choosing, and in Chinese villages in the first free elections of local leaders.

I was able to speak directly, not only to President Jiang and the leaders of the Chinese government, but to the Chinese people themselves about the partnership we hope to build with China for peace and prosperity and about the importance of freedom and what it means to us in America. At this particular moment in history, when for the first time a majority of the world's people live under governments of their own choosing, and when in China the positive impacts of greater openness and personal liberties are already apparent, I'm especially glad to be home for Independence Day -- the day we celebrate the freedom our founders declared 222 years ago this Fourth of July. And this Fourth of July, even as we celebrate, we should be not only grateful for the freedom we enjoy, we should rededicate ourselves to the work of responsible citizenship. For example, on the Fourth of July families and friends come together all over America at backyard barbecues and parks for picnics. As they enjoy their meals, I want to report to you about what I'm doing to make sure the food and drinks we serve our families this Independence Day and every day are safe.

Our food supply is the most bountiful and the safest in the world, but we know we can do better. For nearly six years I've worked hard to put in place a modern food safety system for the 21st century. I signed into law legislation to keep harmful pesticides off our fruits and vegetables. We put in place strong protections to ensure that seafood is safe, and we're modernizing our meat and poultry safety system.

Last year, we launched a nationwide early warning system to catch outbreaks of food-borne illnesses sooner and prevent them from happening in the first place. But as much as we've done, we know we have to do more to keep our families safe and strong. We know older people and children are especially vulnerable to contaminated food. That lesson was driven home tragically last year, when apple juice contaminated with a deadly strain of e. coli caused the death of a 16-month-old child in Washington State and led to the hospitalization of more than a dozen other children.

Today we're taking two important steps to ensure that our food supply is as safe as we can make it. First, I am pleased to announce a new rule that requires warning labels on all packaged juice that has not been pasteurized or processed to kill harmful bacteria. These warnings will help families make better decisions about the juice they buy, and they will help us to prevent thousands of Americans from becoming ill every year.

Second, I'm directing the Department of Health and Human Services and the Department of Agriculture to report back to me within 90 days with a plan to create a new national institute for food safety research. This institute will join the resources of the public and private sectors and bring together the talents of the most esteemed scientists in the government, in universities, and in businesses to develop cutting edge techniques to keep our food safe.

I'm doing what I can to protect our families from contaminated food. Congress must also do its part to ensure the safety of America's food supply. First and most important, it should fully fund my comprehensive \$101 million food safety initiative. Among other important programs, this initiative will pay for 225 new food and drug administrators, inspectors, and employees --- people who can keep unsafe food away from our borders, out of our stores, and off our dining room tables.

Congress should also give the FDA greater authority to halt imports of fruits, vegetables, and other food products that are produced under safety conditions that simply do not match our own strict standards. It should give the U.S. Department of Agriculture new authority to impose tough fines on businesses who violate those standards, and to issue mandatory recalls of unsafe meat and poultry before they reach our tables; and it should confirm a respected, experience scientist, Dr. Jane Henney to lead our food safety efforts as Commissioner of FDA.

Food can never be made entirely safe; therefore, every parent also has a responsibility -- a responsibility to handle food carefully, especially during the summer. Meanwhile, we must do everything we can to protect the food Americans eat and to give our families the peace of mind they deserve. That's one important way on this Fourth of July we can resolve to keep our nation strong as we move into the 21st century.

Happy Independence Day, Americans, and thanks for listening

Food Supply

C> - you asked for - Tom

JK

THE CLINTON/GORE ADMINISTRATION: INCREASING FOOD SAFETY FOR AMERICA'S FAMILIES

I challenge Congress to fully fund our Food Safety Initiative and give Americans peace of mind when they reach for a piece of food. I call on Congress to pass legislation that will allow the federal government to recall contaminated meat and poultry. The present system of recalls was created in an age when meat traveled around the corner. Today, it travels around the country. We need new authority to seize meat that may be contaminated, to protect America's families.

- Vice President Al Gore
July 2, 1998

Today, Vice President Al Gore is joined by Secretary of Agriculture Dan Glickman at the United States Department of Agriculture (USDA), and calls on Congress to fully fund the Administration's Food Safety Initiative and pass legislation giving the USDA authority to order the recall of contaminated meat and poultry and to impose civil penalties for violations of food safety standards.

Addressing The Danger Of Food-Borne Illness. Every year, an estimated 6.5 to 33 million people become sick from food-borne illnesses. The medical costs and productivity losses associated with these illnesses range from \$6-\$34 billion a year. After making revolutionary changes in our meat, poultry, and seafood food safety systems, the Clinton Administration dramatically expanded its food safety efforts last year by launching the Food Safety Initiative, a comprehensive strategy to improve food safety from the farm to the table.

A Call For Congressional Action. The President has requested additional funding in fiscal year 1999 for resources to continue the fight for improved food safety. The House approved less than one-fifth of the Administration's request, and the Senate Appropriations Committee provides even less funding for this important initiative to protect American families. Today, the Vice President challenges Congress to fully fund the Food Safety Initiative, which would:

- **Further expand our early warning system** and strengthen state surveillance activities of food-borne illness;
- **Hire FDA inspectors** to improve the safety of our nation's fruit and vegetables, both domestic and imported;
- **Develop new ways** for federal inspectors to detect food-borne illnesses in meat and poultry and determine the sources of contamination;
- **Improve education outreach** on proper food handling.

Encouraging States To Adopt the FDA's Model Food Code. The Vice President encourages state and local governments, and the retail food industry to adopt and follow the food safety recommendations in the FDA's Food Code, which includes recommended, but voluntary, standards and practices to keep food safe in restaurants, grocery stores,

nursing homes, day care centers, and other local food service operations. By adopting this Code, our citizens would be ensured of uniformly effective safety protection throughout the nation.

Challenging Congress To Pass The Food Safety Enforcement Act. The Vice President challenges Congress to pass legislation sponsored by Sen. Tom Harkin (D-IA) that will give the Department of Agriculture the authority to assess civil fines and order mandatory recalls of unsafe meat and poultry products. Currently, the USDA can only respond to food safety violations by bringing criminal actions or withdrawing inspections, recalls are voluntary and civil penalties are unavailable

ABC - Sub. note
false just

Jordan Tamagni

07/01/98 07:45:32 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Revised Draft -- Sent to AF1: Podesta, Blinken, Engskov

Draft 7/1/98 7:15pm

Jordan Tamagni

Morely
grilling

- budget
recall

food code
responsibility

NYT
JM

FOOD
SAFE

Communications
release

drive thru / GDA

**PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS ON FOOD SAFETY
JULY 4, 1998**

U SDA

strategy

→ AZ. Sm. Lgn

Good morning. I have just returned from my trip to China, a great and ancient nation that is undergoing historic change. I saw evidence of that change in the faces of people free for the first time to work in jobs of their own choosing ... in the new private businesses that are helping China's economy to grow ... and in the first free elections of local leaders in Chinese villages. I was able to speak directly, not only to the Chinese government, but to the Chinese people, about the importance of freedom and what it means to us in America.

Seeing once again the power of these ideals makes me even prouder to be home in time for Independence Day, when we celebrate the freedom our founders fought for more than 220 years ago.

The Fourth of July is also a time for families and friends to come together, at backyard barbecues and public parks all across America. Today, I want to talk to you about what I am doing to make sure that the food and drinks we serve to our families this Independence Day and every day are safe.

America's food supply is the most bountiful -- and the safest -- in the world. For nearly six years, I have worked hard to make food safety a top priority. I signed into law legislation to keep harmful pesticides off our fruits and vegetables. We put in place strong protections to ensure that seafood is safe, and we are modernizing our meat and poultry safety system. Last year, we launched a nationwide early warning system to catch outbreaks of food-borne illness sooner, and prevent them from happening in the first place.

But as much as we have done, we know we must do more to keep our families safe and strong. We know that older people and children are especially vulnerable to contaminated

food.

That lesson was driven home tragically last year, when apple juice contaminated with a deadly strain of E. coli bacteria caused the death of a 16-month-old child in Washington State, and led to the hospitalization of more than a dozen children.

Today, we are taking two important steps to ensure that our food supply is as safe as we can make it. First, I am pleased to announce a new rule that requires warning labels on all packaged juice that has not been pasteurized or processed to kill harmful bacteria. These warnings will help families make better decisions about the juice they buy -- and they will help us to prevent thousands of Americans from becoming ill every year.

Second, I am directing the Department of Health and Human Services and the Department of Agriculture to report back to me within 90 days with a plan to create a new national institute for food safety research. This institute will join the resources of the public and private sector, and bring together the talents of the most esteemed scientists in the government, universities, and business to develop cutting edge techniques to keep our food safe.

I am doing what I can to protect our families from contaminated food. But Congress must do its part to ensure the safety of America's food supply. First and most important, it should fully fund my \$101 Million food safety initiative. Among other important programs, this initiative will pay for 225 new FDA inspectors and employees, to keep unsafe food away from our borders, out of our stores, and off of our dining room tables. Congress should also give the FDA greater authority to halt imports of fruits, vegetables, and other food products that are produced under safety conditions that do not match our own strict standards. It should give the USDA new authority to impose tough fines on food producers who violate those standards -- and to issue mandatory recalls of unsafe meat and poultry before it reaches our tables. And it should confirm a respected, experienced scientist, Dr. Jane Henney, to lead our food safety efforts as commissioner of the FDA.

Food can never be made entirely safe, and every parent has a responsibility to handle food carefully -- especially during the summer. But we must do everything we can to protect the food Americans eat and to give families the peace of mind they deserve. That's one way to keep our nation strong as we move into the 21st Century.

Happy 4th of July, and thanks for listening.

Message Sent To: _____

Sylvia M. Mathews/WHO/EOP
June G. Turner/WHO/EOP
Michael Waldman/WHO/EOP
Ann F. Lewis/WHO/EOP
Ruby Shamir/WHO/EOP
Michelle Crisci/WHO/EOP
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Laura Emmett/WHO/EOP
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Mary L. Smith/OPD/EOP

THE PRESIDENT ANNOUNCES JOINT INSTITUTE FOR FOOD SAFETY RESEARCH AND LABELING OF FRESH JUICES

July 4, 1998

In his weekly radio address, the President will announce the publication of a final rule to improve the safety of fruit and vegetable juices. The new regulation, which will take effect in time for this year's apple cider season, will help prevent illnesses from fresh, unpasteurized juices by requiring labels on these products. In addition, the President will announce a plan to create a Joint Institute for Food Safety Research that will develop a coordinated strategy for conducting food safety research activities consistent with the President's Food Safety Initiative. Finally, the President will call on Congress to provide full funding for his Food Safety Initiative, pass vital food safety legislation, and confirm Dr. Jane E. Henney as the new FDA commissioner.

Warning Labels for Consumers. The President will announce a final rule that will require warning labels on juice products that have not been processed to reduce microbial risk. These labels will state: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." These labels will be required for all packages of untreated, fresh juices but not for juice sold for on-site consumption, such as in restaurants. The rule will be effective for this year's apple cider season. The FDA expects it to reduce significantly the incidence of juice-related illness, now estimated at up to 40,000 cases each year, including both treated and untreated juice.

Food Safety Research Institute. The President will direct the Secretaries of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) to report back to him within 90 days on the creation of a Joint Institute for Food Safety Research that will: (1) develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative; and (2) efficiently coordinate all Federal food safety research, including research conducted with the private sector and academia. The principal goals of this Joint Institute will be to develop the means to identify foodborne hazards more rapidly and accurately, and to develop effective interventions to prevent food contamination at each step from farm to table.

Food Safety Initiative and Legislation. The President also will call on Congress to provide full funding for his \$101 million food safety initiative, which would support a variety of measures including: hiring additional FDA inspectors to examine the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and expanding our early warning system to help detect and respond to outbreaks of foodborne illnesses. The President also will call on Congress to pass two vital pieces of legislation to improve the safety of the nation's food supply. One bill will ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or that do not provide the same level of protection as is required for U.S. products. The second bill will give USDA the authority to issue mandatory recalls and impose civil penalties for unsafe meat and poultry.

New FDA Commissioner. The President also called on Congress to confirm Dr. Jane E. Henney as the new Commissioner of the FDA. The FDA needs the strong leadership of Dr. Henney to help lead the way to improving food safety and assuring the safety and efficacy of pharmaceutical and biological therapeutics, medical devices, blood products, generic drugs, food additives, and cosmetics.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

*February 1998. Administration announces its proposed food safety budget, which requests an approximate \$101 million increase for food safety initiatives.

*May 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply -- "Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems.

*August 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

**THE PRESIDENT ANNOUNCES FOOD SAFETY
RESEARCH INSTITUTE
July 4, 1998**

In his weekly radio address, the President will announce a plan to create a Joint Institute for Food Safety Research that will develop a coordinated strategy for conducting food safety research activities consistent with the President's Food Safety Initiative.

Joint Institute for Food Safety Research. The President will direct the Secretaries of the U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) to report back to him within 90 days on the creation of a Joint Institute for Food Safety Research that will: (1) develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative; and (2) efficiently coordinate all Federal food safety research, including research conducted with the private sector and academia.

Goals of the Institute. The two principal goals of the Joint Institute for Food Safety Research will be to develop the means to identify foodborne hazards more rapidly and accurately, and to develop effective interventions to prevent food contamination at each step from farm to table.

In addition to improving coordination among the Federal agencies, the Institute will serve as a focal point for coordinating research with states, the private sector, and academia, by means of public-private research partnerships, or other appropriate mechanisms. The specific structure and operations of the Institute will be outlined in the agencies' report back to the President, and will be based on extensive consultations with all interested parties, including consumers, farmers, industry, and academia.

Current Status. At present there are at least 12 agencies that conduct food safety research. Under the President's food safety initiative, the White House Office of Science and Technology Policy has established an interagency food safety research working group to help coordinate Federal research priorities and planning. While this interagency process is improving our coordination, a Joint Institute for Food Safety Research will provide an even stronger and better focused research strategy for food safety.

THE PRESIDENT ANNOUNCES NEW FOOD SAFETY RULE REQUIRING LABELING FOR FRESH, UNTREATED JUICES

July 4, 1998

In his weekly radio address, the President will announce the publication of a final rule to improve the safety of fruit and vegetable juices. The new regulation, which will take effect in time for this year's apple cider season, will help prevent illnesses from fresh, unpasteurized juices by requiring labels to alert those most vulnerable to food-borne illness, such as children and the elderly, of the risk associated with these products. The Food and Drug Administration (FDA) estimates that there are up to 40,000 cases of juice-related illness (including both treated and untreated juice) each year, and that this rule, especially when combined with another proposed food safety rule, will significantly reduce that number.

Providing Warning Labels for Consumers. The FDA rule will require any packaged untreated juice to be labeled with a warning statement advising consumers of the potential risks of juice that has not been processed to eliminate dangerous bacteria. This requirement will apply to all processors that package untreated juice for consumption off-site, including retail processors such as grocery stores that squeeze and bottle juice for home use. Retail sellers of juice for consumption on-site -- such as restaurants and juice bars -- will be exempt from this labeling requirement.

As a result of this new rule, consumers will see the following label on juice products that have not undergone pasteurization or a comparable treatment: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems."

Labeling Rule Works Together With HACCP Rule. The labeling rule will work in tandem with another proposed rule that will require that all fruit and vegetable juice processors implement a Hazard Analysis and Critical Control Point (HACCP) system for their products to protect the public from health hazards. The proposed HACCP regulation will ensure that processors take the steps necessary to reduce the number of microorganisms in their products to an amount roughly equivalent to that achieved by pasteurization. Retailers of packaged juice, as well as processors who sell less than 40,000 gallons of fresh juice per year, will be exempt from this requirement. FDA is in the process of seeking comments on this proposal.

Safety of Juices. About 98 percent of all juice sold in the United States is pasteurized, and juice products generally are safe and nutritious. During the past few years, however, several serious outbreaks of foodborne illness have resulted from the consumption of juices that have not been pasteurized or otherwise treated to destroy pathogens. As a result of the two rules described above, FDA estimates that up to 40 million additional gallons of juice will be pasteurized, and the incidence of illness significantly reduced.

**THE PRESIDENT CALLS FOR FULL FUNDING FOR FOOD
SAFETY INITIATIVE AND PASSAGE
OF VITAL FOOD SAFETY LEGISLATION
July 4, 1998**

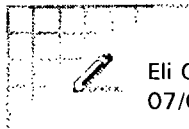
In his weekly radio address, the President will call for full funding of the food safety initiative in his FY99 budget and for passage of two vital pieces of legislation to improve the safety of this nation's food supply into the 21st Century.

Food Safety Initiative. The President's FY99 budget includes a request for \$101 million to improve the safety of the nation's food supply. These resources will support a variety of measures including: hiring additional FDA inspectors to examine the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and expanding our early warning system to help detect and respond to outbreaks of foodborne illnesses.

Congress has so far failed to provide the resources this important initiative requires. The House-passed Agriculture Appropriations bill provided only \$16.8 million of the Administration's requested increase for USDA and FDA, while the Senate Committee-passed bill provided only \$2.6 million. The President will call on Congress to meet his budget request for these measures, which are critical to the safety of the food consumed by America's families.

Enhanced FDA Oversight for Imported Foods. The President will call on Congress to pass food safety legislation, introduced by Senators Milkulski and Kennedy and Reps. Eshoo and Pallone, that gives the FDA greater authority over imported foods. This legislation will ensure that the FDA halts imports of fruits, vegetables, and other food products that do not meet U.S. food safety requirements or that do not provide the same level of protection as is required for U.S. products. The legislation also enables the FDA to halt imports from a country or facility that refuses to allow FDA inspections. This legislation gives FDA authority that is comparable to USDA's existing authority to prevent the importation of unsafe meat and poultry.

Mandatory Recall and Civil Penalties for Unsafe Meat and Poultry. The President also will call on Congress to pass the Food Safety Enforcement Enhancement Act, sponsored by Senators Harkin, Daschle, Johnson, and Leahy, which gives USDA the ability to assess civil fines and to order mandatory recalls of unsafe meat and poultry products. Currently, the USDA can respond to food safety violations only by bringing criminal actions or withdrawing inspections; all recalls are done on a voluntary basis and no civil penalties are available. This new legislation will give USDA additional enforcement tools to prevent consumers from ingesting and becoming ill from dangerous meat and poultry.



Eli G. Attie @ OVP
07/02/98 07:57:17 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Revised food safety remarks for VP

Remarks by Vice President Al Gore
Food Safety Event
Thursday, July 2, 1998

This weekend, millions of Americans will join their families and friends to celebrate the Fourth of July with backyard barbecues. We've come here today to declare America's independence from the dangers of food-born illness.

From the time President Clinton and I took office, we have worked hard to make sure that the food Americans eat -- already among the safest in the world -- is even safer. We put into place improved safety standards for meat, poultry, and seafood products, and expanded research, education, and surveillance throughout the food safety system. We took action to keep harmful pesticides off our fruits and vegetables, and created new protections against dangerous contaminants in our drinking water. As we end this century, we changed the way the meat and poultry inspection system works for the first time since the beginning of the century.

But we must do more. Despite all our progress, tens of millions of Americans become ill each year from eating unsafe food -- and roughly 9,000 of them die from it. All of us must do our part if we are to ensure that the food we serve our children is wholesome, safe, and free from danger.

That is why we have urged Congress to take the next step forward in food safety, by passing the President's Food Safety Initiative -- to make fruits and vegetables even safer, to increase inspections, to teach high-risk populations about food safety, and to expand the early warning system for food-borne illness we put in place last year.

But as Americans fire up their barbecues, it saddens me to report that some in Congress are firing up their opposition. House Republicans have passed a budget that cuts our Food Safety Initiative by more than 85 percent. Senate Republicans are poised to make cuts of a similar magnitude. That means fewer new food

inspectors, fewer new safeguards for fruits and vegetables, and a smaller chance of a life-saving early warning. This shouldn't be a partisan issue. We need new weapons in the war on unsafe food -- not a war on food safety in the Congress. The Republican food safety cuts are wrong -- and they would put America's children at risk.

I challenge Congress to fully fund our Food Safety Initiative and give Americans peace of mind when they reach for a piece of food. And I call on Congress to pass legislation that will allow the federal government to recall contaminated meat and poultry. The present system of recalls was created in an age when meat traveled around the corner. Today, it travels around the country. We need new authority to seize meat that may be contaminated, to protect America's families.

According to the Centers for Disease Control, most outbreaks of food-borne illness come about because of the mishandling of prepared food. That's why all the relevant parts of our government came together to ^{improve} develop the first "Food Code" -- a collection of the most up-to-date, science-based food safety standards available. As we begin this 4th of July weekend, I encourage all state and local governments, as well as restaurants, grocery stores, nursing homes, day care centers, and others, to follow the recommendations in the "Food Code." If we want our friends and families to be safe, this is one code that shouldn't be broken.

And something as important as the food we prepare demands personal responsibility as well. We'll hear more about this in a moment. But some basic rules are good reminders to all of us. Defrost the meat evenly. Make sure the meat you cook has been properly refrigerated. Keep hot food hot and cold food cold. Make sure your utensils and counter tops are clean. And, while red, white, and blue are great for waving -- red hamburgers and steaks are bad for eating.

The 4th of July is more than just a long weekend. It is a time when we remember what it means to be Americans, in the company of our families, our communities, and our fellow citizens. I hope that all Americans have a safe 4th of July -- and don't let avoidable food-borne illnesses endanger their life, liberty, or pursuit of happiness.

Message Sent To: _____



U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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MESSAGE: Also omittedHome & 332 3570

Why is food safety research so important?

Food safety research is critically needed to develop the means to identify and characterize foodborne hazards more rapidly and accurately, to provide information and tools for regulatory programs and enforcement, and to develop effective interventions that can be used as appropriate to prevent food contamination at each step from farm to table. New pathogens appear or grow more resistant, and we need the best science available to better improve food safety.

Why do you need a National Food Safety Research Institute?

Currently, there are approximately (xx) agencies that conduct food safety research. Under the President's food safety initiative, the White House Office of Science and Technology Policy has established an interagency food safety research council to help coordinate Federal research priorities and planning. While this interagency process is improving our coordination, a National Food Safety Research Institute will provide an even stronger and better focused research strategy for food safety.

In addition to improving our coordination Federally, the Institute will serve as a focal point for coordinating research with states, private sector, and academia, including public-private research partnerships, as appropriate.

What exactly will the Institute do? How much money will it have?

The specific structure and operations of the Institute, including funding, will be outlined in USDA's report back to the President, and will be based on extensive consultations with all stakeholders.

What's the budget for food safety research? Will Congress fund it?

The Administration requested \$33 million for research in the FY 99 Food Safety Initiative. The Senate has not provided any of the requested increase, and the House has provided only approximately \$ 5 million for new research. The Administration continues to work with Congress to identify additional funding for the entire \$101 million food safety initiative.

Is the Food Safety Institute related to the new Research Act the President recently signed?

The institute is not specifically related to the new law, which does recognize food safety as a high priority area for research. The new research law provides mandatory funding for research, but the House has reduced this funding in its FY 99 appropriations bill. If this new funding is provided to USDA, some of it may go to this food safety institute, but that is one of the issues USDA will be evaluating as it develops the plan to create the institute.

IMPROVING THE SAFETY OF AMERICAN MEAT AND POULTRY THE FOOD SAFETY ENFORCEMENT ENHANCEMENT ACT

USDA is continuing to put in place a state of the art, science based meat and poultry inspection system. We have lived with the old system for 90 years, but the world is different today. We know that traditional sight-touch-and-smell inspections overlook the hidden dangers in our food—bacterial pathogens like *E. coli* 0157:H7 and *Salmonella*—that pose the greatest threat to public health. The heart of USDA's new system is Hazard Analysis and Critical Control Points (HACCP). The new system requires that food producers put in place controls to prevent contamination and verify that the controls are working.

However, USDA needs new enforcement tools to hold industry accountable and better protect consumers when USDA finds violations of food safety standards. The Food Safety Enforcement Enhancement Act will give USDA the ability to assess civil fines and to order mandatory recalls of unsafe meat and poultry products.

Civil Penalties

Civil penalties serve as an effective deterrent and can be imposed more quickly than criminal penalties or the withdrawal of inspection. They can be appropriately tailored to the nature and scope of the violation as well as to the size and type of business. As USDA moves to the HACCP-based inspection system, more flexible enforcement tools will become even more important.

Food safety problems can also arise outside of federally inspected meat and poultry plants. USDA has only limited enforcement tools. The ability to assess civil fines will give USDA an enforcement tool against distributors, transporters, and retailers who do not meet their food safety responsibilities.

Civil fines are a common tool to enforce Federal laws. The FAA has the ability to impose fines for violations of airline safety laws. The CPSC has the ability to fine companies that distribute products in violation of product safety standards. USDA can also impose civil fines for a wide variety of situations, such as mistreating animals, exchanging food stamps for cash, and failing to keep appropriate records on watermelons. But, USDA does not have this authority for violations of food safety laws.

Mandatory Recall

USDA does not have the authority to order unsafe meat or poultry from the market. Under current law, all recalls are done on a completely voluntary basis. For the most part, this voluntary system works. If, however, the system does not function smoothly and without delay in the future, American consumers will be exposed to potentially dangerous meat or poultry.

In the past, most food was produced and distributed locally. Today, meat or poultry produced by one plant can be distributed across the country to hundreds or thousands of distributors, grocery stores, and restaurants. USDA does not have the resources or the information to locate and seize all suspect product in the food distribution system. The power to order a recall will help ensure that this occurs.

Other government agencies have the power to order mandatory recalls. The CPSC can recall unsafe toys; the EPA can recall dangerous chemicals; and the FDA can recall infant formula.

Why does USDA need civil penalty authority for violations of meat or poultry inspection laws?

Civil penalties can serve as an effective deterrent to prevent violations of meat and poultry regulations and can be imposed more quickly than seeking criminal penalties. Civil penalties can also be tailored to nature and scope of violation and size and type of business and are a more appropriate penalty for certain violations, such as recordkeeping. Civil penalties can also be used against those outside of Federal plants who violate food safety standards, such as distributors, transporters, retailers, where USDA does not have inspectors to ensure compliance with food safety laws.

Civil penalties are a common enforcement tool. USDA can impose fines for a wide variety of offenses, such as mistreating animals, exchanging food stamps for cash, not keeping proper records on watermelons. Why not food safety?

Why does USDA need mandatory recall authority for meat and poultry products?

Mandatory recall should really be viewed as an insurance policy for American consumers. The current system is completely voluntary and works well in most cases. But if a company refused to conduct a voluntary recall, USDA would have no power to order the company to recall the product. Giving USDA this authority would ensure that all contaminated product is removed from the market.

Mandatory recall authority is a common tool for other agencies. The Consumer Product Safety Commission can recall unsafe toys; EPA can recall dangerous chemicals; FDA can recall infant formula and other products. USDA should have similar authority.

The legislation also imposes a **Mandatory Notification** requirement that will ensure USDA is informed when contaminated product is on the market. That way, the public health experts at USDA can act quickly to ensure that all potentially contaminated product is removed from the market. Currently, there is no such notification requirement.

What is the status of the legislation?

Senator Harkin introduced the Food Safety Enforcement Enhancement Act, S. 1264, on introduced the legislation on October 7, 1997, for the Administration, with original cosponsors Sens. Daschle, Leahy and Johnson. The Senate Agriculture Committee held a hearing on October 8, 1997, and Secretary Glickman testified for the Administration. There has been no further action on the bill, which now has 11 cosponsors --Boxer, Durbin, Torricelli, Murray, Dodd, Kennedy, Moseley-Braun, and Mikulski.

Has the legislation been introduced in the House?

No. But on June 16, 1998, Rep. Nita Lowey offered an amendment during full House Appropriations Committee of the FY 99 agriculture appropriations bill that mirrored the civil penalties language of the FSEEA. The amendment was defeated by a vote of 19-25.

Bel fees

The President today
~~announced~~ ordered FDA to
produce a plan by the end
of the year which would

- ① Give guidelines to foreign food
producers for how food must be
grown and processed for entry into
the U.S. The President ordered

that within one year FDA create

- ② a full-scale hazard review system.

The President also announced legislation

- ③ to increase FDA's ability to prevent
contaminated food from entering the U.S.
and give it ~~an~~ increased resources for
enforcement.

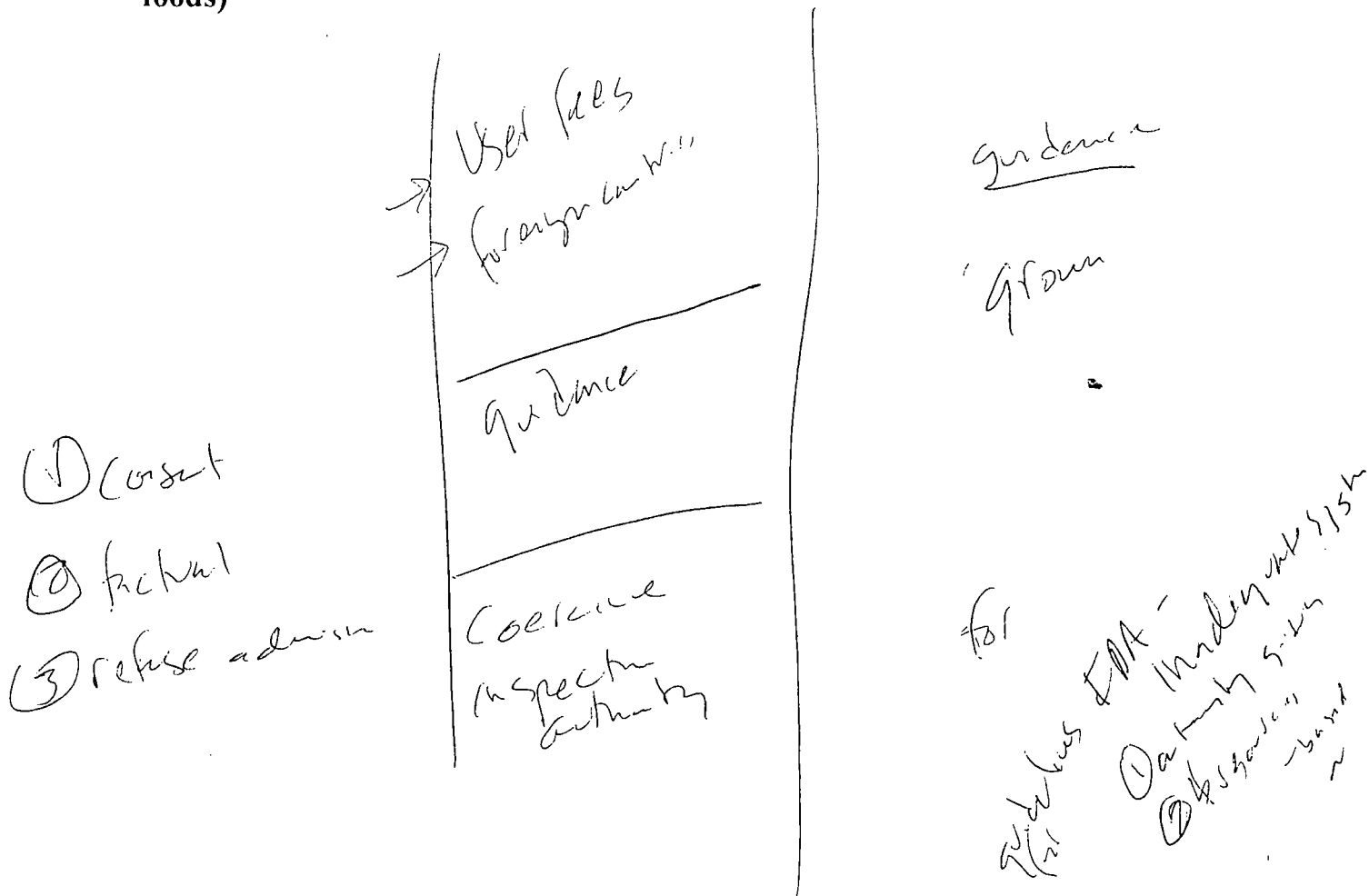
FDA IMPORTED FOOD SAFETY PROPOSAL

1. Develop and Implement HACCP for Fruits and Vegetables

- Propose Good Agricultural Practices Regulations and Good Manufacturing Practices regulations for fruits and vegetables by December 31, 1997.
- Propose fruit juice HACCP regulations by December 31, 1997.
- Propose HACCP regulations for all fruits and vegetables by October 1, 1998.

- on farm
practices
- worker health
- pest jobs
- type of water
chems.
- OFFER

2. Propose legislation requiring that food entering the United States be imported only from countries meeting U.S. food safety standards (i.e., expand the current requirement for imported meat and poultry to all foods)



MEMORANDUM

TO: BRUCE REED, ELENA KAGAN
FROM: TOM FREEDMAN, MARY L. SMITH
RE: COUNTRY OF ORIGIN LABELING FOR FOOD
DATE: SEPTEMBER 23, 1997

SUMMARY

A search of Nexis on the keywords "country" and "origin" revealed basically 3 pieces of legislation pending on the Hill that require labeling of country of origin: (1) "Imported Produce Labeling Act of 1997," (2) "Imported Meat Labeling Act of 1997," and (3) H.R. 2332, which amends the Tariff Act of 1930 to require country of origin. All three pieces of legislation have bipartisan support. USDA indicated that it has taken no formal position on any of these pieces of legislation.

LEGISLATION PENDING ON THE HILL

1. **Imported Produce Labeling Act of 1997**
H.R. 1232 (65 Co-sponsors --31 Democrats and 33 Republicans)
S. 1042 (7 Cosponsors --5 Democrats and 2 Republicans)
Sponsored by Rep. Bono (R-CA) and Sen. Larry Craig (R-ID).

This legislation provides that a retailer of a perishable agricultural commodity is required to inform consumers of the country of origin by "means of a label, stamp, mark, placard, or other clear and visible sign." There are fines for failure to inform consumers.

2. **Imported Meat Labeling Act of 1997**
H.R. 1371 (25 Co-sponsors --11 Democrats and 14 Republicans)
S. 617 (9 Cosponsors --3 Democrats and 6 Republicans)
Sponsored by Rep. Chenoweth (R-ID) and Sen. Tim Johnson (D-SD).

This legislation amends the Federal Meat Inspection Act to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin.

3. **H.R. 2332 (40 Cosponsors --21 Democrats and 19 Republicans), Sponsored by Rep. Everett (R-AL):** This bill amends section 304 of the Tariff Act of 1930 to require the marking of frozen produce with the country of origin on the front panel of the package for retail sale.

OTHER RELATED LEGISLATION THAT DOES NOT INVOLVE IMPORTS

1. **S.16, "Cattle Industry Improvement Act of 1997,"** Sponsored by Sen. Daschle (D-SD): Part of this legislation amends section 7 of the Federal Meat Inspection Act (21 U.S.C. 607) to require the labeling of meat produced in the United States to indicate the United States origin of the meat.

Ek

TLF

ms

ENL Ols

S

CD

FDA

FDA

FDA

O'Leary - HHS

m.h.f

OSTP

1)

2)

3)

4)

5)

we should put away our

5b. Increase surveillance of imports at the border for bacterial pathogens

- to increase to 1% - need 24 CSI's and 77 additional microbiologists

- to increase to 5% - need 145 CSI's - 466 microbiologists

1996 - 0.2% of import entries ^{samples} for micro



6. Require certificates from exporters that imported products do not violate FDA standards re: microbiological and chemical contamination.

7. Increase research for rapid methods development.

8. 1998 appropriation language to ARS ~~ARS?~~ ~~ARS?~~
400,000 plus to NAS

- ① heat the story - expand / new
- ② H's
- ③ exp → assumed
- ④ House proposal

-
- ① know
 - ② activity
 - ③ cost
 - ④ use till

Eric Olson
720-3809

→ Quality Control Systems

→ HACCP - meat / poultry

- Identify hazardous points
- focuses on control points
- regulatory

→ fibre

Paulina Mulicki

1. GAPs/GMPs for Fresh Fruits and Vegetables:

Directive: The FDA will develop good agricultural practices (GAPs) and good manufacturing practices (GMPs) guidance for fresh fruits and vegetables. The agency will also convene a public meeting on fruits and vegetables, leading to the future development of mandatory HACCP procedures for fresh fruits and vegetables.

FDA will propose mandatory Hazard Analysis and Critical Control Point (HACCP) regulation for the manufacture of juices in January, 1998.

FDA and the USDA's Agricultural Research Service (ARS) will accelerate the research outlined in the FY98 food safety initiative, to develop intervention technologies to eliminate and/or reduce levels of pathogens. This research will provide scientific data for future development of HACCP programs for fresh fruit and vegetable products. ARS will work with FDA to identify needed research, giving high priority to FDA needs associated with fresh fruits and vegetables.

Time: Publish GAPs/GMPs for fresh fruits and vegetables for which data exist and propose mandatory juice HACCP by January, 1998. FDA will urge industry to adhere to the GAP/GMP guidance upon publication. Public comment will be solicited to improve the guidance and to facilitate development of appropriate HACCP programs.

Resources needed:

1. Implementing GAP/GMPs - Additional resources are needed to assimilate data for GAPs/GMPs, as well as conduct surveillance, testing, and other work overseas.

- Implementing HACCP - HACCP requirements for any fruit or vegetable product will require at least 1 year to develop the proposal, 1 year for analysis of comments and preparation of a final regulation, and 2-3 years for phased-in implementation of the regulation.

Resources Needed: 185 FTEs and \$20.0 million

Develop/monitor Mutual Recognition Agreements:	15 FTEs
Foreign visits/evaluations:	100 FTEs
Reg writers, policy, program evaluators:	27 FTEs
Administrative support:	3 FTEs
Filer audits, review of HACCP plans, entry screening:	40 FTEs

2. \$ 8.0 million (37 FTEs) - Research to develop intervention/prevention technologies, e.g., antimicrobials, to reduce levels of or eliminate pathogens, and baseline pathogen data for development of HACCP.

Fairness

FY 1998 = 15.7 mil. -

235 40 mil 60 mil

= 10 mil 90 FTEs

15 - mil

3 FY 99

2. Legislative proposal:

Directive: a. FDA will develop a legislative proposal, to be put forward by the Administration, requiring that no food may be imported into the U.S. unless it is produced under a food safety system that provides the same level of protection as provided by the U.S. food safety system. This proposal will enhance FDA's ability to prevent the importation of unsafe food in a manner consistent with U.S. trade agreements.

Section 402 of the FFDCA should be amended by adding at the end thereof the following new subsection (h):

"(h)(1) If it is a food offered for import into the United States, unless such food has been prepared, packed or held under a system or conditions, or subject to measures, that provide a level of protection that is the same as the level of protection provided under this Act for food prepared, packed, or held in the United States at the time such food is offered for import. The importer of the food shall be required to demonstrate objectively that the system, conditions, or measures relevant to such food achieve the same level of protection.

(2) The Secretary may promulgate regulations to implement this subsection, including regulations identifying those systems, conditions, or measures that are equivalent within the meaning of this section."

b. FDA will also develop a legislative proposal to facilitate traceback of foodborne illness to the causative food. The Act should be amended by adding a new section 415 requiring maintenance of records as follows:

"Manufacturers and distributors of food, including importers, shall include among the records they maintain, records of receipt and distribution of such food, which shall include such information as the Secretary finds necessary to permit the distribution of such food to be traced. These records shall be maintained for a reasonable period of time beyond the shelf-life of the food."

The Act should also be amended to permit access to those records by amending section 704 by adding a new paragraph (a)(4) as follows:

"An officer or employee making an inspection under paragraph 704(a)(1) of a food which may pose a hazard to public health or has been associated with foodborne illness shall be permitted at all reasonable times to have access to and to copy and verify any records required to be kept under section 415."

Finally, the act would be amended to make it a prohibited act (subject to injunction or prosecution) to fail to maintain required records for traceback. A new subsection 301(x) should be added as follows:

“The failure to maintain the records required under the authority of section 415.”

- c. The Administration should also pursue mandatory recall authority for FDA; as previously proposed by the agency.

Resources:

MARIA

GLICKMAN

FARMER

September 21, 1997

MEMORANDUM FOR ERSKINE BOWLES

**FROM: BRUCE REED
 ELENA KAGAN**

RE: FOOD SAFETY AND FAST TRACK

This morning we convened a meeting of representatives from FDA, USDA, USTR, the White House Fast Track Working Group, and OMB including Sally Katzen, to discuss possible food safety initiatives to mitigate health concerns from imports following passage of fast track legislation.

Below is a list of policy options that we've asked the agencies to explore and respond to by tomorrow morning. We asked that they consider these proposals for their feasibility for a formal Administration announcement within the next two days.

- 1. Upgrade Standards.** We are currently implementing new procedures for domestic seafood and meat and poultry production, the Hazard Analysis and Critical Control Points system (HACCP). This is a regulatory scheme, considered more effective than simply increasing the number of inspectors, that involves companies identifying the danger points in their processing system, actions to take to avoid the contamination, and creation of a paper trail for inspectors to periodically review and see whether the program is working. Imported products must be produced under equivalent food safety systems. The proposal would expand HACCP to include fruits and vegetables, essentially creating US standards and then applying them to foreign countries. The FDA is developing this proposal.
- 2. Application of Existing US Standards.** There already exist a limited patchwork of existing US standards for fruits and vegetables. This approach would delineate what the existing US standards are, and require them to be applied to imports. This has been tasked to FDA.
- 3. Expand USDA Involvement.** USDA has research and education programs in this area that could be expanded. Further, if HACCP is enlarged to include fruits and vegetables, there will be a need for the creation of an education program for US farmers, a program that could be a model for foreign farmers and companies. USDA has a presence in foreign countries and could work cooperatively to encourage the adoption of equivalent practices there.

Dan Pink

5-30417

205-4102

DRAFT: 5-11-97; 4:40PM

Statement of Vice President Al Gore
Food Safety Announcement
Washington, DC
May 12, 1997

Dan - need to
be clear this is me
in a series of steps
Clinton/Gore have taken
(1997) Gore plan, seafood
meat, poultry, animal

Good morning. Today, we act to protect America's children from invisible hazards in their food -- and to make sure America's bountiful food supply is safe, sanitary, and wholesome.

Earlier this year, President Clinton directed Secretary Shalala, Secretary Glickman, and Administrator Browner to report to him ~~on the state of food safety in America, and to devise a strategy for battling the threat to public health.~~ *on next steps to*

This morning, I am pleased to accept their report -- "Food Safety From Farm to Table." *in our continued battle to improve the safety of the nation's food supply.* This important document confirms that America's food supply is among the safest in the world. But it reminds us that our nation has more to do. A series of changes -- economic, demographic, and biological -- has raised new challenges. For example, a generation of consumers that has grown up with the microwave and the freezer often hasn't been schooled in proper food-handling techniques. The population of Americans especially vulnerable to foodborne illnesses -- the elderly and those with compromised immune systems -- is growing. And microorganisms themselves are adapting to the environment, becoming craftier, developing greater resistance to human intervention.

Each year in America, unsafe food is responsible for as many as ~~33~~⁵ million illnesses and ~~up to 9,000~~ deaths. That is unacceptable. *thousands of premature.*

Today's report outlines a series of aggressive measures to combat this hidden danger, and to make sure the food Americans eat is healthy and safe. Our plan has five key components.

First, moments ago, cabinet agencies, representatives of the food and restaurant industries, and consumer advocates signed an agreement to launch an unprecedented public education campaign about the dangers of foodborne illnesses. This campaign will teach all Americans -- from chefs in fancy restaurants to barbecuers in their own backyards -- that they can prevent many serious problems with a few simple safety measures . . . for example, cleaning utensils, wiping down food preparation surfaces, cooking foods at high enough temperatures, and washing fruits and vegetables. This campaign, which will begin later this year, is an unprecedented partnership to nourish the public with information about food safety. This campaign will supply Americans with food for thought so they can safely enjoy the food they eat.

Second, we're going to improve food inspections. The Food and Drug Administration will hire additional inspectors for seafood plants. And we'll expand a promising approach called Hazardous Analysis Critical Control Points that we began as part of our reinventing government

9 poultry
initiative. Under the HACCP ("HASS-upp"), food manufacturers identify the key points where contamination is likely to occur, and then devise a strategy for preventing it. This approach is already in place for meat and seafood. Our plan extends it to the manufacture of fruit and vegetable juice, which will reduce terrible incidents like the one Laurie Girand just described. *proposes to*

for example Third, our plan boosts *and risk assessment* investments in research to develop new tests for detecting and combating food contaminants. Our proposal will target \$16.5 million to critical research needs. This will give food safety officials across the country new tools to detect the most elusive threats -- like the Hepatitis A virus and cyclospora, which cannot now be detected in many foods. And it will aid in developing new strategies for fighting other pathogens that have developed resistance to time-tested controls such as refrigeration and heat. *outbreaks of*

Fourth, we will strengthen coordination and improve efficiency among the agencies that have a role in protecting public health. The Agriculture Department, the CDC, the FDA, and the EPA will form a new intergovernmental group to improve our response to foodborne illnesses.

Fifth, we'll continue building an Early Warning System to detect outbreaks of foodborne illnesses before they erupt into larger threats. We'll add an eighth ~~Center for Disease Control~~ "sentinel site" to spot incidents early. Each site will be a Paul Revere of public health: it will sound the cry, spread the word, and *get our citizens ready to respond*. We'll also make sure that the dedicated public health professionals who work as America's "disease detectives" have high-tech tools like DNA fingerprinting to track down illnesses, stop them in their tracks, and work to prevent their recurrence. *help governments, industry and communities make quick actions*

Ensuring the safety and integrity of America's food supply is not ~~of~~ something any individual or institution can do alone. It is a challenge we must meet together -- consumers, producers, industries, universities, physicians, and government working together toward a common goal. Just as we came together to combat the dangerous of meat-packing plants at the dawn of the Industrial Age, we can come together to combat new hazards using the tools of the Information Age.

Busy parents have enough on their minds. They shouldn't have to worry that the juice their baby drinks or the sandwich their son eats in the school cafeteria or the hamburger their daughter orders for dinner will be hazardous to their health. When children reach for a piece of food, parents deserve to have peace of mind.

I thank all of you for your working with us on this effort.

I thank Secretaries Shalala and Glickman and Administrator Browner for their hard work. And I congratulate them on beginning to put in place *this* plan to keep our food safer and our children healthier. *And I thank*

###

*Federal law to provide traffic funds
for states who change their*

1. Modify current law so that traffic violators can choose between attending 7 hours of traffic school, or enrolling in the volunteer voucher program. The current tuition of \$50 would continue to be paid, \$ 10 of which could go to present a 1 hour traffic safety video, and the rest, \$ 40 would be used to fund the establishment of the program. At the time, a blank voucher would be delivered to the traffic violator, along with a description of the program.
2. Establish the volunteer voucher program, allowing city governments, county and state agencies and 501(c)(3) organizations to designate an official empowered to acknowledge and verify the receipt of the six hours of volunteer labor, along with a description of the services rendered. The services would have to be rendered within a reasonable period, such as two months, after issuance.
3. Establish, as part of the program, a state matching service within the DMV-much like what happens now-to insure that volunteer agency authorizations and traffic violator certificates match up.
4. Allow violators the same option they have today, to attend a school once every eighteen (18) months.

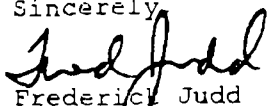
I think the benefits of this program are self-evident, and could easily be administered. I don't know the number of traffic school attendees on an annual basis, but I'd estimate it to be very, very high. This program would convert six wasted hours into (I) the opportunity for real volunteer services, (II) an opportunity for a citizen to "have" to learn about volunteer agencies in his neighborhood, and their missions, and (III) an opportunity to lead that citizen into future volunteerism as he catches the spirit of what he is doing and is introduced to a charity he may continue to support.

While there will be administrative costs, I doubt they would be any larger than the rules and regulations now imposed on traffic schools. (My last instructor appeared to have a real fear that an inspector was in the class room, and was downright paranoid about it.) In any event, the costs or fees now paid by violators could easily fund the program.

As the Chief Financial Officer for a newly public company, I am intensely interested in finding a way for our society to prepare for the coming welfare reform "wall". I don't think my suggestion will solve all of the problems, but I would be very interested in brainstorming through this suggestion with your advisers, and would love to see it become law. I suppose it wouldn't be too popular with the traffic school companies, but think of what another 600,000 volunteer hours could accomplish, and the positive changes it could make in both the lives of violators and recipients.

I hope this proves useful, and if I could provide any other assistance, I'd be glad to help, or to be involved in its implementation. Please call me at (800) 800-8600 if you have any questions.

Sincerely,



Frederick Judd

Vice President Finance, Procom Technology, Inc.

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.

SCHEDULING REQUEST FOR THE FIRST LADY

Date: September 10, 1997

_____ Accept

_____ Regret

_____ Pending

TO: Patti Solis-Doyle
Director of Scheduling
Office of the First Lady

FROM: Thurgood Marshall, Jr.
Assistant to the President and Cabinet Secretary

REQUEST: The First Lady's participation in the kick-off event to launch the Food Safety Education Partnership Campaign.

PURPOSE: To kick-off of the massive food safety education campaign targeted to consumers. The President's 1998 Food Safety Initiative included an extensive education component, the center piece of which is a public/ private partnership to promote consumer awareness of safe food handling. This campaign, the first project of the Partnership for Food Safety Education, is designed to raise consumer awareness of the need for safe food handling by everyone in the food chain. Consumers will be alerted to the role they must play to reduce foodborne illness. Basic safe food handling messages are presented in a clever and educational format. Messages will be delivered through the media, schools, grocery stores, industry, state and federal governments, public health officials, consumer and community groups.

BACKGROUND: It is estimated that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food related. Public education is one component of the Administration's new initiative to protect the public health by improving food safety.

Educating people about steps they must take to prevent and control foodborne illness is a vital link in the food preparation chain. Choices consumers make about how they handle food prepared at home and whether they eat unsafely prepared food can have a significant impact on the incidence of illness. Consumers understanding and practicing proper food handling procedures could significantly reduce foodborne illness.

Representatives of the food industry, government agencies, and consumer groups have joined together in a partnership with the primary goal of preventing illness by changing consumers' unsafe food handling behavior. The partnership has worked together to develop a new public awareness and education campaign based on the presentation of four critical food handling messages. The messages are packaged in a very clever design and theme. The campaign theme is: "FIGHT BAC -- Keep Food Safe

from Bacteria." It features BAC, a cartoon "critter" that provides a personification to harmful bacteria that cannot be seen, smelled or tasted. BAC constantly tries to get onto food, but is consistently thwarted by the safe handling practices of cleaning, cooking, chilling and keeping foods separate. The campaign character, logo and messages have been extensively focus-group tested and have proven to be understandable, popular and persuasive. The campaign is particularly effective because everyone can FIGHT BAC -- the government, industry and consumers.

PREVIOUS

PARTICIPATION: The First Lady addressed the USDA/FDA/CDC Food Safety Education Conference, "Changing Strategies, Changing Behavior" in June. The First Lady's July 4, 1997 syndicated column, "Talking It Over," discussed food safety issues.

DATE AND

TIME: September 30, 1997. The time can be set to accommodate the First Lady's schedule.

LOCATION:

The Partnership requests that the event be held at the White House, Washington, DC. The Rose Garden, the Indian Treaty Room or Room 450 OEOB could all accomodate the event. Another suggested location could be the White House kitchen to visually convey food safety principles. Alternatively, the event could be held at the National Press Club, the USDA Jefferson Auditorium or the HHS Auditorium.

PARTICIPANTS: Members of the Partnership, including Industry CEO's and Secretaries of Agriculture, Health and Human Services, and Education; other Federal officials, Members of Congress; Consumer group representatives, including children; Public Health and Education associations. Expect an audience of 150-200.

OUTLINE

OF EVENTS:

The First Lady would host the event and introduce speakers. Mrs. Clinton would discuss the importance of food safety education. She would then introduces the Secretaries Glickman and Shalala. Secretary Glickman and Secretary Shalala will announce the FIGHT BAC campaign. An animated Public Service Announcement is shown. The critter BAC (a person in a mascot-type "suit") makes an appearance to greet Mrs. Clinton and the children in the audience.

REMARKS:

REQUIRED:

Yes. Approximately 10 minutes.

MEDIA

COVERAGE: Yes. In light of the recent recall of 25 million pound of frozen ground beef from the Hudson Foods Company, we expect the announcement to receive extensive coverage.

RECOMMENDED

BY: Secretary Dan Glickman
Secretary Donna Shalala

CONTACT: Patrick Steel, Deputy Chief of Staff, USDA
Telephone: 720-7231; Fax: 690-2119
Mary Beth Donohue, Deputy Chief of Staff, HHS
Telephone: 690-7431; Fax: 401-5783

10/14/97 19:30 FAX 102 030 1118 0328 0328
(131)
Mexican Produce, 0556

Mexican growers welcome U.S. produce inspections

PHOENIX (AP) Some Mexican farmers say they welcome plans for U.S. inspectors to check their produce for contamination before it crosses the border.

"We have no fears," said Diego Ley, whose family farm in northern Mexico is one of the biggest exporters to the United States of tomatoes, cucumbers and bell peppers.

But some Mexican growers worry that President Clinton's proposal to send U.S. Food and Drug Administration inspectors into foreign countries is merely a ploy to appease opponents of his push for free-trade pacts such as the North American Free Trade Agreement.

"Before NAFTA we used to see technical barriers used against us to block our exports," said Mario Robles, research manager for the Confederation of Agriculture Associations of Sinaloa.

"Now they seek other ways to put the brakes on Mexican imports. One way is to generate panic among consumers by saying our produce is contaminated."

Backers of the inspection proposal cite fears of food-poisoning outbreaks from increasing produce imports from other countries.

Last year, for example, an outbreak of the parasite cyclospora that sickened about 1,400 people was linked to Guatemalan raspberries. And an outbreak of Hepatitis A in Michigan schools was linked to frozen strawberries grown in Mexico, although investigators have not determined where or how those berries were contaminated.

"A sick person preparing food, a restaurant handler not washing his hands or an unsafe water supply used to wash vegetables and fruits is a more likely source" than contamination from the fields, said Lee Frankel, president of the Fresh Produce Association of the Americas, which represents 105 produce importers and related businesses in Nogales.

Mexican farms export much of the United States' fresh produce, especially during the winter months. For example, more than 80 percent of cucumbers and zucchini and about two-thirds of all tomatoes in U.S. supermarkets come from Mexico.

About 70 percent of Mexico's fruit and vegetable exports are grown in northern Mexico and shipped through Nogales. More than 3.89 billion pounds of produce came through Nogales from July 1996 to June 1997.

Food safety inspections of foreign produce are limited to samplings of the foods once they arrive in the United States. Clinton's proposal would send inspectors to the fields where that produce is grown and picked.

Border inspections are now largely limited to size, color, weight and sugar content, said Lloyd Brown of the Arizona Department of Agriculture.

"What we don't do is inspect for food safety," Brown said.

Food importers say many Mexican growers already are taking steps to ensure food safety, including providing workers with bathrooms and sinks in the fields and washing produce with sanitized water once it is picked.

In northern Mexico's Sinaloa state, "there has not been one single case in which one of our products has been contaminated by a microbe that has caused illness or generated an epidemic in the U.S., at least over the last 30 years," Robles said.

(PROFILE

(CAT:Agriculture;)

(CAT:Business;)

(CAT:Political;)

(SRC:AP; ST:CA;)

)

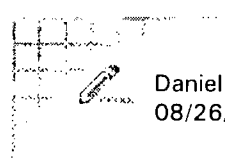
AP-NY-10-13-97 1419EDT

:SUBJECT: AGRI CA CONW POL

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Received by NewsEDGE/LAN: 10/13/97 2:25 PM

Food
Safety



Daniel D. Heath
08/26/97 06:00:01 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc: See the distribution list at the bottom of this message
Subject: Food Safety Plan

① actions against potential world

OMB is working with USDA to generate a planning response to the recent Hudson Foods meat recall. Within the next two days we expect to have draft legislation circulated to you for comments through OMB's standard LRD process.

At this point, Secretary Glickman favors a simple request for increased authority for dealing with tainted food crises, including recalls and levying of civil penalties. Other suggestions for a comprehensive Administration plan include a broader pathogen reduction approach, such as the Administration proposed in 1994, and increased authorities for FDA as well as USDA. If you have thoughts about the strategy or coordination of the Administration's response to the food safety issues raised by the recent events, please feel free to discuss them with TJ Glauthier at OMB (x54561). Comments on the legislation proper should be directed to LRD.

love

Please let me know of any others who should included in these reviews.

② RTT frame - bmc

Message Sent To:

- Sylvia M. Mathews/WHO/EOP
- Elena Kagan/OPD/EOP
- Thomas L. Freedman/OPD/EOP
- Jerold R. Mande/OSTP/EOP
- Jennifer L. Klein/OPD/EOP
- Phillip Caplan/WHO/EOP
- Barbara D. Woolley/WHO/EOP
- Donald H. Gips/OVP @ OVP
- Toby Donenfeld/OVP @ OVP
- Donald R. Arbuckle/OMB/EOP
- K. Lisa Grove/OMB/EOP
- Ronald K. Peterson/OMB/EOP
- Alison C. Perkins/OMB/EOP

③ people want to be there

Message Copied To:

- G. E. DeSeve/OMB/EOP
- T J. Glauthier/OMB/EOP
- Ronald M. Cogswell/OMB/EOP
- Mark A. Weatherly/OMB/EOP
- Adrienne C. Erbach/OMB/EOP
- Alecia Ward/OMB/EOP
- Jim R. Esquea/OMB/EOP

374-0704

Lawrence
Alschuler →
4/5/98
825-0511

system.

- **San Diego County.** A Domestic Violence Council operates from the DA's office, increasing service-provider contacts and public awareness. The Domestic Violence Council recently supported billboards and bus kiosk advertisements regarding domestic violence. There are several specialized domestic violence units within the criminal justice system and other local agencies. A local Family Violence Project is a collaboration between the probation department and children's services for children affected by domestic violence.
- **San Francisco.** The Family Violence Prevention Fund provides advocacy and coordinates services. Agencies engage in joint trainings, have many formal service contracts, and often co-manage services. A group of professional women raises money for domestic violence causes. A recent public-awareness campaign targets the Filipino community with culturally sensitive messages regarding domestic violence.

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

October 2, 1997

Today President Clinton will announce an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. The President will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables and other food products produced in countries that do not meet U.S. food safety requirements. The President will direct the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation -- comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries -- will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President will also commit to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to make effective use of its new authority.

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Improvement of Monitoring and Inspection Activities Abroad. In addition to committing substantial resources to expand the FDA's international food inspection force, the President will direct the Secretaries of Health and Human Services and Agriculture to report within 90 days on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce. The President will urge consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education and surveillance activities throughout the food safety system.

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THE WHITE HOUSE
Office of the Press Secretary

Food Safety

For Immediate Release

October 2, 1997

October 2, 1997

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Ensure the Safety of Imported
and Domestic Fruits and Vegetables

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

Today, I hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

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First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

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Clinton Administration Accomplishments In Improving Food Safety

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PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

October 2, 1997

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We continue to build on these efforts to improve food safety, and it's a challenge that government alone cannot fulfill. The fact is, we don't yet have a silver bullet that gives us a 100% guarantee of safety. Until we do, each of us -- consumers, industry, government and scientists -- must do our part. That's the thinking behind the President's Food Safety Initiative: we must secure safety at each point from farm to table.

This Administration's 1999 budget proposes a \$101 million *increase* in funding for our initiative. We will have an extra \$36 million to better ensure the safety of fruits and vegetables -- both domestic and imported -- as well as the success of our new inspection systems; we have a \$14 million increase for our education campaigns; we have \$33 million more for food safety research; an \$11 million boost to our efforts to improve our estimations of risks associated with food-borne hazards; and \$7 million more for enhanced nationwide surveillance.

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The 2 page Summary is
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PRESIDENT WANTS F.D.A. TO REGULATE FOREIGN PRODUCE

ILLNESSES LEAD TO ACTION

Fruit and Vegetables Could Be Banned if Farming Methods Did Not Meet Standard

By JAMES BENNET

WASHINGTON, Oct. 2 — Acting after several outbreaks of disease linked to the burgeoning global trade in produce, President Clinton announced today that he would ask Congress to require Federal regulators to ban imports of fruit and vegetables from countries that did not meet expanded American food safety standards.

The move, urged by regulators since shortly after Mr. Clinton first took office and welcomed today by industry and consumer groups, would empower the Food and Drug Administration to insure the safety of foreign fruit and vegetables in much the same way that other Federal regulators check meat and poultry from overseas.

Mr. Clinton said he would ask for more money from Congress next year for the F.D.A. to hire investigators to inspect not just produce but also foreign farming methods and government safety systems. In a change that might irk some United States trading partners, countries that blocked the new inspections would be forbidden to sell fruit and vegetables in the United States, the Administration said.

"At the time when Americans are eating more and more food from around the globe, we must spare no effort to insure the safety of our food supply from whatever source," Mr. Clinton said at a Rose Garden ceremony to announce his proposals today. "Our food safety system is the strongest in the world, and that's how it's going to stay."

Imports of produce have increased sharply in recent years, to 38 percent of the fruit consumed by Americans and 12 percent of the vegetables. With those imports, however, have come recent outbreaks of diseases brought across borders by Guatemalan raspberries, Mexican cantaloupes and Thai coconut milk, causing public alarm that might make Congress sympathetic to Mr. Clinton's proposals. But American trading partners may eventually choose to protest any ban on their products to the World Trade Organization,

much as the United States on Wednesday said it would file a complaint with that organization protesting Japan's stringent test for pesticides on American nectarines, cherries and other fruit. The United States sells twice as much food abroad as it imports.

Donna E. Shalala, the Secretary of Health and Human Services, said that Mr. Clinton would ask for \$24 million annually to support the Food and Drug Administration's new international inspections. Another official said that if Congress acted on Mr. Clinton's proposal, the F.D.A. would phase in its system for such inspections over the next several years.

Today, Mr. Clinton also directed Dr. Shalala and Agriculture Secretary Dan Glickman to develop new voluntary standards within a year for growing, processing, shipping and selling fruit and vegetables. The President said he also expected a

Proposing the same scrutiny of foreign fruit and vegetables as of meat.

report from them within 90 days on how to improve the monitoring of fruit and vegetables grown abroad.

Though they backed the President's proposal, consumer and industry groups said they were anxious about the details in the legislation, which the Administration plans to offer next year.

"What the President proposed today addresses many of the gaps," said Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest. But, she added, "I would like to have mandatory standards rather than voluntary guidelines" for food manufacturers and handlers. For their part, White House aides predicted that meeting the voluntary guidelines would become an eye-catching industry selling point.

A senior White House official, who spoke on the condition of anonymity, said it was hard to predict whether the President's initiative could raise produce prices. But producers or sellers may have to pass on the costs of any modifications to consumers, he said.

The main initiative announced today, requiring the F.D.A. to bar foods imported from countries with substandard safety systems, was recommended more than four years ago by David A. Kessler, then the Commissioner of Food and Drugs. Dr. Kessler warned then that the nation's food-safety laws, essentially unchanged since 1938, were in "urgent need" of an overhaul.

Contaminated food, he noted, kills an estimated 9,000 Americans a year and sickens millions, perhaps tens of millions. It still does. The food-safety system was marked by "enormous inefficiencies," he warned. It still is, according to a Federal report published in May.

The White House has already moved to institute one of Dr. Kessler's central proposals, a scientific system for controlling the risk of disease borne by seafood, meat and

poultry. But no such system yet exists for fruit and vegetables, domestic or imported.

The White House said today that Mr. Clinton has been adopting Dr. Kessler's proposals piecemeal, addressing the most urgent needs first. Michael D. McCurry, the White House press secretary, said that Mr. Clinton was prompted to tighten monitoring of fruit and vegetables partly by several outbreaks of illness and reporting on the potential hazards by news organizations, including The New York Times.

Mr. Clinton's move on food safety comes as he is seeking enhanced authority from Congress to negotiate trade deals. His opponents have charged that the new rules, under which trade deals once negotiated would have to be voted on quickly and without amendment by Congress, would lower barriers to food-borne diseases.

Some opponents of granting the President such fast-track authority hailed Mr. Clinton's announcement today. "I'm glad the fast-track debate has energized the President to do this," said Representative Sherrod Brown, Democrat of Ohio. Mr. Brown and 85 other members recently sent President Clinton a letter linking food safety and trade pacts.

The White House said Mr. Clinton did not connect food safety to promoting his trade goals. The senior Administration official said that he expected some members of Congress to use the initiative as political cover for voting to give the President greater trade authority.

Senator Richard Lugar, the Indiana Republican who heads the Agriculture Committee, will hold hearings on the initiative next week.

The Administration consulted with some foreign governments before today's announcement, one Administration official said, but still expected criticism from abroad. "There will be some negative reaction in some places, but it won't be the end of the world," he said.

Some foreign representatives here worried that Mr. Clinton's proposals might be used to create trade barriers. The safety of imported food is "a serious issue coming very fast toward all of us in this new global world," said Ambassador John Biehl of Chile. He called the President's initiative "a good thing as long as it is equal for everyone" and not "used as an artificial barrier to free trade."

Administration officials repeatedly said today that there was no evidence that imported fruit and vegetables were less safe than American ones. But there is little data about the relative safety of domestic versus imported food, according to the Centers for Disease Control and Prevention, in Atlanta. One percent or fewer of the actual number of food-borne illnesses are reported, analyzed, identified and successfully traced.

While the Department of Agriculture monitors meat and poultry, produced here or abroad, the F.D.A. is charged with safeguarding all other food, including fruit, vegetables, grains and seafood. But, unlike the Agriculture Department, the F.D.A. can now send its investigators abroad only if they are invited, and agency inspections of the imports have dropped to less than half what they were five years ago. If Congress approves the President's proposal, the F.D.A. is expected to hire 100 more investigators, who will examine foreign farming methods and food safety systems.

The New York Times

FRIDAY, OCTOBER 3, 1997

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Debate Aside, Fund-Raising Doesn't Stop

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By RICHARD L. BERKE

HOUSTON — Shortly after 9 P.M., as the 70 or so guests picked over the last crumbs of their almond tuile with peaches, plums, pears and seasonal berries, President Clinton scanned the candlelit room of eight round tables filled with the wealthiest Democrats in Texas.

"When you go home tonight," Mr. Clinton told his dinner companions in the elaborately decorated 10-car garage at a sprawling Houston mansion, "I hope you will think about it and be glad you came."

Officials at the financially struggling Democratic National Committee were certainly glad they came to the dinner, held Sept. 26 at the home of a restaurant magnate, Tilman J. Fertitta. In a process that took only two and a half hours, Mr. Clinton and his entourage converged on Mr. Fertitta's home; the President posed for photographs, gave a speech, departed on schedule (before many guests had sipped their second cup of hazelnut coffee), and won about \$700,000 in mostly unregulated "soft money" donations.

It was another successful evening for the Democratic Party's premier, and most proficient, fund-raiser: Bill Clinton. As inquiries deepen into his fund-raising practices in the 1996 campaign, and as the President himself calls for legislation that would prohibit dinners like Mr. Fertitta's, Mr. Clinton is stepping up his appearances on the money circuit.

(In this, Mr. Clinton is not alone: from Speaker Newt Gingrich on down, Republicans are even more skilled at staging big-money events, but they do not have a President to help attract guests.)

As lavish as the Fertitta party was

Continued on Page A12

Continued From Page A1

— with an entry fee of at least \$10,000 per person, a 900-pound ice sculpture of the White House by the pool and chairs covered with yellow silk and and yellow and white roses — the event was fairly typical. It demonstrates how the hunt for money is almost a preoccupation for Mr. Clinton, and shows the way in which the fund-raising zeal and skill of the White House and the Democratic Party combine to carry out the mission. It also shows how sensitivities over fund-raising have forced some changes, like more careful scrutiny of guest lists.

In addition to Mr. Clinton, Vice President Al Gore and Hillary Rodham Clinton have been the star attractions at dozens of fund-raising events this year. Because the fund-raising occasions have become so routine and because they usually occur at night — long after most reporters' deadlines — Mr. Clinton's appearances are not widely publicized. Yet, they often drive his entire schedule on any given day and, as happened in Houston, determine why he travels to a particular state.

Despite the climate of concern in the capital about fund-raising practices, neither Mr. Clinton nor Mr. Fertitta had any apologies. Asked whether it was unfair for the wealthy to get such access to the President, Mr. Fertitta said in an interview: "That's like saying someone who could afford front-row seats at a fight shouldn't go to it. That's the way the world is."

Everyone from the President on down pronounced the event a success. It, like so many others, took months of planning and strategizing and hundreds of decisions large and small.

Host and Guests Chosen Carefully

The selection of Mr. Fertitta as the host of the event arose out of a master plan for raising money late last year. Although the White House eagerly approved the idea, outlined in an "event scenario" by the Democratic National Committee, there was a snag when Representative Martin Frost of Texas, chairman of the Democratic Congressional Campaign Committee, complained that the fund-raising event might interfere with his own ability to hit up donors for candidates for Congress and the State Legislature.

A compromise was reached: White House officials agreed to dispatch Mr. Gore to Dallas in November to raise money for the Democratic Congressional Campaign Committee.

Once the date was approved, most of the preparations went to officials at the Democratic National Committee. As one White House official put it: "This is their event. I just provide the body."

Although White House officials had initially planned to hold the event at a Westin Hotel here, they relented to the wishes of the 40-year-old host, Mr. Fertitta, the multimillionaire president and chief executive of Landry's Seafood Restaurants. Mr. Fertitta said he was proud of his home and wanted a more intimate approach. "We're not fake people," he said.

Mr. Fertitta had been selected by party officials because he was a generous giver who had put on a dinner at his home for Mr. Clinton a year ago, when he transformed his front yard into an Old West town. He also picked up \$75,000 in costs from this year's event, from the food to the catering staff to the string quartet to the tent over his carport.

Trolling for guests, the party sent a feeler letter to reliable big donors in Texas asking if they would attend a dinner for the President. Then Mr. Fertitta and others made calls on their own to add to the list. In early September, Alan D. Solomont, the party's finance chairman, said he spent a day in Houston and a day in Dallas meeting with donors and reminding them "why it was so important to the party" that they help retire its debt of more than \$15 million. Gov. Roy Romer of Colorado, the party's general chairman, made a follow-up trip. Not everyone had to pony up \$10,000. A handful of politicians were given complimentary tickets, including former Gov. Ann Richards and Representative Sheila Jackson Lee.

Just days before the event, White House aides found an official reason for Mr. Clinton to travel to Houston: they scheduled a speech at San Jacinto College. That way, some of the cost would be paid through the White House travel budget.

As the date grew closer, party officials examined the guest list to make sure that none of those invited had been in prison or had other embarrassing information in their files. Officials said that with all the inquiries into the party's lax procedures in the 1996 campaign, they have become more vigilant in screening guests. Two people were disinvited from Mr. Fertitta's dinner because of concerns about their histories, officials said, but they would not give the reasons.

Party officials put together a seating chart, making sure each table had the right mix of people. The party's finance chairman, Mr. Solomont, chose a prized spot for himself: he sat next to Carl Lewis, the Olympic sprinter who lives down the street. Mr. Lewis was the only African-American spotted among the guests.

"I did say the person I want to sit beside is Carl Lewis," Mr. Solomont said. "He's a very substantive guy. And I'm a little bit of a track-and-field devotee."

Chefs Prepare A Seafood Feast

As officials of the party and the White House were reviewing the seating, the two executive chefs — Kathy Ruiz of Landry's Seafood Restaurants and Lindell Mendoza of the San Luis Resort in Galveston, Tex., which is also owned by Mr. Fertitta — were putting final touches on the menu.

Though she sought advice from stewards at the White House, Ms. Ruiz said the menu fell into place easily. "I know the President likes mangoes," she said, "so that was kind of a no-brainer." She also said she wanted to take advantage of the fresh seafood from her restaurant. So the main course was "Texas Gulf Red Snapper topped with Galveston Bay Jumbo Lump Crab Meat and Mango-Roasted Pepper Vinaigrette."

While the chefs were torn over whether to serve an appetizer of duck tamales with mole sauce or a seafood ceviche, they went with the seafood because even though several convection ovens were installed for the event, they did not think Mr. Fertitta's kitchen was large enough for a hot appetizer and entree. Each ceviche appetizer was served in an individual ice sculpture designed as a big scallop shell. For dessert, Ms. Ruiz wanted something light. She knew that the President did not like chocolate. Thus, the almond tuile with fruit. For a personal touch, every plate had a cookie shaped like a saxophone. (The press, police and support staff were served barbecue in a tent across the street.)

Villa Mount Eden vineyards of Central California donated five cases of its 1995 Special Grand Reserve Chardonnay.

A couple of days before the dinner, the chefs met with the Secret Service to discuss the menu. "They made

The New York Times

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NATIONLINE

Teen accused in killings wrote note, officials say

The Pearl, Miss., teen-ager accused of a killing spree that left his mother and two classmates dead had written an angry manifesto blaming mistreatment by others for the slayings, prosecutors said Thursday.



Woodham: Pleads innocent in slayings of three people

Luke Woodham, 16, pleaded innocent to all charges and was ordered held without bail. Authorities say that moments before opening fire Wednesday in the crowded schoolyard at Pearl High School, Woodham passed a handwritten note to a classmate: "I am not insane. I am angry. I killed because people like me are mistreated every day. I did this to show society push us and we will push back. Murder is not weak and slow-

witted, murder is gutsy and daring."

Some classmates said Woodham was "weird" and often was picked on by other students. Police say he stabbed his mother at home before driving to school, pulling a rifle from his trench coat and opening fire. Killed were Christina Menefee, 16, who had dated Woodham, and Lydia Kaye Dew, 17. Seven other students were wounded. Woodham was arrested in his mother's car parked outside the school.

JET CRASH: An F-14 Tomcat fighter jet crashed in the Atlantic Ocean off North Carolina, the Navy said. One crew member was rescued; a search for the pilot was under way. The fighter was assigned to the Oceana Naval Air Station at Virginia Beach. The Navy was investigating the cause of the crash, the seventh of a military plane since Sept. 13. The six earlier accidents within one week led to a one-day halt in training flights for a safety review by all the services.

Runaway bus kills one, injures two



Mayhem in Manhattan: A New York City bus rests against a crockery store on Fifth Avenue after it raced out of control for several blocks, killing a man pushing a handcart and critically injuring a bicyclist. A bus and at least three cars also were hit. The driver, Charles Alston, 55, was hospitalized in stable condition. The cause of the crash is being investigated.

MIR GOOD-BYES: After dropping off a new central computer and a new American crewman, the astronauts aboard space shuttle Atlantis hugged their Mir comrades goodbye. The shuttle crew was scheduled to undock today and head home Sunday with American astronaut Michael Foale. Foale spent 4½ months aboard the Russian space station; astronaut David Wolf is slated for a four-month stay.

BLACKBEARD REVISITED: Researchers began surveying a North Carolina wreck site where they believe the flagship of the infamous English pirate Blackbeard sank 279 years ago. A team of underwater archeologists and divers will map the shallow water within 2 miles of the beach at Beaufort Inlet before attempting to retrieve artifacts that could prove the wreck to be Blackbeard's vessel Queen Anne's Revenge, which ran aground in 1718. Blackbeard, was killed a few months later by an officer of the British navy in Okracoke, N.C.

FUND-RAISING MURDER: A Jackson Township, N.J., teen accused of sexually assaulting and strangling an 11-year-old neighbor is believed to be the victim of molestation himself, by a man he met in an on-line chat room, prosecutors said Thursday. The 15-year-old boy is accused of killing Eddie Werner, who disappeared Saturday while selling candy and wrapping paper door-to-door for a school fundraiser. Officials say that Stephen Simmons, 43, of New York City, was charged Sept. 25 with sexually assaulting the 15-year old. Eddie was killed two days later. Police say Simmons met the suspect last year in an America Online chat room. Prosecutors say Simmons had sex with the youth three times between August and December 1996.

ALSO THURSDAY . . .

► **MEMPHIS SLAYINGS:** Raymond Neal, 21, whom police described as "mentally challenged" after finding him sobbing outside a house, was charged with fatally shooting four people inside, believed to be his adoptive family.

► **JEWISH HOLY DAYS:** Jews around the world celebrated Rosh Hashana, the Jewish New Year.

Murder, assault charges dismissed

An Idaho magistrate dismissed state murder and assault charges against Kevin Harris stemming from the 1992 standoff at Ruby Ridge.



Harris: Accused of Ruby Ridge killing

Magistrate Quentin Harden ruled that the charges violate a state law that bars prosecution of someone who already has faced prosecution in another "state, territory or country." Harris was acquitted on federal murder charges in 1993.

Harris, 39, of Republic, Wash., was accused of killing deputy U.S. Marshal William Degan and shooting at another agent in the Aug. 21, 1996, shootout that sparked the 11-day siege at white separatist Randy Weaver's cabin. Weaver's 14-year-old son, Sam, was killed in the gunfight.

Weaver's wife, Vicki, was later shot and killed by an errant FBI sniper's bullet. The FBI marksman, Lon Horiuchi, has been charged with involuntary manslaughter. His case is pending.

The FBI had Weaver on weapons charges. After the siege he was acquitted of murder but sentenced to 18 months on charges related to the weapons offenses.

Written by John Bacon with staff and wire reports

Produce industry questions motive behind food plan

By Daniela Deane
and Anita Manning
USA TODAY

The president's latest food safety proposal follows a series of outbreaks of food poisoning traced to contaminated berries, lettuce, sprouts and other fruits and vegetables, many of them imported.

Among recent outbreaks:
► About 1,400 Americans became ill this year and last after ingesting cyclospora, a parasite that causes diarrhea and other symptoms, including weight loss and fatigue that can last for weeks.

Most cases were linked to raspberries imported from Guatemala, but this year, outbreaks were also traced to basil and lettuce. Scientists believe the basil and lettuce were imported but have not yet determined their country of origin.

► In March, an outbreak of hepatitis A linked to frozen strawberries from Mexico affected 230 people in Michigan, including 173 school children. Hepatitis A infection causes fever, jaundice, nausea and appetite loss for several weeks.

► Alfalfa sprouts grown from seeds contaminated with E. coli, a dangerous bacterium that can cause severe diarrhea and hemorrhagic colitis, made more than 100 people sick (90 in Michigan and 48 in Virginia). The source of the sprouts hasn't been traced.

Industry officials insist these incidents are isolated and do not represent a widespread food safety problem. They argue that with Americans eating a half billion servings of fruits and vegetables every day, outbreaks such as these are minuscule when compared with the vast amount of fresh produce consumed in this country. Americans are increasingly seeking healthier diets, with lots of fruits and vegetables, prompting retailers to troll world markets in an effort to stock a year-round supply of fresh produce.

"We reject 100% that we have a food safety problem," says John Aguirre of the United Fresh Fruit and Vegetable Association. He called the measures "unwarranted."

President Clinton asked Congress Thursday to pass legislation allowing the Food and Drug Administration

(FDA) to ban imports of fruits and vegetables that do not meet U.S. food safety standards. He also sought to boost the FDA's budget for foreign food inspections.

Critics charge that the food plan is an effort by the president to bolster support to grant him "fast-track" trade authority.

That enables him to negotiate trade agreements that Congress would have to approve or reject but could not amend. Opponents say that legislation, currently pending in Congress, could open the door to more tainted food from overseas.

"We are concerned about fast-track legislation getting linked to food safety," says Brian Sansoni of the Grocery Manufacturers of America. "We hope the motivation behind this isn't to appease opponents of fast-track legislation."

But the FDA, which has been pushing for the changes since 1993, says it hasn't kept pace with Americans' food supply. "The whole infrastructure of food safety needs to be strengthened," Associate Commissioner William Hubbard says.

Foreign food imports have doubled to 2.2 million shipments a year since 1992, while FDA border inspections were cut in half. Only 2% of imported foods are checked for contamination at entry docks.

If Congress approves the legislation, the FDA will have the same authority to halt imported produce that the U.S. Department of Agriculture has over imported meat and poultry. But industry officials worry what effect the proposal would have on trade and trading partners.

"We do not want to see anything that would increase trade barriers, or unnecessarily increase tensions between trading partners," Sansoni says.

"Clearly, being the world food police complicates the trade environment we operate in," Aguirre says.

They also argue that since a recent report found that 40% of cancers were avoidable with a proper diet, which includes plenty of fresh fruit and vegetables, the consumption of fresh produce should be strongly encouraged, rather than discouraged, among Americans.

► Food crackdown urged, 1A

'Young and the ruthless' never materialized

Youth violent crime declines

Violent crime arrest rate for juveniles 10-17 years old:

Year	Rate per 100,000	Change
1987	311.3	-1.9%
1988	327.4	5.2%
1989	382.5	16.8%
1990	428.9	12.1%
1991	481.6	7.6%
1992	482.8	4.6%
1993	605.1	4.6%
1994	527.4	4.4%
1995	511.9	-2.9%
1996	464.7	-9.2%

Source: Justice Department

By Kevin Johnson
and Gary Fields
USA TODAY

WASHINGTON — Three years ago, with the country still reeling from a plague of violent crime, leading criminologists predicted that something much worse was looming.

They talked of an approaching wave of youth crime, driven by a surge in teen population expected to jump nearly 44% by the year 2010.

So far, the ominous predictions about a group Northeastern University professor James Fox dubbed the "young and the ruthless" have been wrong.

The teen-age population is

rising and on track to top out at 39 million in slightly more than a decade, but for the past two years violent crime arrests involving teen-agers have dropped to a level that has surprised even Justice Department officials.

Thursday, Attorney General Janet Reno said her own doubts about the prospect of achieving a sustained decline have all but disappeared given the 9% drop recorded last year in arrests of juveniles in violent crimes.

Reno stopped short of declaring an outright victory, but some of the same criminologists who offered their threatening forecasts acknowledged Thursday that there was hope

to be found in the new FBI statistics.

"I think that the efforts that various cities and towns are making are paying off," Fox said. "From Boston to Anaheim, citizens are investing in their communities."

Among the most effective are community mentoring programs and federal grants cities are using to put more police on the streets.

"What we should take from (this decline) is a feeling of hope but not overconfidence," Fox said.

"(Our problems) are hardly over," he said. "If a crash dieter goes off his diet, he gains weight. He has to permanently

change his eating habits."

Jack Levin, Fox's colleague at Northeastern, acknowledged the improvement but warned that two years' worth of statistics is not enough to celebrate a complete reversal.

"It took us 20 to 30 years to get into this mess," he said. "It's going to take at least a decade to get out of it."

Levin says the criminologists who served as doomsayers actually deserve credit for raising the issue.

"What is responsible for this good news is fear," Levin said. "We're so scared of our kids, we're watching them."

► Arrest rate falls, 1A

Jordan hit prompted toxic swirl of intrigue

By Abraham Rabinovich
SPECIAL TO THE WASHINGTON TIMES

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JERUSALEM — Two Western-looking men were lounging on the sidewalk when Hamas politburo chief Khaled Mishal approached his office in Amman, Jordan, last week.

One of the men approached Mr. Mishal as if to ask him a question. While he was distracted, the other clapped a mysterious metallic object to the ear of the Hamas official, eventually sending him into a coma. The two then sped away in a waiting getaway car.

Thus began a bizarre cloak-and-dagger episode involving a car chase, secret toxins and top-level negotiations among King Hussein of Jordan, Israeli Prime Minister Benjamin Netanyahu and, by some accounts, President Clinton.

The drama — which led Canada last night to withdraw its ambassador from Israel — climaxed with the release from an Israeli jail at 2

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JORDAN

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a.m. Wednesday of Hamas leader Sheik Ahmed Yassin, who is now resting in a Jordanian hospital, where he was visited yesterday by Palestinian Authority President Yasser Arafat.

King Hussein denied yesterday that the release of the 61-year-old sheik was part of a deal involving the fate of suspected Israeli Mossad agents now in Jordanian custody.

"A deal is usually this for that. None of this has happened," the king said after Mr. Arafat's visit with the founder of the extremist Islamic group, who is quadriplegic and nearly blind.

But deal or not, details emerging from Arab officials and Jordanian and Israeli media accounts add up to a bizarre tale of intrigue and drama worthy of a Tom Clancy novel.

Mr. Mishal, the Hamas official in Amman, appeared more startled than injured immediately after the Sept. 25 sidewalk attack. Accounts say he made his way to his office, where he told colleagues that an attempt had been made to kidnap him.

Soon afterwards, he collapsed and was taken to a hospital, where for days he lay near death from a mysterious poison that doctors could not identify.

After the attack, meanwhile, Mr. Mishal's bodyguard hailed a taxi and chased the assailants to another part of the city, where the two men got out and made their way toward another car in which

three men were waiting, Arab sources said.

The bodyguard tried to stop them, starting a fight that led bystanders to summon police. The two men were taken into custody and identified themselves as Canadian tourists, producing passports that appeared to be forged.

Hamas politburo member Mohamed Nazzal told the Christian Science Monitor that the two men held both Canadian and Israeli citizenship, were Jewish, "and belong 100 percent to Mossad," the Israeli security service. Diplomats said the two have Canadian accents but declined to be represented by the Canadian Embassy.

Canadian Foreign Minister Lloyd Axworthy said at the United Nations last night that neither man was Canadian and that their passports were forged. He announced Canada was withdrawing its ambassador from Israel, saying that Ottawa takes "great exception to the use of the reputation of Canadian passports for those kinds of purposes."

One source said that, despite Jordan's official denials, a total of five Mossad operatives are being held in Amman, out of a total of eight who were involved in the plot.

It is not clear why Israel would have wanted to murder Mr. Mishal, but the episode came days after

gunmen fired on two Israeli security men assigned to the Israeli Embassy in Amman, wounding them in their legs. Jordanian authorities suspect Israel was retaliating for that attack.

According to the Tel Aviv daily, Yediot Ahronot, an angry King Hussein issued a message on Tuesday regarding the attack on Mr. Mishal: "We know who you are and we demand that activities of this kind never occur again on the territory of Hashemite kingdom of Jordan."

Other reports said the king called Mr. Netanyahu personally to protest the infringement of Jordanian sovereignty.

Jordanian sources said the king ordered that the Hamas leader be treated in Jordan's top military hospital, and sent his own American doctor, who already was in Jordan on a visit. But the man's life was not saved until an antidote to the poison was produced by Israel itself, Jordanian newspapers said.

Diplomats told the Associated Press that Israel provided the antidote only after Mr. Clinton telephoned Mr. Netanyahu. Other sources said the king warned Israel that if Mr. Mishal died, Jordan would have no choice but to hang his killers.

Jordan's Crown Prince Hassan was reported to have traveled secretly to Israel on Sunday, but Israeli Channel 2 said that Israel's top Cabinet officials, Ariel Sharon, Danny Naveh and Minister of Defense Yitzhak Mordechai, made their own secret visit to Amman over the weekend.

• This article is based in part on wire service reports.

The Washington Times

FRIDAY, OCTOBER 3, 1997

Clinton seeks ban on inferior foreign foods

By Lorraine Woellert
THE WASHINGTON TIMES

President Clinton yesterday asked Congress for the authority to ban imported food that doesn't meet U.S. safety standards, an action immediately criticized as a way to boost public relations rather than dramatically affect public policy.

"Our food-safety system is the strongest in the world, and that's how it's going to stay," Mr. Clinton said yesterday in a formal Rose Garden ceremony.

In principle, the hastily drafted proposal won't necessarily make the nation's food supply safer. The Food and Drug Administration and other federal agencies already have the authority to stop tainted food at the border and inspect overseas farms and manufacturing plants under global trade rules.

"This proposal is designed to try to deflect criticism from imported food-safety problems in an effort to pass [the] fast-track [bill]," said Lori Wallach, director of Public Citizen's Global Trade Watch, a consumer group that last week issued a study critical of the nation's food-safety efforts.

The so-called fast-track bill would give the president freedom to make trade agreements that Congress could not amend. The measure has alarmed some lawmakers, who fear in part that lower trade barriers could allow tainted foreign food to slip into the United States.

Trade rules under the North American Free Trade Agreement and the World Trade Organization already have led the FDA to draw up guidelines for ensuring that foreign food producers meet standards "equivalent" to those in the United States. However, trade critics question whether "equivalent" standards will be enough to protect the nation's food supply.

"This is a battle over fast track, it's not a question of food-safety authority or legislation," said Rod Leonard, ex-

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FOODS

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ecutive director of the Community Nutrition Institute.

Food manufacturers yesterday expressed concern that the Clinton plan, though still vague, could lead to more regulation and complicate existing trade agreements. About 20 percent of the fruit and vegetables Americans eat annually is imported.

"The whole question is, is this new authority needed? That has yet to be determined," said Brian Sansoni, spokesman for the Grocery Manufacturers of America. "We are concerned about the timing of this to a certain extent. This issue should not be mixed up with fast-track trading authority."

Mr. Clinton said his proposal should not complicate the trade environment.

"We're not trying to unfairly target foreign producers of food into our market," he said.

Mr. Clinton said he would boost next year's FDA budget for foreign-food inspections by about \$24 million from the current level of \$43 million.

He also ordered the secretaries of health and human services and agriculture to draw up voluntary guidelines on growing, processing, shipping and selling produce.

FDA officials said the Clinton plan will give them more authority to guarantee food safety at the source, not at the border.

"Currently, the inspection of produce from foreign countries is done only when those materials reach the United States," said Richard Rominger, deputy secretary of agriculture.

"By looking more carefully at the land-management practices, the farming practices, the fertilization, the water supplies at each of these areas, it's possible to look at the public-health issues in a particular country and then to realize how best one can minimize the risks and maximize the benefits."

Demand for electronic aircraft spurs economic

By Dave Skidmore
ASSOCIATED PRESS

Surging demand for electronic components and aircraft boosted manufacturing while unemployment-benefit applications remained low, the government said yesterday in reports depicting a strong but not overheated economy.

"The reason everything is so wonderful is we're not in a boom. We've got solid moderate growth that therefore can be sustained," said economist David Orr of First Union Corp. in Charlotte, N.C.

Orders to U.S. factories jumped 1.3 percent in August to a seasonally adjusted \$335.4 billion, the Commerce Department said. It was the third consecutive increase but overstated manufacturing's momentum.

The strength was almost entirely concentrated in two categories. Orders for electronic components such as semiconductors and circuit boards soared 76.9 percent, the largest increase since February 1960.

Aircraft orders jumped 30.8 percent, spurred by retooling at U.S. airlines and demand from foreign carriers.

Without those two gains, orders overall would have been down 1.7 percent.

Moreover, a report Wednesday from the National Association of Purchasing Management showed manufacturing momentum slowed in September.

New applications for unemployment benefits inched up by 1,000 last week to 308,000, the Labor Department said. It was the first increase in a month but left claims at a level reflecting continued demand for workers.

A four-week moving average of claims, which analysts track because it smooths weekly fluctuations, fell by 4,250 to 308,750, the lowest since mid-August.

"It's certainly at a level that fits with the idea that labor markets are extremely tight," said economist Dan Laufenberg of American Express Financial Advisers in Minneapolis. "There's all kinds of help-wanted signs everywhere

and special programs for workers, such as finders fees and bonuses."

Meanwhile, same-store retail spending in September rose just 0.4 percent over the same period a year ago, reported TeleCheck Services Inc. The Houston-based company compared the dollar volume of checks written at more than 27,000 locations.

William Ford, TeleCheck's chief economic adviser, suggested the increase was so small because Princess Diana's death and funeral kept many potential shoppers home watching television.

The mix of data left Wall Street unruffled. The Dow Jones average of industrial stocks rose 12.03 points to close at 8,027.53. Bond prices increased slightly, sending the yield on the 30-year Treasury bond to 6.30 percent from 6.32 percent the day before.

Markets were cheered this morning by the Federal Reserve's decision to hold short-term interest rates steady. However, minutes released yesterday of the Fed's previous interest-rate meeting on Aug. 19 showed many policy-makers worried that strong demand for labor would accelerate wage increases, forcing companies to raise prices more quickly than before.



The Washington Times
FRIDAY, OCTOBER 3, 1997

Clinton Calls For Changes On Produce

Plan Aims to Boost Safety for Imports

By Peter Baker
Washington Post Staff Writer

In response to public skittishness over food safety, President Clinton yesterday proposed a new program of standards and inspections aimed at blocking contaminated fruits and vegetables grown overseas from reaching the United States.

During a Rose Garden ceremony, Clinton detailed his plans to ask Congress to authorize the Food and Drug Administration to halt imports of produce from foreign countries that have lower safety requirements or do not permit FDA inspections. The administration also will develop new guidelines and monitoring procedures, he said.

"With these efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports or reach our dinner tables without meeting the same strict standards as those grown here in America," the president said. "Our food safety system is the strongest in the world, and that's how it's going to stay."

The plan, the broad outlines of which were released last week, was fashioned to reassure consumers worried by recent outbreaks of food-borne illnesses that fruits and vegetables will be examined as closely as meat and poultry. The FDA recommended more scrutiny of produce in 1993, but the administration did not act until recent widely publicized incidents raised political pressure.

Even as it was being unveiled, though, the proposal immediately became entangled in the politics of Clinton's "fast-track" free trade proposal. On one side, critics charged that the food initiative was a ploy to allay congressional fears that lower trade barriers would make it easier for tainted food from other countries to get into the United States. On the other, industry officials warned the plan could hurt domestic growers if foreign governments retaliate by adopting their own stricter standards against American products.

"This whole plan of his is pure



BY WILFREDO LEE—ASSOCIATED PRESS

President Clinton discusses food safety outside White House, flanked by Vice President Gore, left; food representatives Tom Stenzel, Manley Molpus, Carol Foreman and Caroline Dewaal; and HHS Secretary Donna Shalala.

cosmetics to get fast track passed," Rep. Sherrod Brown (D-Ohio) said by telephone from the Mexican border, where he was studying the impact of the North American Free Trade Agreement (NAFTA). "I don't think anybody in Congress is going to change their vote because of this rather inadequate food safety proposal of the president's."

The Clinton legislation would give the FDA the same kind of power over produce imports that the Agriculture Department already has over meat and poultry, officials said. While fruits and vegetables are not the main source of food illnesses, there is some evidence that their involvement is growing. Vegetables now are involved in about 15 percent of E. coli O157:H7 outbreaks in the United States, three times as much as several years ago.

The administration plans to ask for \$24 million for more international inspectors to travel abroad to examine produce suppliers. Clinton asked aides to report back in 90 days with plans to toughen border inspections and aid foreign countries and in a year with specific safety standards for growing, processing, shipping and selling produce.

About 38 percent of the fruit and 12 percent of the vegetables consumed by Americans last year came from foreign growers, according to the administration. Officials said they were not responding to any great threat from overseas produce. "We don't see a huge problem out

there," Deputy Agriculture Secretary Richard E. Rominger said.

However, some food industry officials said they fear a backlash from foreign governments because of the Clinton plan.

"I've seen countries do a lot of things to protect their markets, and it wouldn't surprise me at all to see other countries use this to protect their markets if our government isn't careful how they structure this program," said Chris Schlect, president of the Northwest Horticultural Council, which represents growers of apples, pears and cherries in the Pacific Northwest.

But Ralph Nader's Public Citizen group sharply dissected Clinton's plan, calling it weak in some elements and counterproductive in others.

Lori Wallach, director of the group's trade section, said the FDA already has the power to seize contaminated fruit and vegetables at the border. Moreover, she said, Clinton's proposal would apply a looser standard than current law—requiring that foreign safety standards be equivalent rather than equal to U.S. rules.

The most beneficial aspect of the plan, she said, is the provision allowing the FDA to block produce imports if its inspectors are barred from another nation.

"It's a crass political move," she said. "It's about fast track, not food safety."

Staff writer Paul Blustein contributed to this report.

The Washington Post

FRIDAY, OCTOBER 3, 1997

Campaign Reform's Fate on Fence

McCain Woos Potential Swing GOP Votes, Concedes Passage Is Unlikely

By Guy Gugliotta and Edward Walsh
Washington Post Staff Writers

If Sen. John McCain (R-Ariz.) expects the Senate to pass a campaign finance reform bill this year, he must find decisive support from a pool of about 15 Republican colleagues on one or more critical preliminary votes next week.

When asked whether he could sway enough of these fence-sitters, McCain said yesterday, "No doubt the odds are stacked against us." Interviews with most of the potential swing senators showed that the support, at this point, simply is not there.

Preparing for the worst, Senate Minority Leader Thomas A. Daschle (D-S.D.) vowed yesterday that even if the bill is stopped next week, the Democrats will offer it "as an amendment to whatever piece of legislation comes before the body."

But no matter how many times the Democrats try to force a vote, the bill will never pass unless those pivotal Republicans have a change of heart.

The key Republicans, according to Senate sources following the bill, include moderates, senators sympathetic to campaign reform, senators running for reelection next year and senators who have sought support from traditional Democratic constituencies.

The first vote, likely to come on an amendment to curb labor union spending on elections, could be a cliffhanger. All 45 Democrats will oppose the measure as a "poison pill," but McCain and four other Republicans will have to join them in order to defeat it. Even Republicans who support the reform bill so far have refused to commit themselves on this vote.

If McCain and his supporters should manage to beat the amendment, they will then have to muster 60 senators to defeat a Republican filibuster in order to bring the legislation to a vote. That means 15 Republicans will have to join the Democrats, and thus far, prospects are dim. "My own sense is that we are far short," said Sen. Arlen Specter (R-Pa.), one of four Republican co-sponsors.

"I'm not even close," said Sen. Pete V. Domenici (R-N.M.), thought to be a potential supporter because of his long record of trying to reform Senate procedures. "I'm willing to look, but I haven't seen anything yet."

Senate Majority Leader Trent Lott (R-Miss.) succeeded in muddying the voting calculus Monday when he introduced the union amendment, a measure that virtually no Republican senator—even among those who favor the reform bill—wants to oppose.

"I find myself in a quandary," said

Sen. Susan Collins (R-Maine), another co-sponsor of McCain's bill. The amendment is "good public policy," but Democrats "say it's a killer amendment," she added. "At the end of the day, I want both" the amendment and the bill.

At present this seems impossible. The amendment would forbid unions to use regular membership dues to finance political activities unless individual members specifically authorize it in advance. The reform bill has a provision that applies only to non-union members who can request a refund for the portion of their fees used by the union for political purposes.

This is a considerable difference, and for Democrats, beneficiaries of the vast majority of union political expenditures in 1996, the Lott amendment is unpalatable—"the definition of a 'poison pill,'" said Sen. Russell Feingold (D-Wis.), McCain's co-author. "This is an intentional effort to kill campaign finance reform."

But while Collins and others may recognize the Lott amendment's disruptive nature, McCain is the only Republican who so far has said he will vote against it. Sen. Fred D. Thompson (R-Tenn.), another GOP co-sponsor, is undecided, and Specter, a moderate running for reelection in pro-labor Pennsylvania next year, was noncommittal.

Sen. Olympia J. Snowe (R-Maine), another moderate thought to be able to provide a decisive vote, said she will support the Lott amendment, but will try to work out a compromise before "partisan positions harden." Yesterday Snowe met with Collins, Sen. John H. Chafee (R-R.I.), and staffers for Specter and Sen. James M. Jeffords (R-Vt.) to discuss a compromise, but reached no conclusions, aides said. Snowe has proposed extending the requirement for prior approval of political spending to all membership organizations "ranging from the National Rifle Association to the Sierra Club."

But interviews made clear that in a few short days the Lott amendment had its intended effect of hardening partisan positions substantially, particularly among Republicans who had been battered by union money during the last election.

"It's like a drive-by shooting," said freshman Sen. Gordon Smith (R-Ore.) of union involvement. Unions paid for most of \$1 million in campaign ads run on behalf of his opponent in a period of a few weeks in 1996, he said, "and no one was responsible for them to whom I could respond. Yes, I have strong feelings."

Smith, thought to be a swing vote because of Oregon's tradition of political moderation, regarded the Lott amend-

ment as the "linchpin" of campaign finance reform. So did Sen. Tim Hutchinson (R-Ark.), whose brother Asa is a leading advocate of campaign finance reform in the House.

Hutchinson said his conversations with Asa had led him to contemplate a ban on the unregulated campaign funds known as "soft money," the centerpiece of the McCain-Feingold bill. But he noted that Republicans traditionally enjoy a substantial advantage in raising soft money, and they needed something like the Lott amendment before they would give up the edge. "Anything else is unilateral disarmament," he said.

Some senators said they had not made a final decision on the Lott amendment, among them Sen. Alfonse D'Amato (R-N.Y.), running for reelection next year in a strong union state.

"I heard about 'poison pills' just now," said D'Amato, giving no clue as to his intentions. "I have no problems with [the McCain-Feingold bill] as it relates to soft money, but I certainly resent legislation being characterized as 'poison pills.'"

Others, like Sen. Spencer Abraham (R-Mich.), a former campaign strategist for House Republicans, refused to comment. "I don't get the sense he's ready to discuss this with a reporter right now simply because he's been dealing with other things," Abraham's press secretary, Joe McMonigle, said.

Still, with the exception of Snowe, who will vote to break a Republican filibuster even if the Lott amendment passes, all of the swing senators interviewed said the Lott amendment had to pass first. Also in this camp was Sen. Sam Brownback (R-Kans.), a reform-minded newcomer, and probably Sen. Richard G. Lugar (R-Ind.), known for taking thoughtful positions on controversial subjects.

But, like Domenici, first-term Sens. Bill Frist (R-Tenn.) and Chuck Hagel (R-Neb.) said they opposed the bill regardless of the Lott amendment.

Meanwhile, Daschle's threat yesterday to keep pushing for action on McCain-Feingold this year appeared to signal a tougher stance by Democrats. Daschle said that if Lott blocks the bill and attempts to bring up other legislation, even if it is the huge transportation funding bill or President Clinton's proposal for "fast-track" trade negotiating authority, "we're going to amend it."

McCain said that if he couldn't get a vote on his full bill, he was "committed to getting an up-or-down vote on the soft money ban," which has stronger backing than some other parts of the bill.

Staff writer Helen Dewar contributed to this report.

The Washington Post

FRIDAY, OCTOBER 3, 1997

Too Soon to Sell Reactors to China

Of all the nuclear powers, China has been the most reckless in exporting technology and materials that other countries can use to develop their own bombs. In the 1990's, Iran, Iraq, India and Pakistan have received Chinese help in evading international restrictions on nuclear trade. Iran and Pakistan still receive Chinese assistance. Despite recent promises to exercise restraint, China remains the only nuclear-weapons state selling material and technology to countries that close some of their nuclear installations to international inspectors.

That should be reason enough to maintain restrictions on exporting civilian nuclear reactor technology to China. Yet there is strong support within the Administration for lifting those controls in time for the visit of Jiang Zemin, China's President, to Washington this month. President Clinton should resist the pleas of diplomats eager to improve relations with Beijing and of exporters like Westinghouse, General Electric and ABB looking to tap the \$2 billion Chinese nuclear market. He should keep current restrictions in place until China shows responsibility on its own nuclear exports.

Getting China to change its policies is hard. But Washington now has a lever for seeking tighter export restraints. China is planning to expand its nuclear power program and very much wants to gain access to American civilian nuclear technology, the world's best. That leverage can be deftly used by promising an early lifting of the American export restrictions once tighter Chinese controls are established and verifiably in place.

American companies may not sell reactors to China until the President informs Congress that Beijing is neither directly nor indirectly helping non-nuclear countries develop nuclear weapons. For the last 12 years, no American President has felt able to give such assurances.

The Administration has been pressing China to observe stricter export safeguards since last year's discovery that a Chinese military corporation was selling ring magnets, a bomb-making tool, to Pakistan. Beijing appears to have stopped shipping nuclear materials and technologies to installations that bar international inspectors. But that is not enough, since recipient countries can simply divert such nuclear contraband to unmonitored installations. The solution is for China to refuse to sell to countries that bar inspectors from any facility. China must also establish better controls over the export activities of its military-run corporations.

Those two steps would solve the Pakistan problem, but not the Iranian one. Iran keeps all its known facilities open to inspectors, but the Central Intelligence Agency reports it is secretly developing nuclear weapons anyway. China is also aiding Iranian efforts to make chemical weapons and medium-range missiles. American diplomats are trying to firm up Chinese promises to halt this dangerous assistance to Iran. But there will be no way of knowing whether these pledges are reliable in time for the coming summit meeting. In an area this dangerous to international security, promises are not enough.

Safety Standards for Imported Food

Global trade allows Americans to satisfy their appetites for strawberries in spring, apples in mid-summer and asparagus in autumn. Last year 38 percent of fruits and 12 percent of vegetables consumed here came from foreign fields. But getting fresh produce year round also means that consumers are exposed to foreign food production systems that may not be well regulated. Although the vast majority of the 30 billion tons of food imported annually is wholesome, recent incidents of illness caused by tainted Guatemalan raspberries and E. coli-contaminated domestic meat and fruit juices have made food safety a public concern.

Yet even as food imports have doubled since the 1980's, Federal health inspections of imports have been cut in half. Since the Food and Drug Administration samples less than 1 percent of food imports at the docks, tainted food can easily reach consumers undetected.

In a sensible effort to tighten food safeguards, President Clinton asked Congress yesterday to give the F.D.A. power to halt imports of fruits, vegetables and other food products from countries that do

not maintain food safety standards equivalent to those in the United States. That would give the agency the same authority that the Department of Agriculture has long exercised over imports of meat and poultry. Monitoring the agricultural and food handling practices in exporting nations will be far more effective than random checks at the border. The Administration will seek \$24 million in 1999 to send F.D.A. inspectors abroad.

The President is also asking government agencies and representatives of the agricultural sector to draft standards of good agricultural practices, such as keeping latrines away from vegetable fields and screening food workers for hepatitis, to guide both domestic and foreign growers.

Foreign producers are already denouncing the plan as an unfair trade barrier. But there is no reason to believe that asparagus growers in Mexico will be asked to live by higher standards than growers in Washington State. In the long run, Federal efforts to bolster consumer confidence in the wholesomeness of imported food will help the American appetite for foreign produce grow.

The New York Times

FRIDAY, OCTOBER 3, 1997 |

Weather

Today: Partly sunny, milder.
High 76, Low 54. Wind 6-12 mph.
Saturday: Partly sunny, breezy, mild.
High 78, Low 58. Wind 8-16 mph.
View: Temp. range 44-65.
Poll: Count 20. Details, Page D2.

The Washington Post

FINAL

Inside: Weekend
Today's Contents on Page A2

120TH YEAR No. 302

FRIDAY, OCTOBER 3, 1997

Price: 50¢ per copy (incl. GST)
Subscription: \$10.00 per month (incl. GST)

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Troubled From the Start

Basic Conflict Impeded Justice Probe of Fund-Raising

By Susan Schmidt and Roberto Suro
Washington Post Staff Writers

Two weeks ago, after she abruptly replaced the leadership of the Justice Department task force investigating allegations of campaign fund-raising abuses, Attorney General Janet Reno insisted she still had confidence in the original team, and told reporters it had done "a very professional, very fine job."

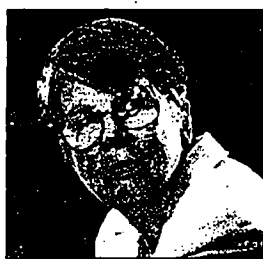
Yet an examination of the task force's 11-month effort, and interviews with more than a dozen Justice Department and FBI officials who participated in or have direct knowledge of its efforts, indicates that the investigation was plagued by a disagreement over its mandate that was so fundamental it may have crippled its efforts from the start.

And even as Reno repeatedly assured

increasingly demanding congressional Republicans that all was proceeding as it should, with "no stone" left unturned, investigators wrestled with extensive internal restrictions on things as basic as what information they could share with each other, and difficulties as prosaic as the lack of an adequate system to even look at—let alone analyze—the hundreds of thousands of documents they acquired.

The result, despite Reno's protestations that the task force functioned professionally and effectively, was an investigation that, even after months, could point to little visible achievement.

The clearest evidence of the task force's failings shows up today, when Reno announces she will take the next legal step under the Independent Counsel Act, opening a preliminary investigation that could lead to the appointment of an independent



BY NARIN COOPER—ASSOCIATED PRESS
Attorney General Janet Reno faces deadlines today and Oct. 15 on the investigation.

counsel outside her control to look into Vice President Gore's fund-raising activities. Her deadline for a similar decision on President Clinton is Oct. 15. The information that may result in an independent counsel came not from the task force that had spent nearly a year investigating the 1996 campaign, but from a newspaper account of Gore's activities.

At the core of the task force's difficulties See JUSTICE, A24, Col. 1.

Reno Decides to Expand Investigation of Gore

By Roberto Suro and Bob Woodward
Washington Post Staff Writers

Attorney General Janet Reno has decided to take the next step in a legal process that could lead to an independent counsel investigation of Vice President Gore's White House fund-raising solicitations before last year's election, government officials said yesterday.

Reno's decision to open a 60-day preliminary investigation of Gore's fund-raising calls was based on procedures outlined in the Independent Counsel Act, which requires the attorney general to conduct such an inquiry when the Justice Department encounters unresolved allegations that top administration or campaign officials may have committed a criminal act.

Ginny Terzano, Gore's spokeswoman, said last night that the vice president had not been notified of Reno's decision but that he and his attorneys, who have been talking regularly with Justice Department officials, were not surprised by it.

"We would not be surprised if the Justice Department decided to go to an extended re-

view," Terzano said, "because there simply has not been enough time in 30 days for them to fully explore this matter."

A government official said that Reno had made no final decision on ordering a similar review of President Clinton's White House fund-raising solicitations but that such a decision was not likely because Justice Department investigators had so far uncovered no evidence that the calls violated federal law. Reno must decide whether to order such a review of Clinton's fund-raising efforts by Oct. 15.

Last month, Reno ordered the Justice Department to conduct a 30-day review of Gore's White House calls. Gore aides have provided records showing he made at least 46 fund-raising phone calls from his White House office. The review ordered by Reno was to determine whether the calls violated the 114-year-old Pendleton Act, which covers fund-raising by government officials on federal property. A second issue under study is whether any federal laws were broken when money raised by the Gore calls was deposited into

See RENO, A26, Col. 1

Soulsby Says He'll Revive Police Unit

Chief Outlines Plans To Close Slaying Cases

By Cheryl W. Thompson
Washington Post Staff Writer

D.C. Police Chief Larry D. Soulsby announced yesterday plans to reinvestigate the department's under-achieving homicide unit, promising more personnel, better training, new equipment, stricter accountability and improved investigative procedures will bring "a significant increase in the [case] closure rate" within months.

"We have to find new ways to do things," the chief said at a news conference, responding to a drumbeat of reports in recent weeks about the unit's dismal success rate in solving homicides. Soulsby and others have blamed the problem on poor management by the unit's supervisors, all of whom have been ousted.

In outlining plans to improve the unit's performance yesterday, Soulsby denied that he, as chief, was directly responsible for the failings. Instead, he pointed a finger at Capt. Alan Dreher and the rest of the unit's purged leadership, saying they are to be for the shoddy investigative work, disorganized record-keeping and massive amounts of overtime pay collected by detectives in the unit.

"As chief of police, ultimately I'm responsible for everything," Soulsby said. "But what you had was five layers of supervision between me and homicide."

Although the unit's problems have been festering for years, according to reports by consultants, Soulsby said he was not aware of them until recently.

"I didn't have time and don't get involved in day-to-day operations," he said. He was appointed chief by Mayor Marion Barry in the fall of 1996. See HOMICIDE, A9, Col. 1.

ANOTHER POWERFUL PERFORMANCE



BY RICH LEBLANC—THE WASHINGTON POST
Brady Anderson hits a two-run home run in the seventh inning of the Orioles' 9-3 victory over the Seattle Mariners in the second game of their first-round playoff series, which will resume Saturday in Baltimore. Details, Page C1.

Clinton to Propose Board To Act as IRS Watchdog

National, Local Citizen Panels Envisaged

By Clay Chandler and Albert B. Crenshaw
Washington Post Staff Writers

President Clinton will propose the creation of an independent Citizen's Review Panel to field complaints from taxpayers about the Internal Revenue Service, a senior Clinton administration official said yesterday.

The proposal, which Clinton hopes to present to Congress as early as next week, will call for the establishment of a watchdog entity that includes a national review board and 33 local review boards assigned to monitor the actions of each IRS district office.

The proposal comes a week after congressional hearings spotlighted abuses by IRS officials and energized a contest between the adminis-

tration and many members of Congress over reform proposals for the tax collection agency.

The panels would be modeled on citizen review boards set up in many cities to act as a check on local police departments.

Administration officials are also considering how members of the IRS review panels would be selected and whether to recommend that the entities have authority to discipline IRS agents.

A special commission, set up by Congress, spent a year studying the agency and earlier this year recommended a series of changes in IRS governance and operations. Among its proposals is one for an oversight board made up primarily of private-sector individuals to review the agency's budget and chart its strategy. See IRS, A12, Col. 1.

SPORTS AGENTS

GROWING FORCE BETWEEN STAR ATHLETES AND THEIR TEAMS

With Money at Stake, Game Is Hardball

First of Two Articles

By Bill Brubaker
Washington Post Staff Writer

Gus Sunseri, the agent for Redskins defensive tackle Sean Gilbert, was explaining on a Washington radio talk show why his client was refusing to report to work. Gilbert is worth upward of \$5 million a year, Sunseri said, and the Redskins have offered a mere \$3.6 million. When the WTEN interviewer told him many fans do not believe Gilbert is worth \$5 million—the Redskins, after all, had one of the worst defenses in pro football last season—Sunseri responded: "We care about how we're judged in God's eyes—and not the public's eyes. ... Ninety-nine percent of the people only know 1 percent of the facts."

The interview, several days before the Redskins' 1997 season opener, brought a strong response from WTEN

listeners. "The 1 percent I do know is that Sean Gilbert has a very arrogant agent," one caller said. "God also says it's not good to be greedy," said another. Others called Sunseri a "jerk" and "dirtball" and "total moron" who "reinforces every negative stereotype you ever had of an agent"—insults Sunseri later dismissed with a hearty laugh.

As professional athletics has grown into a multibillion-dollar industry, where star players can earn hundreds of thousands of dollars per game, agents have become, to many fans, the scourge of the sports world—responsible for skyrocketing salaries, high ticket prices, even the win-loss records of their favorite teams.

"More people are saying: Kill the agent," said Brian Cook, a Boston-based hockey agent who threatened to sue the Washington Capitals this summer.

See AGENTS, A14, Col. 1



COURTESY OF SCOTT BORAS CORP.
Agent Scott Boras represents 70 pro baseball players.

WorldCom Would Shift MCI's Focus

Bidder Plans to Shed Residential Service

By Mike Mills
Washington Post Staff Writer

MCI Communications Corp. would jettison its approximately 20 million residential long-distance customers and focus solely on more profitable business customers if a proposed \$30 billion buyout of MCI goes through, according to a top official of the company that would make the purchase.

John Sidgmore, vice chairman of WorldCom Inc., said in a telephone interview that the residential customers likely would be transferred to other long-distance companies, potentially including the regional Bell companies.

For example, he said, "an MCI customer would become a Bell Atlantic customer."

Under this scenario, calls would still be carried by WorldCom and MCI wires. But the job of setting rates, providing operators and billing the customers would belong to the other companies. The customer would never hear the MCI name or deal with the ny.

WorldCom would "sell" MCI customers to other long-distance companies, who would pay for rights to serve established accounts. Because customers are legally guaranteed the right to choose their long-distance provider, they would not have to stay with the company they were moved to.

Precisely when and how all this See MCI, A13, Col. 1

Md. Counties Awash in Pollution-Causing Nutrients

Reports Suggest State Faces Battle Controlling Agricultural Runoff Into the Bay

By Joby Warrick and Todd Shields
Washington Post Staff Writers

State policymakers preparing to do battle against the Chesapeake Bay's fish-killing microbe are about to get some harrowing news from the field: Farm counties of the Eastern Shore are awash in pollutants linked to *Pfiesteria piscicida*, reports show, and the tools now used to control them aren't doing the job.

New data emerging in the wake of the recent fish kills show eastern counties literally overdosing on nature's fertilizer—

waste from tens of millions of chickens and other livestock. Top poultry counties now produce more than enough manure to meet the needs of every crop, yet they continue to import commercial fertilizers by the thousands of tons.

Meanwhile, voluntary programs for farmers have backfired in some areas by focusing on a single chemical—nitrogen—while allowing other nutrients in the soil to build to the point of saturation.

Some fields are so overloaded with plant nutrients that each new rain is washing large quantities of them into rivers and

streams, where they become a hazard to aquatic life, scientists say. Meanwhile, chemicals now locked away in soil and ground water will continue migrating into waterways for decades.

The new reports by the U.S. Department of Agriculture, the federally led Chesapeake Bay Program and other agencies highlight the enormous dimensions of the agricultural waste problem, in the Delmarva Peninsula, a region of Delaware and parts of Maryland and Virginia that generates about a million tons of manure

See NUTRIENTS, A22, Col. 1



Soccer in English, Fútbol en Español

Today's sports section inaugurates a new feature, two pages devoted to soccer in both Spanish and English. The feature will appear every Friday through the end of the World Cup qualifying round in late November.

Publishing this feature in Spanish is an experience. Readers are invited to give us their reactions.

See Sports, Pages C8 and C9

INSIDE

Diplomatic Protest

Canada recalled its ambassador to Israel yesterday to protest the use of forged Canadian passports by two men in an alleged assassination of a militant Islamic leader last week in Amman, Jordan.

A, Page A20

Baseball Playoffs

Baltimore	9
Seattle	3
New York	5

Laser Test Slated

The Army is scheduled to fire a ground-based laser at an Air Force satellite, despite concerns by State Department officials and congressional leaders and satellite manufacturers.

The Post on the Internet
www.washingtonpost.com





United States Department of Agriculture
Food Safety and Inspection Service

FAX

To:

Tom Freedman

Fax #:

456-7431

Subject:

Date:

Pages: including this cover sheet.

COMMENTS:

Py 1999 Food
Safety Initiative

5 pages

From the desk of

Thomas J. Billy
Administrator
331-E Jamie L. Whitten Building
Washington, DC 20250

202-720-7025
or 720-8217
Fax 205-0158

Background

U.S. Department of Agriculture

Department of Health and Human Services

Revised February 1998

1999 National Food Safety Initiative

On January 25, 1997, the President announced the National Food Safety Initiative. The initiative includes components for reducing the incidence of foodborne illness from farm-to-table. Key components include expansion of the Federal food safety surveillance system, improved coordination between Federal, State, and local health authorities, improved risk assessment capabilities, increased inspection, expanded research, consumer education, and strategic planning. Utilizing the funds provided by Congress in 1998, an increase of \$43 million, the U.S. Department of Agriculture (USDA) and Department of Health and Human Services (HHS) have initiated changes to ensure the safety of a wider variety range of food products from a broader range of hazards. In addition, USDA and HHS have identified measures that need to be taken to ensure the safety of fresh fruits and vegetables consistent with the President's directive on this issue. USDA, HHS, and other interested parties will seek input on measures that can be taken to improve food safety during production, transportation, storage, distribution, and in the home.

1999 Budget Request

For 1999, the Administration is proposing an increase of \$101 million for the National Food Safety Initiative. Of this amount, \$46 million is allocated to USDA and \$55 million to HHS. The 1999 National Food Safety Initiative builds on the successes of the 1998 initiative as well as fills the gaps that have been identified in the past year. In 1999, the focus of the initiative is on enhancing the safety of imported and domestic fruits and vegetables, targeting food safety education, implementing of Hazard Analysis and Critical Control Point (HACCP) systems in appropriate sectors of the food supply, and developing of scientific information and tools to control a greater range of food safety hazards. Funding is requested for the following activities:

Enhance surveillance and investigation to improve outbreak response (+\$7 million):

HHS (+\$6.7 million): The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will work with States to identify potential food safety threats early. CDC and FDA will further build the capabilities and coverage of the FoodNet early-

warning surveillance system and will improve monitoring of threats to food by expanding the range of pathogens under surveillance. The agencies also will improve information sharing among agencies and with the public, and provide training and technical assistance to State/local agencies for outbreak investigation.

USDA (+\$0.3 million): The Economic Research Service (ERS) will evaluate the effectiveness of food safety measures by analyzing foodborne illness surveillance data. New estimates will be developed for the national incidence of foodborne disease, distribution of illness among subpopulations, and rates of illness.

Strengthen coordination and improve efficiency (+\$0.2 million):

HHS will work with other Federal agencies and States to expand assistance to states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordination in response to foodborne outbreaks. Standard operating procedures for sharing information and data among agencies and with the public on foodborne outbreaks will be developed.

Improve capability to estimate risks associated with foodborne hazards (+\$11 million):

HHS (+\$7 million): FDA will initiate a program of research in quantitative risk assessment (particularly for microbial hazards) that is targeted to address the limitations in risk assessment methodologies and available data related to 1) dose-response relations for the general population and high risk groups (e.g. neonates, elderly, immune-compromised), 2) the impact of production, processing, distribution, marketing, and preparation practices, and 3) the quantification of factors contributing to incidence and prevalence of pathogenic microorganisms in raw ingredients and finished products. FDA will continue to build the activities of the interagency Risk Assessment Consortium at the Joint Institute for Food Safety and Nutrition (JIFSAN) that provides a forum for coordination of federal microbial risk assessment research and serves as a clearinghouse for risk assessment information and expertise.

USDA (+\$4 million): The Agriculture Research Service (ARS), Cooperative State Research, Education and Extension Service (CSREES), ERS, FSIS, and the Office of the Chief Economist (OCE) will conduct quantitative risk assessments to identify food safety hazards and controls, make faster and more accurate regulatory decisions, target program resources more effectively, and facilitate the development and evaluation of surveillance plans and risk reduction strategies.

Expand inspection and compliance efforts, implement new preventive measures with a new emphasis on domestic and imported produce, and facilitate the implementation of HACCP (+\$36 million):

HHS (+\$28 million): FDA will enhance protection of American consumers by seeking legislation that would decrease the risk of importing unsafe food products from countries with food safety systems for exported products that are not on a par with the U.S. system or that refuse to allow entry of U.S. investigators into facilities producing products offered for import. FDA will verify implementation of seafood HACCP and implement HACCP for juices. FDA will provide technical assistance and educational outreach to promote the appropriate application of voluntary good agricultural practices/good manufacturing practices (GAP/GMP) guidance in the domestic fresh produce industry.

USDA (+\$8 million): The Food Safety and Inspection Service (FSIS) will provide special onetime assistance to State meat and poultry inspection programs to facilitate implementation of HACCP.

Continue to build the national food safety education campaign (+\$14 million):
USDA (+\$10 million) and HHS (+\$4 million) for the following activities:

Consumer and Food Handler Education--USDA (+\$5 million) and HHS (+\$4 million): Building on the national campaign launched by the public-private Partnership for Food Safety Education in 1997, FSIS, CSREES and FDA will target specific programs to change unsafe behaviors used by home food handlers, cooks and food handlers in retail settings and in congregate feeding sites. CDC, FSIS and FDA will begin development of materials to assist in educating school children about how to prevent foodborne illness. FDA will target vulnerable groups (e.g., those affected by *Vibrio* in raw oysters and pregnant women and *Listeria*) with specific food safety messages. FDA will develop multilingual training programs for food service and retail workers and provide technical assistance to domestic and foreign fresh produce industries to promote appropriate application of good agricultural and manufacturing guidance. FSIS will target vulnerable groups (e.g., senior citizens and people with compromised immune systems) and will launch a campaign to promote thorough cooking of meat and poultry products.

School Food Service Provider Education--USDA (+\$2 million): The Food and Nutrition Service (FNS) will develop and operate training workshops to educate local school food service professionals about the latest safe food handling practices specific to their needs and the updated Food Code.

Producer Education--USDA (+\$3 million): FSIS and CSREES will work with industry and academia to educate food animal producers and fruit and vegetable producers on food safety assurance practices, risk management, and risk communication.

Accelerate food safety research efforts (+\$33 million):
(USDA +\$24 million and HHS +\$9 million)

Research will be conducted to enhance understanding of pathogen growth and control and will focus in the four areas identified in interagency research planning as critical to reducing microbial risk in produce. Improved detection methods, particularly rapid tests, will be developed that identify a broader range of pathogens on food products, particularly fresh fruits and vegetables, throughout the food production, manufacturing, and distribution system. Development of prevention/intervention strategies is another area of focus, with research on development of alternative food production, processing, and handling systems that eliminate or reduce pathogen contamination. Research on identification of conditions under which food products become contaminated during food handling, distribution, and storage will play an integral role in this research. FDA and USDA will conduct research on resistance to traditional preservation techniques and antibiotic resistance. USDA will develop a microbiological baseline for pathogens on fresh fruits and vegetables utilizing existing program infrastructure.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
and
U.S. DEPARTMENT OF AGRICULTURE
Washington, D.C.



FEB 24 1998

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Attached is our report, as requested in your October 2, 1997 Directive, on progress made on the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. The report is a synopsis of the progress we have made in providing Good Agricultural Practices and Good Manufacturing Practices guidance to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables.

The report also discusses our plans for extending existing programs in order to improve the monitoring of agricultural and manufacturing practices domestically and abroad, to assist domestic and foreign producers to improve those practices, where necessary, to prevent the distribution and importation of unsafe produce, and to accelerate research to support these activities.

Sincerely,

Donna E. Shalala
Secretary of Health and Human Services

Enclosure

Dan Glickman
Secretary of Agriculture

Handwritten notes and signatures:
- *Shalala*
- *W. J. Clinton*
- *Don Glickman*
- *on farm safety*
- *Stover*
- *Kennedy*
- *Seaver*
- *Porter*
- *Arnsperg*

Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables: Status Report

Background

American consumers enjoy one of the safest food supplies in the world. However, over the last several years there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables. In May 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services (DHHS), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern. On October 2, 1997, President Clinton announced a new initiative to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards.

The President called on Congress to give the Food and Drug Administration (FDA) the authority to better assure that food imports meet existing United States food safety laws and regulations. Legislation has been introduced in the House of Representatives that would enhance FDA's ability to ensure the safety of all foods imported into the U.S. The legislation would enhance FDA's ability to protect U.S. consumers while being consistent with U.S. trade rights and obligations.

In addition, the President directed the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever safety guidance for the growing, processing, shipping, and selling of fruits and vegetables. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. This second component of the President's Directive — voluntary guidance — is an important outreach and education effort, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President's FY 1999 budget includes funds necessary to expand FDA's international capabilities; full implementation in FY 1999 will be contingent on receiving adequate appropriations.

This Report

The President asked the two Secretaries to report back to him with a plan and schedule for developing this guidance. This report presents the progress made to develop voluntary guidance for the growing, processing, shipping, and selling of fruits and vegetables and the schedule and plans to accomplish these and the other elements of the President's produce initiative. To meet the President's goal that our produce meet the highest health and safety standards, the Departments will develop voluntary Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance for produce (henceforth referred to as guidance). GAPs cover production practices including growing, harvesting, handling, and transportation. GMPs primarily address harvesting and transportation, but also include aspects of manufacturing such as processing and packaging. GAPs and GMPs by necessity, overlap and are interrelated.

This report also describes interdependent activities that will help industry successfully apply the voluntary guidance. For example, the domestic and foreign industry may require technical assistance from U.S. agencies to effectively apply the voluntary guidance. Education and outreach efforts will be provided to the domestic and foreign industry and these activities will be based on a strong underlying, accelerated research program. In the long-term, research and risk assessment on fresh produce will be incorporated in the multi-year Food Safety Initiative research planning process. Development of this interagency research planning process is being facilitated by the White House Office of Science and Technology Policy.

The U.S. produce industry, states, and many countries exporting fresh fruits and vegetables to the U.S. have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly in developing the voluntary GAP/GMP guidance, recognize this effort and build on it.

I. Good Agricultural Practices/Good Manufacturing Practices Guidance

Status: FDA, working with the USDA, is preparing a general GAP/GMP guidance document. FDA plans to publish the document as proposed voluntary guidance with opportunity for public comments. This guidance, titled "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables", describes science-based good agricultural practices that farmers and producers may use for water quality, manure management, sanitation (both field and facility sanitation, as well as worker hygiene), and handling and transportation. The guidance also describes use of producer identification and information on the flow of the product through distribution channels. This information can facilitate source identification, should a commodity be associated with a foodborne illness outbreak. This guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The guidance, which is a science-based evaluation of risks, will be consistent with World Trade Organization obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers. The agencies recognize that appropriate use of pesticides and related antimicrobial agents play an important role in controlling microbial contamination, but caution that excessive or inappropriate use of these substances does not take the place of GAPs/GMPs. X

FDA and USDA sponsored, with states, a series of public meetings from mid-November to mid-December, 1997, in which the agricultural community, the international trade community, consumers, and the scientific community participated. The purpose of these meetings was to give participants the opportunity to offer their perspective on the working draft guidance and provide comments, technical information, and suggested modifications to the draft guidance. The National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (a USDA/FDA advisory committee) was present at the first public meeting. Based on information exchanged at that first public meeting and Subcommittee members' expertise, the Subcommittee provided recommendations that were incorporated into the working draft guidance document. This revised working draft document was subsequently used as the basis of discussion at a series of meetings for the agricultural community. These "grassroots" meetings were held at six regional locations around the country during December. The agencies also presented the draft guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting in December. Feedback from the agricultural community through the "grassroots" meetings and other fora is essential to be sure that the guidance being developed is practical and applicable. Development of the final guidance will draw on scientific data and ✓

other information that describes the fresh fruit and vegetable industry domestically and in countries exporting products to the U.S.

FDA, with USDA, will oversee a task force (with representation from other federal agencies and states) to assist in developing additional guidance if sound science, risk, or experience with general guidance indicate a need. The additional guidance may be tailored to reduce the potential for microbial contamination with specific pathogens (e.g., *E. coli* O157:H7, *Cyclospora*) and to reduce contamination associated with particular hazards (e.g., microbially-derived toxins) and commodities. This type of guidance can also be designed to minimize microbial contamination through particular pathways, such as control of water quality, worker sanitation and health, field and facility sanitation, and transportation and handling of produce. Options are being explored to determine the most efficient ways to provide industry with effective guidance that yields the most benefit for the resources expended. Any additional guidance will be developed through an open process involving industry, consumers, academia, states, and public health professionals, including the FDA public review and comment process.

The general guidance may be augmented as information about scientific advances and risks associated with fresh produce received from a variety of sources, (e.g., foodborne illness outbreaks and research) indicates the need for targeted guidance or refinement of the general guidance.

Timeline:

Short-term — October - December 1997

- a. FDA drafted proposed voluntary GAP/GMP guidance
- b. FDA and USDA held a public meeting and a meeting of the National Advisory Committee on Microbiological Criteria for Foods to solicit comments and recommendations on the guidance
- c. FDA and USDA conducted grassroots and international meetings to receive comments and information from the public

Mid-term — January - May 1998

- a. FDA, working with representatives from USDA, EPA, Occupational Safety and Health Administration (OSHA), and the State Departments of Agriculture and of Health from California, Florida, and Michigan, will analyze comments and information from the public, grassroots, and international meetings and revise guidance incorporating that information
- b. Publish revised guidance as a proposal in the Federal Register
- c. Comment period of 75 days for public to submit comments and information pertaining to the guidance

Long-term — June 1998 and beyond

- a. Evaluate comments and revise guidance into final guidance
- b. Publish final guidance in the Federal Register by October 2, 1998
- c. Create an interagency committee to evaluate the need for additional guidance and, if additional guidance is needed, oversee and direct the development of that guidance
- d. Develop a strategy to refine existing guidance, incorporating advances in science and knowledge about produce safety and information about new risks
- e. Develop risk assessment techniques to use in evaluating the effectiveness of and refining (based on that evaluation) implemented food safety control strategies

Supporting Information: To complement data and information being developed domestically, comparable data and country information, such as epidemiologic data on human health and food safety legislation and regulations affecting production, handling, and storage of produce for selected countries that export produce to the U.S. will be compiled by mid-July, 1998.

Timeline:

Short-term — November 1997 - June, 1998

- a. Identify and compile current data concerning primary sources of fresh fruits and vegetables
- b. Identify and compile available data about domestic agricultural practices and foreign food safety legislation and regulation for selected countries that export produce to the U.S. This information will support the scientific (including evaluation of risks) approach.
- c. Identify gaps in current data

Mid-term — June - August 1998

Federal and state government agencies will develop a proposal to fill data gaps in consultation with industry

Long-term — September 1998 and beyond

Using available funding, implement a plan to fill gaps.

II. Technical Assistance and Education and Outreach

Technical Assistance:

Technical expertise and resources must complement the voluntary guidance to achieve improvement in the safety of fresh fruits and vegetables. The guidance will be most effective when safety is bolstered at every step in the process, from in-field operations through distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with appropriate U.S. and foreign government public health and agricultural agencies, as well as with industry groups, to provide technical assistance needed to support appropriate application of the guidance by the produce industry. If a foreign government is interested in learning more about the U.S. guidelines and systems for assuring the safety of domestically produced and imported fresh fruits and vegetables, overseas personnel from USDA and State Department will collaborate as necessary to facilitate these visits. Likewise, in order to provide technical assistance or followup to foodborne illness outbreaks, these overseas personnel will facilitate visits of FDA and/or Centers for Disease Control and Prevention (CDC) investigators or scientists to foreign operations to ascertain the source of problems that may pose a safety hazard in produce exported to the U.S.

USDA and FDA plan to work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S. to promote appropriate application of the guidance and improve production and processing practices. These include officials from the health and agriculture agencies in foreign countries, the Food and Agriculture Organization, the World Health Organization, and subsidiary organizations (e.g., Pan American Health Organization), as well as exporter associations and multinational banks. In the U.S., the agencies will work with appropriate land grant colleges and universities, state agencies, and industry associations. In working with domestic and foreign groups, it is critical that in addition to technical assistance, we provide clear guidance on the legal requirements for offering fresh food for sale in the U.S. With this understanding, the foreign and domestic government, industry, and academic groups can

guide producers' decisions about what, if any, modifications of current practices are appropriate for industry to satisfy U.S. legal requirements for foods. As part of this effort, USDA and FDA will share new technologies as they are developed to enhance the safety of fresh fruits and vegetables, such as improved manure treatment methods, more sensitive analytical methods, and post-harvest treatments to reduce levels of or eliminate pathogens on produce.

Timeline:

Short-term — November 1997 - September 1998

- a. Form an interagency cadre to establish procedures to develop technical assistance and education outreach programs, to identify gaps in data to understand agricultural practices, and to assess effectiveness of the programs
- b. Identify ongoing programs providing technical assistance to domestic producers and selected foreign countries that export to the U.S. related to produce safety
- c. Integrate the goals of the President's Directive into ongoing programs where appropriate
- d. Identify gaps where technical assistance may not be available

Long-term — September 1998 and beyond

- a. Develop and implement a strategy to provide technical assistance necessary to achieve the goals of the President's Directive
- b. Evaluate effectiveness of GAP/GMP guidance and update the guidance accordingly

Education and Outreach: Education and outreach programs are essential to foster appropriate application of the guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to industry's understanding of the essential principles of the guidance, as well as the scientific and practical reasons for application of the guidance as everyday production and processing practice. Others in the distribution chain from the fruit and vegetable producers to the final user—the consumer—must be reached by these programs in order to assure that the care taken to prevent microbial contamination in growing, harvesting, processing, and transporting is not thwarted by later mishandling.

USDA, through its partnership with State Cooperative Extension Services in the United States, will provide leadership for the Directive's producer outreach and educational strategy. USDA, FDA and CDC will plan a national food safety scientific and education conference in 1998 to share current scientific and educational information on food safety risks that can further enhance the microbiological safety of fresh fruits and vegetables, to apprise scientific experts and extension professionals of the voluntary general guidance document, and to discuss methods for promoting appropriate application of the guidance. The guidance will be incorporated into extension programs focused on the best management practices in fruit and vegetable production. It will also serve as a basis for directing program resources to help assure appropriate application of production practices which minimize contamination of fruits and vegetables. State and local extension agents can play a vital role in the successful application of the guidance, since they are knowledgeable about on-farm production practices and can provide expert advice on how producers can incorporate interventions recommended in the guidance to reduce the risk of microbial contamination at the farm level.

To reach the domestic produce industry workforce, the guidance and associated educational materials must be available in native languages and must use terms understood by this diverse community. Multi-lingual materials are also needed for use in foreign countries. To meet these needs, FDA and USDA will work with industry and foreign governments to provide translations of the guidance documents, as well as associated training and information materials, as the documents are finalized.

We anticipate that education and outreach activities will reach beyond the immediate needs of the growers, harvesters, processors, and distributors of fresh produce to the wholesale and retail segments of the industry and to the consumer. Expanded education efforts will be directed to increasing awareness of how to enhance the safety of fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce.

The information provided at the grassroots and international meetings will help the agencies prioritize outreach activities and preparation of materials. FDA and USDA anticipate drawing on the resources and expertise of other agencies and industry groups to provide outreach and education, particularly targeted to specific regional needs in the U.S. The agencies have met with representatives of state agriculture departments and the industry to begin discussions of how best to make available needed training and information. We anticipate that industry itself will be a primary vehicle for outreach and education activities.

In the international arena, USDA will be instrumental in facilitating the development of education and training programs. The USDA's International Cooperation and Development staff can facilitate development of cooperative training programs on the guidance, in collaboration with other agencies capable of providing funding for these activities. The State Department will facilitate FDA and USDA contacts with foreign governments and industry groups to inform them of the guidance and provide technical assistance. USDA will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the Food and Agriculture Organization and the Inter-American Institute for Cooperation on Agriculture, in order to facilitate discussions on produce safety issues. FDA and USDA will evaluate the scope of GAP/GMP education programs and materials needed to educate foreign governments and organizations, factoring in information provided at the international meeting.

Timeline:

Short-term — March - May 1998

- a. Working with industry, develop a program to provide growers, harvesters, distributors, and other aspects of the industry with background and information about the hazards, particularly microbial, associated with fresh produce
- b. FDA and USDA will convene a National food safety and education conference on fruits and vegetables to discuss the draft guidance
- c. Pending finalization of the guidance, take preliminary steps to determine mechanisms for providing information and assistance to the domestic industry in applying guidance. Likewise, preliminary steps will be taken to develop a program targeted to foreign producers.

Mid-term — July - September 1998

- a. FDA and USDA will develop a strategy to educate producers and promote the appropriate application of the final voluntary general guidance which involves federal agencies, states, and the industry.

- b. Work with other groups (foreign governments, foreign industry groups) to develop a strategy for promoting the appropriate application of voluntary guidance

Long-term — October 1998 and beyond

- a. Develop a strategy for refining outreach efforts to meet needs identified by specific producer and industry sectors.

III. Focused Inspections and Verifying Application of Guidance

Inspection and Testing: Inspections of fresh fruit and vegetable operations in combination with sampling and testing provides FDA and USDA with scientific information about the microbial quality of both domestic and imported products. Identification of microbiological problems allows implementation of prevention or intervention measures before illness occurs. It also aids in targeting educational outreach and technical assistance.

FDA will expand its fresh fruit and vegetable inspection and testing program for domestic and imported produce. Additional resources will be focused particularly on sampling products from areas, in the U.S. and abroad, where there is evidence that a potential hazard exists and preventive measures are lacking.

Verification: Verifying the application of the guidance, particularly in segments of the industry where microbial foodborne illnesses have occurred, is integral to determining its effectiveness in reducing the risk associated with fresh fruits and vegetables. The USDA and FDA will use evaluation of risks and survey techniques, such as USDA's Fruit Survey and Vegetable Survey and FDA field surveys of processors, to determine the extent of application of the guidance by both the domestic and foreign industry and the effectiveness of the GAP/GMP program in reducing the occurrence of pathogenic microorganisms and the incidence of produce-associated illnesses. The first survey will be conducted to determine current practices, specifically those practices that have the most impact on public health and those that are covered in the general guidance. This baseline information will be augmented with information from other sources, such as foreign governments and state agencies, on current practices. A second, more extensive, survey on practices will be conducted at a later date. This information — from the surveys and other sources — will be used to evaluate application of the guidance and to make necessary adjustments in the GAP/GMP program, including refinements of the guidance.

Sum
eval

Timeline: FDA's inspection and sample collection and analysis activities will be expanded. Increased inspection and testing efforts are budget dependent and would be desirable to help evaluate the effectiveness of the general and additional guidance. The verifying activity will begin in FY 1999.

IV. Accelerated Food Safety Research

Successful implementation of this initiative relies on scientific research and characterization of the risks to public health posed by microbial contamination. The overall research goal identified in this initiative is development of cost-effective intervention and prevention strategies to reduce the incidence of foodborne illness. Research will also support development of improved detection methods useful in a variety of environments and targeted to sources of contamination. These methods will be used to support long-term surveillance and monitoring of both domestic and

imported produce at the point of production and harvest (e.g., methods for detection of *Cyclospora* and Hepatitis A on produce) and to support development of control and prevention strategies that augment use of general and additional GAP/GMP guidance.

FDA and USDA both have vigorous research programs in areas related to development of pathogen detection and quantification methodology, as well as development of control and prevention interventions. EPA and USDA research would be conducted to assess the significance of pathogen concentrations in natural (free-flowing) and agricultural water supplies and potential subsequent contamination of fruits and vegetables through irrigation practices.

FDA and USDA are individually and collectively reviewing their respective FY 1998 research projects related to fresh fruits and vegetables to identify specific research that can be accelerated. USDA and FDA have held research planning meetings with other agencies conducting food safety related research, including the CDC, EPA, Department of Defense, Department of Energy, National Science Foundation, and National Institutes of Health (NIH). In addition, the agencies have met with industry and consumer representatives to determine what food safety research is currently ongoing or in the developmental stages outside the government and to identify research needs from this outside perspective.

The agencies are developing a coordinated research plan for reducing microbial risk in produce. The research plan is scheduled to be available in early 1998. Four specific areas for research focus have been identified as: improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of intervention strategies. Research is currently underway in all these areas. Among the areas to be further investigated are: packaging, storage, and preservation technologies; production practices; and use of post-harvest treatments to reduce levels of unavoidable microbial contamination. NIH research on pathogenicity and clinical human disease will support both development of detection methods and the risk assessments necessary to evaluate control strategies for the target pathogens.

Research and characterization of risks is a high priority. Research on preventive technologies and intervention strategies to reduce or eliminate microbial contamination is a specific priority. Work will be conducted on manure treatment or composting techniques to assure that the manure is acceptable for application to a specific commodity. Post-harvest chemical (such as use of antimicrobial agents in wash water) and physical treatments will be investigated for fruits and vegetables, as will methods of preventing the persistence and growth of pathogens on both whole and minimally processed produce during storage and transportation. Another area of research that will be accelerated is methods development, specifically methods to detect *Cyclospora* and Hepatitis A on produce. Studies of chemical pattern recognition (trace-element fingerprints) to identify where specific foods were grown or processed will also aid in tracebacks to determine both the source of foods and the pathogens implicated in foodborne illness outbreaks.

Timeline:

Short-term — September 1997 - March 1998

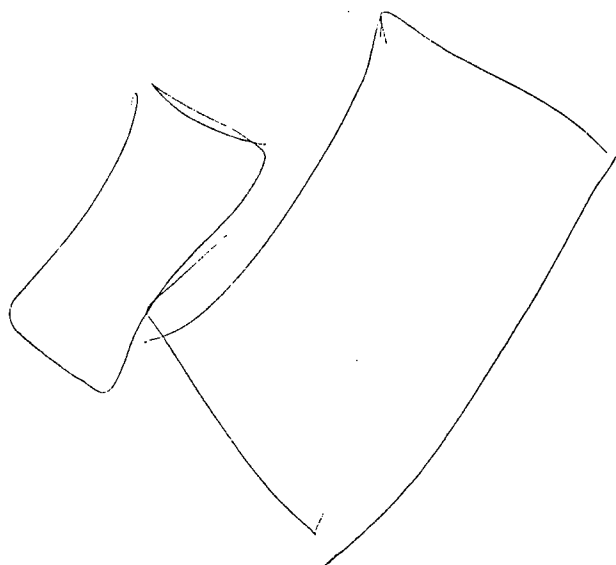
- a. Initiated interagency review of research related to safety of fresh fruits and vegetables
- b. Research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research

Long-term — April 1998 and beyond

- a. Develop an ongoing process for interagency review of research progress and identification of new research needed
- b. Develop schedule for making the updated research plan available periodically

V. Participants in this Initiative

The following agencies are contributing to this initiative: the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention in the Department of Health and Human Services; the Agricultural Marketing Service, the Agricultural Research Service, the Animal and Plant Health Inspection Service, the Cooperative State Research, Education, and Extension Service, the Economic Research Service, the Foreign Agricultural Service, the Food Safety and Inspection Service, the National Agricultural Statistics Service, the Natural Resources Conservation Service, and the Office of Risk Assessment and Cost Benefit Analysis in the U.S. Department of Agriculture; the Environmental Protection Agency; the Department of Labor's Occupational Safety and Health Administration; and the Department of Defense's U.S. Army-Natick Research Development and Engineering Center are also working on segments of the initiative.



*Food
Safety*

October 8, 1997

Dear xxx:

Thank you for your letter dated September 24, 1997, expressing concern about the effects of increased trade on food safety. I share your concern about the safety of food for all Americans, and I will not permit any trade policy to impair the health and safety of the American people.

I have committed this Administration to ensuring that the food that Americans eat is the safest in the world. We have put in place improved safety standards for meat, poultry, and seafood products, and have begun the process of developing enhanced safety standards for fruit and vegetable juices. Together, we have enacted legislation in this area, including the Safe Drinking Water Act of 1996 and the Food Quality Protection Act of 1996.

This month, I announced an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. I asked Congress to enact legislation that will require the Food and Drug Administration to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. I also directed the Department of Health and Human Services and the Department of Agriculture to work cooperatively with the agricultural community to develop guidance on agricultural and manufacturing practices for fruits and vegetables within one year. Finally, I committed to providing the necessary funds in my

The Honorable xxxx
Page Two

Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force so it can inspect food safety conditions abroad and at points of entry. The added resources will allow the FDA to make effective use of its new legislative authority. I am attaching a fact sheet on my new proposal, as well as the directive I sent to Secretaries Glickman and Shalala.

This new initiative will help guarantee the safety of food in the United States. It provides the improved inspection capacities and increased regulatory powers we need to prevent contaminated imports from reaching American tables. I am committed to continuing to improve the safety of food that Americans eat, and I look forward to working with you on this vital project. Thank you again for your letter.

Sincerely,

The Honorable xxxxx
House of Representatives
Washington, D.C. 20515

THE WHITE HOUSE

WASHINGTON

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

October 2, 1997

Today President Clinton will announce an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. The President will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables and other food products produced in countries that do not meet U.S. food safety requirements. The President will direct the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation -- comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries -- will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President will also commit to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to make effective use of its new authority.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President will direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, to develop guidance on good agricultural and manufacturing practices within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, the President will also direct the FDA and USDA to develop coordinated outreach and educational activities.

Improvement of Monitoring and Inspection Activities Abroad. In addition to committing substantial resources to expand the FDA's international food inspection force, the President will direct the Secretaries of Health and Human Services and Agriculture to report within 90 days on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce. The President will urge consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

Clinton Administration Accomplishments In Improving Food Safety

The President's announcement builds on a strong record of food safety initiatives, ensuring that Americans eat the safest possible food. The Administration has put into place improved safety standards for meat, poultry and seafood products, and has begun the process of developing enhanced standards for fruit and vegetable juices. The Administration also has expanded research, education and surveillance activities throughout the food safety system.

*October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

October 2, 1997

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Ensure the Safety of Imported
and Domestic Fruits and Vegetables

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

Today, I hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

more

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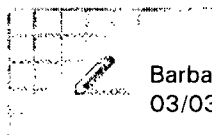
First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

#



Barbara D. Woolley
03/03/98 08:33:17 PM

Record Type: Record

To: Toby Donenfeld/OVP @ OVP, Thomas L. Freedman/OPD/EOP, Mary L. Smith/OPD/EOP, Jerold R. Mande/OSTP/EOP

cc:

Subject: List of Participants - food safety

Food Safety Event
March 4, 1998
Roosevelt Room

List of Participants

Speaker

Gloria Doyle, Speaker
Chevy Chase, MD
Denis Doyle, husband
Kelly O'Rourke
Snowden J. Manson

Consumers/Industry

Carol Tucker Foreman, Safe Food Coalition
Caroline Smith DeWaal, Center for Science in the Public Interest
Kelly Johnston, National Food Processors Association
Dagmar Farr, Food Marketing Institute
Steven C. Anderson, President, American Frozen Food Institute
Gene Grabowski, Grocers Manufacturing Association
Brett Kay, National Consumer League
Nancy Danielson, National Farmers Union
John Aguirre, United Fresh Fruit & Vegetable Association
Terri Robinson
George Berlstein

HHS

Michael Friedman
Diane Thompson
Melinda Plaisier
Rich Tarplin
James O'Hara

① ✓ can last w/o
same standard - CF.

② failure to inspect

is a factor ~~STDA~~
can use. But a
single factor.

Volunteer
Guidance - Oct '98
6 town meetings
conf. ~~2/7~~
75 comment day

tech asst. - far. /
educ. done 5/2

not coming yet

Inspection / testing
↑ review

USDA

Keith Pitts

Maureen Kelly

Catherine Wotecki

Families

Sue and Stephen Doneth

Marshall, Michigan

Lindsay Doneth

Robin and Richard Dimmock

Potomac, MD

Bryan Dimmock

Kyle Dimmock

David Dimmock

Remarks of Vice President Al Gore
Food Safety Event
Wednesday, March 4, 1998

On behalf of the President, I'd like to welcome all of you to the White House as we announce several new steps in our efforts to make sure the food we feed our families is safe and healthy.

Food safety is everyone's issue. All of us live our lives trusting that the food we eat is grown, harvested, packaged, shipped, stored, and prepared in ways that pose no threat to our health. Every bite of food is an act of faith. We want to make sure that faith is justified.

In almost every case, it is. American consumers enjoy the safest food supply in the world. We can be reasonably confident that whether we're giving a baby a bottle, preparing a meal at home, or eating out for the evening, the food we're eating is safe.

And yet, our record is not perfect. Each year in America, unsafe food is responsible for more than 30 million illnesses and up to 9,000 deaths. And small children are most likely to be stricken by food-borne illness -- as their immune systems are still developing and still vulnerable. Our food supply may be the safest in the world, but it's not safe enough.

That's why -- in our first administration -- we launched a new program to prevent and control outbreaks food-borne illness, issued new rules on seafood safety, and modernized the meat and poultry inspection system for the first time since the man on the horse behind me was living in this building. [gesture to Teddy Roosevelt]. We also took action to keep harmful pesticides off our fruits and vegetables and required drinking water systems to protect against dangerous contaminants.

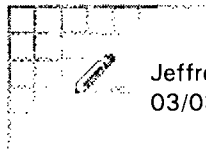
Last year, we launched an aggressive new Food Safety Initiative, as an ongoing effort to improve the safety of the nation's food supply.

As the President announced last October, this Food Safety Initiative includes new efforts to enhance oversight of imported foods, and begin toughening safety standards for fruits and vegetables.

In addition, the President's Food Safety Initiative includes a 1999 budget increase of more than \$100 million for food safety activities -- a jump of more than 13 percent. This will provide additional resources for enhancing the safety of imported and domestic fruits and vegetables, increasing food safety education efforts targeted to high risk populations, and developing new tools to address a broad range of food safety hazards.

There is no activity more clearly the province of progressive government than actively and aggressively ensuring the safety of the nation's food supply. It's a cause this administration has taken on with enthusiasm, and one you can count on us to continue.

It's my pleasure now to introduce a great partner in this effort -- the straight-talking Senator from the safe-seafood state of Maryland -- the Honorable Barbara Mikulski....



Jeffrey A. Shesol
03/03/98 08:18:14 PM

Record Type: Record

To: Michelle Crisci/WHO/EOP, Thomas L. Freedman/OPD/EOP, Elena Kagan/OPD/EOP

cc:

Subject: Food Safety

Draft 03/03/98 8:00PM

**PRESIDENT WILLIAM J. CLINTON
REMARKS ON THE SAFETY OF IMPORTED FOOD ACT
THE ROOSEVELT ROOM
March 4, 1998**

Acknowledgments: VPOTUS; Sen. Barbara Mikulski; Sen. Edward Kennedy; Rep. Anna Eshoo; Rep. Frank Pallone; Rep. Lynn Rivers

Last night I was in New York, celebrating the heroes who have made this the American Century. I spoke about one of my heroes, Franklin Roosevelt. But it's Theodore Roosevelt that I'm thinking of today. At the beginning of this century, he made an unprecedented national commitment to protecting American families from unsafe food. That was at the dawn of the Industrial Age--when Americans were moving from the farm to the city, and for the first time buying their food from others rather than growing it themselves. Theodore Roosevelt ensured Americans that their food was safe--whoever grew it and wherever it was grown.

Now, as we move into the 21st century, the health and well being and productivity of Americans remain our top priorities. But the world is changing, and it takes new methods to protect enduring values. The Vice President has just told you what our administration has done to modernize food safety. America's food supply is the safest in the world, but we have yet to meet all the challenges of the global marketplace.

It wasn't long ago that you could walk through the produce section of your local grocery store, look around, and find no more than a dozen items that would be there all year. Today, thanks to the global food market, it's not uncommon to find up to 400 varieties, and almost all of them year-round. You can get summer squash during the chill of winter, and winter squash in the heat of summer. And the farmer who grows those vegetables no longer lives down the road. That farmer might live across the ocean or on the other side of the world. It is more important than ever that the food we eat be inspected and protected from orchard to fruit basket, from farm to table--wherever that orchard or farm may be. And when

the families that join us here today--and the millions of Americans like them--walk through the produce section, they shouldn't have to worry where that food comes from or whether it's safe.

Food safety is part of the basic contract between American consumers and their government. Any food that doesn't meet our clear and strict standards shouldn't make it into the United States. It's that simple.

Last fall, I announced a new initiative to ensure that fruits and vegetables coming from abroad are every bit as safe as those grown here at home--and to halt at the border or at the dock any food that fails to meet our strict standards. I also directed the Secretary of Health and Human Services and the Secretary of Agriculture to report on our progress in improving food safety at home and abroad. It's a good, thorough report. And it underscores my belief that Congress must now take the next, important step to protect America's families from food-borne illness. I call on Congress to enact the bill introduced by Senator Mikulski in the Senate and Representatives Eshoo and Pallone in the House. This is not a political issue--it is not a Democratic or Republican issue--it is simply an issue whose time has come. By giving the FDA the tools and the technology it needs to do its job, this legislation gives American families the extra protection they deserve.

Theodore Roosevelt recognized nearly a century ago that new challenges demand a new kind of government--in this case, a government that demands responsibility from industry and producers but also provides clearer, stricter standards of safety--and provides the means to enforce them. American families enjoy the greatest bounty and variety of food in the world. We must ensure that when they walk the aisles of their supermarket to buy food for their children, they can continue to do so with confidence and without fear. Acting now will strengthen America today--and throughout the 21st century.

**Q&A for Presidential Announcement on Food Safety Legislation
and Report to Ensure Safety of Imported Fruits and Vegetables
March 4, 1998**

Q: What did the President announce today?

A: The President announced the introduction of food safety legislation in the Senate that will ensure that the FDA denies the entry of imports of fruits, vegetables, or other food from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country. This legislation was introduced in the House in November of last year. The President also announced the release of a report on how the Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture and the agricultural community, will develop guidance on good agricultural and good manufacturing practices for any fruits and vegetables that are sold in the U.S. market.

Q: Why is your Administration proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

We have changed as well. Americans are eating more fresh fruits and vegetables than ever before, and our nation's health experts tell us we will live longer, better quality lives as a result. Our environment is also changing. We are finding "new" exotic bugs such as cyclospora and *E. coli* O157:H7 on our food that once were not there.

We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and my actions accord with their recommendations.

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back to imports, and it is important to ensure that foreign fruits and vegetables meet U.S. food safety requirements or otherwise achieve the level of protection required. The steps we are taking today are adding additional layers of protection. We are making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and

seafood.

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than \$40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, \$101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Questions on Food Safety Legislation

Q: What does the legislation do?

A: This legislation helps ensure that the FDA will refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country.

Q: How is this different from current authority?

A: This legislation increases the FDA's authority to refuse imports for foods from countries or facilities that do not meet U.S. food safety requirements or otherwise achieve the level of protection required. Currently, the FDA can only refuse imports after inspection or testing at the border when the FDA determines that the food appears to be unsafe or otherwise violates U.S. law. This new legislation will enable the FDA to ensure that food products entering this country were grown and processed in conditions that meet U.S. food safety requirements or otherwise achieve the level of protection required. This authority is necessary because experience has shown that inspection and testing of products at the border may not be sufficient in all cases to ensure the safety of food products. It may be necessary to identify and address the source of potential contamination to ensure that products offered for sale in the United States meet domestic food safety requirements or otherwise achieve the level of protection required. FDA currently has such authority with respect to domestic production.

Q: Does this legislation give FDA additional authority to inspect in other countries?

A: No. Foreign inspections will continue to be done by consent. In making the determination that a food offered for import into the U.S. is adulterated, the legislation does permit the Secretary to consider whether FDA has been refused access to conduct inspection of the places where such food has been prepared, packed or held. The Secretary may deny importation to foods from such location or establishment on the basis of such refusal and other relevant factors. Because denying reasonable access is one factor in making that determination, the exporting country and the food establishment both have a strong incentive to allow such access.

Q: There is concern that this legislation is the first step in providing FDA with the authority to inspect farms in the U.S. Is that next?

A: Under current law, FDA already has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation occurs. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

Q: Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?

A: This legislation is consistent with free trade and all our treaty obligations. We have no obligation to open our borders to imports that pose a greater risk than domestic products to American consumers. As long as we are not imposing any greater requirements on foreign countries -- as long as we are only holding them to our standards -- we are acting consistently with our trade policy and international obligations.

Q: What makes you think this new legislation can be effective? Do you seriously think you are going to be able to put FDA inspectors in every country abroad?

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

Questions Related to Report on Guidance

Q: Why has this report been prepared?

- A:** On October 2, 1997, President Clinton announced an initiative to ensure the safety of imported and domestic fruits and vegetables which included the development of good agricultural practices and good manufacturing practices for fresh fruits and vegetables that would include ways to prevent potential contamination. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The guidance effort will include outreach and education, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President requested this status report about progress made toward providing industry with good agricultural and good manufacturing practices guidance for fresh fruits and vegetables. It also presents a plan for outreach to the domestic and foreign industry.

- Q: When you say good agricultural practices (GAPs) and good manufacturing practices (GMPs), are you talking about mandatory GAPs and GMPs?**

- A:** No, the GAP/GMP guidance is voluntary. We are developing this science-based guidance with input from USDA, states, the agricultural community, industry, academia, consumers, and organizations representing the foreign produce industry. The guidance is intended for appropriate use by growers, packers, manufacturers of minimally processed products and produce distributors. Because the guidance is broad-based, it may be used, where applicable, by both the domestic and foreign produce industry to reduce the risk of microbial contamination.

- Q: Does the report give a timeline for publishing the guidance?**

- A:** Yes, we anticipate publishing the draft guidance in late March with a 75-day comment period. We anticipate that the guidance will be available in final form in October 1998.

This may come up because the deadline for the importation of Guatemalan raspberries is March 15.

- Q: What is the status of the Guatemalan raspberries?**

- A:** On November 20, 1997, FDA notified the Guatemalans that fresh raspberries will not be allowed entry into the U.S. during the period of March 15 through August 15, 1998. However, if the source of *Cyclospora* contamination is found and corrected or if intervention technologies are developed that will prevent cyclosporiasis in humans, we will revisit this decision. FDA has assisted Guatemala in seeking a resolution to this problem since 1996. In fact, we currently have people in Guatemala reviewing the interventions they have reportedly put in place.

**Q&A for Presidential Announcement on Food Safety Legislation
and Report to Ensure Safety of Imported Fruits and Vegetables
March 4, 1998**

Q: What did the President announce today?

A: The President announced the introduction of food safety legislation in the Senate that will ensure that the FDA denies the entry of imports of fruits, vegetables, or other food from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country. This legislation was introduced in the House in November of last year. The President also announced the release of a report on how the Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture and the agricultural community, will develop guidance on good agricultural and good manufacturing practices for any fruits and vegetables that are sold in the U.S. market.

Q: Why is your Administration proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

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We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and my actions accord with their recommendations.

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Q: What makes you think this new legislation can be effective? Do you seriously think you are going to be able to put FDA inspectors in every country abroad?

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

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Elisa Millsap

03/04/98 11:14:01 AM

.....

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: Revised--Members Attending Food Safety Announcement 

EVENT: Food Safety Announcement

DATE: Wednesday, March 4, 1998

TIME: 1:30pm-2:15pm

LOCATION: The Roosevelt Room

MEMBERS CONFIRMED TO ATTEND (7):

Sen. Barbara Mikulski (D-MD)

Sen. Edward Kennedy (D-MA)

Rep. Anna Eshoo (D-CA)

Rep. Frank Pallone (D-NJ)

Rep. Joe Kennedy (D-MA)

Rep. Juanita Millender-McDonald (D-CA)

Rep. Julia Carson (D-IN)

Message Sent To: _____

CSPI

Center for
Science in the
Public
Interest

Date: 4/26/99

Publisher of **Nutrition Action Healthletter**

Time: 5:33pm

FAX COVER SHEET

TO: Tom Freedman
Fx 456-7431

Company: _____

Fax Number: _____ Phone Number: _____

Total Number of pages INCLUDING this cover sheet: 6

SENDER: Zoe Enga for Caroline Smith DeWaal
(x 366)

SENDER'S Phone Number: _____

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SUBJECT: HR 3676

COMMENTS:

Caroline will get you a section by section summary of the Pallone bill tomorrow.

105TH CONGRESS
2D SESSION

H. R. 3676

To establish a comprehensive program to ensure the safety of food products intended for human consumption which are regulated by the Food and Drug Administration.

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1998

Mr. PALLONE (for himself, Mr. BONIOR, Mr. GREEN, Ms. DELAURO, Mr. WYNN, Mr. FROST, Mr. LEWIS of Georgia, Ms. FURSE, Mr. KENNEDY of Rhode Island, Mr. ROTHMAN, Ms. MCCARTHY of Missouri, Mr. PASCRELL, Mr. MARTINEZ, Ms. JACKSON-LEE, Ms. CARSON, Mr. SERRANO, Mr. RUSH, Mr. ENGEL, Mr. ANDREWS, Mr. SAWYER, Ms. KAPTUR, Mr. CUMMINGS, Mr. WAXMAN, Mrs. LOWEY, Mr. MCGOVERN, Mr. MANTON, Ms. ESHOO, Mr. SANDERS, Mr. MARKEY, and Mr. MENENDEZ) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To establish a comprehensive program to ensure the safety of food products intended for human consumption which are regulated by the Food and Drug Administration.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Consumer Food Safety Act of 1998”.

6 (b) **TABLE OF CONTENTS.**—

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.

TITLE I—NATIONAL FOOD SAFETY PROGRAM

- Sec. 101. Administration of national program.
- Sec. 102. Registration of processors and importers.
- Sec. 103. Process controls to reduce the adulteration of food products.
- Sec. 104. Inspections of processors and importers.
- Sec. 105. Tolerances for contaminants in food.
- Sec. 106. State and Federal cooperation.
- Sec. 107. Imports.

TITLE II—RESEARCH AND EDUCATION

- Sec. 201. Public health assessment system.
- Sec. 202. Public education and advisory system.
- Sec. 203. Research.

TITLE III—ENFORCEMENT

- Sec. 301. Amendments to the Federal Food, Drug, and Cosmetic Act.

TITLE IV—AUTHORIZATION

- Sec. 401. Authorization of appropriations.

1 SEC. 2. DEFINITIONS.

2 For purposes of this Act:

3 (1) The term "contaminants" includes bacteria,
4 chemical contaminants, natural toxins, viruses, para-
5 sites, and physical hazards that when found on or in
6 food can cause human illness or injury.

7 (2) The term "facility" includes any factory,
8 warehouse, establishment, or importer that handles
9 or processes food.

10 (3) The term "process" means the commercial
11 harvesting, preparation, manufacture, or transpor-
12 tation of food products.

13 (4) The term "Secretary" means the Secretary
14 of Health and Human Services.

TITLE I—NATIONAL FOOD SAFETY PROGRAM

SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM.

(a) IN GENERAL.—

(1) Persons who produce or process food for human consumption have the responsibility to prevent or minimize food safety hazards related to their products. The Secretary shall administer a national program for the purpose of protecting human health by ensuring that the food industry has effective programs in place to assure the safety of food products consumed in the United States.

(2) The program shall—

(A) be based on a comprehensive analysis of the hazards associated with different food products and with the harvesting, processing, and handling of different food products, including the identification and evaluation of—

(i) the severity of the potential health risks;

(ii) the sources and specific points of potential contamination that may render food products unsafe for human consumption; and

1 (iii) the potential for persistence, mul-
2 tiplication, or concentration of naturally
3 occurring or added contaminants in foods
4 and food products;

5 (B) take into consideration the distinctive
6 characteristics of food production and process-
7 ing;

8 (C) establish inspection and oversight pro-
9 cedures to monitor that facilities are utilizing
10 preventive controls to minimize or eliminate
11 identifiable hazards; and

12 (D) require each food processing facility to
13 annually register with the Secretary.

14 (b) PROGRAM ELEMENTS.—The program shall pro-
15 vide for—

16 (1) implementation of a national system for the
17 registration and quarterly inspection of facilities and
18 importers. Quarterly inspections can be waived by
19 plants that meet the Secretary's standards for ex-
20 ceptional or negligible-risk facilities or importers;

21 (2) development of a program to oversee the
22 implementation of process controls in food process-
23 ing facilities;

24 (3) the establishment and enforcement of
25 health-based standards for (A) substances which

1 may contaminate food and (B) safety and sanitation
2 in the processing and handling of food products;

3 (4) implementation of a sampling program to
4 ensure that industry programs to prevent food con-
5 tamination are effective and that food products meet
6 the standards established in paragraph (1);

7 (5) implementation of procedures and require-
8 ments to ensure the safety of imported food prod-
9 ucts;

10 (6) coordination with other Federal agencies or
11 State governments in carrying out inspection, en-
12 forcement, and monitoring;

13 (7) implementation of a national surveillance
14 system to assess the health risks associated with the
15 human consumption of food products, in cooperation
16 with the Secretary of Agriculture and the Centers
17 for Disease Control and Prevention;

18 (8) development of public education and advi-
19 sory programs; and

20 (9) implementation of a research program in
21 furtherance of the purposes of this Act.

22 **SEC. 102. REGISTRATION OF PROCESSORS AND IMPORT-**
23 **ERS.**

24 (a) **IN GENERAL.**—Any facility engaged in processing
25 of food products and any person who imports food prod-

CSPI

Centre for Science in the Public Interest
Centre pour la science dans l'intérêt public

Publisher of
Éditeur de

Nutrition Action Healthletter

Date:

8/10/15

Time:

1pm

FAX COVER SHEET

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456-5587

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SENDER:

Diana Birkett

SENDER'S Phone Number:

(202) 332-9110 x364

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SUBJECT:

petitions

COMMENTS:



Center for
Science in the
Public
Interest

Publisher of **Nutrition Action Healthletter**

The Honorable Trent Lott
United States Senate
Washington, DC 20515

October 14, 1999

Dear Senator Lott:

Just last month, the Centers for Disease Control released new data showing that the incidence of foodborne illness has increased. Americans are told that we have the safest food supply in the world, yet 76 million people become ill and 5000 die each year because of contaminated foods. Consumers are concerned, and with good reason. Our members have asked for our help to get a message to you. Enclosed please find 18 petitions from citizens of Mississippi and five petitions from members of the Armed Forces, asking that you:

- **Support funding for the National Food Safety Initiative.**
- **Sponsor S.18, the Safer Meat and Poultry Act of 1999.**
- **Sponsor S. 908 and H.R. 1612, the Consumer Food Safety Act of 1999.**
- **Sponsor S. 1281 and H.R. 2345, the Safe Food Act of 1999.**

By the time you get these petitions, funding for the National Food Safety Initiative should already be approved. Thanks for your support of this important initiative, which is helping to rebuild the infrastructure of our food safety agencies.

Rebuilding these programs is only part of the solution, however. We also need to modernize them. Our members support legislation, including S. 18, S. 908 and H.R. 1612, that will modernize FDA and USDA by giving them risk-based inspection mandates and enforcement authorities. In addition, CSPI supports the creation of a single food safety authority in Washington, to bring the food-safety functions currently performed by numerous federal agencies under one roof. Proposals to accomplish this restructuring are contained in S. 1281 and H.R. 2345.

Your constituents want food safety programs in Washington that better protect them from food poisoning. With 76 million illnesses a year, the odds of getting sick from contaminated food are just too high! Please sponsor these important food safety bills.

Sincerely,

Caroline Smith DeWaal

Caroline Smith DeWaal

Director, Food Safety

Center for Science in the Public Interest

*P.S. We have
mailed 15,750 petitions
to your colleagues in the
Senate.*

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

CSPI

Center for
Science in the
Public
Interest

Publisher of

Nutrition Action Healthletter

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October 14, 1999

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*P.S. Thanks for
your leadership on
food safety issues.
We have mailed a total
of 15,778 petitions
to members of
the Senate.*

Sincerely,

Caroline Smith DeWaal

Caroline Smith DeWaal

Director, Food Safety

Center for Science in the Public Interest

Tel: (202) 332-9110

Fax: (202) 265-4954

Home Page: www.csipinet.org

E-mail: cspi@csipinet.org

Suite 300

1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

Food Safety Citizen Petition to Congress

Dear Senator Cochran, Senator Lott and Representative Wicker,

As a member of the Center for Science in the Public Interest, I urge you to sponsor legislation endorsed by the Recipe for Safe Food Campaign, a consumer-oriented legislative platform designed to clean up America's food supply.

Specifically, I call on you to:

1. Support funding for the National Food Safety Initiative to improve existing food-safety programs.
2. Cosponsor the Safer Meat and Poultry Act (S. 18) with Senator Tom Harkin to give USDA the power to order mandatory recalls of contaminated meat and poultry and to fine violators.
3. Cosponsor the Consumer Food Safety Act with Representative Frank Pallone to give the FDA new powers to keep contaminated foods off the market.
4. Cosponsor the Safe Food Act with Senator Richard Durbin and Representative DeLauro to combine all government food-related functions into a single, more efficient agency, the U.S. Food Safety Administration.

Please act now to stop the thousands of unnecessary deaths and illnesses that have resulted from contaminated food and to ensure that American consumers have the safest possible food supply.

Signature

Mr. John Welock
2800 W. Main Street #27B
Tupelo, MS 38801-3027

Food Safety Citizen Petition to Congress

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3. Cosponsor the Consumer Food Safety Act with Representative Frank Pallone to give the FDA new powers to keep contaminated foods off the market.
4. Cosponsor the Safe Food Act with Senator Richard Durbin and Representative DeLauro to combine all government food-related functions into a single, more efficient agency, the U.S. Food Safety Administration.

Please act now to stop the thousands of unnecessary deaths and illnesses that have resulted from contaminated food and to ensure that American consumers have the safest possible food supply.

Signature

Ms. Barbara Brinkman
P.O. Box 905
Columbia, MS 39429-0905

Food Safety Citizen Petition to Congress

Dear Senator Cochran, Senator Lott and Representative Shows,

As a member of the Center for Science in the Public Interest, I urge you to sponsor legislation endorsed by the Recipe for Safe Food Campaign, a consumer-oriented legislative platform designed to clean up America's food supply.

Specifically, I call on you to:

1. Support funding for the National Food Safety Initiative to improve existing food-safety programs.
2. Cosponsor the Safer Meat and Poultry Act (S. 18) with Senator Tom Harkin to give USDA the power to order mandatory recalls of contaminated meat and poultry and to fine violators.
3. Cosponsor the Consumer Food Safety Act with Representative Frank Pallone to give the FDA new powers to keep contaminated foods off the market.
4. Cosponsor the Safe Food Act with Senator Richard Durbin and Representative DeLauro to combine all government food-related functions into a single, more efficient agency, the U.S. Food Safety Administration.

Please act now to stop the thousands of unnecessary deaths and illnesses that have resulted from contaminated food and to ensure that American consumers have the safest possible food supply.

Signature

Mrs. Anna L. Buckley
1007 Winn Street
Jackson, MS 39204-5242

MORLEY WINOGRAD

Tom Goodman 1/9.

Please give me
your reaction.

Morley

cc: P. Henstein.

~~CONFIDENTIAL~~

Tom

Rm 213

Assembly
Food S.

DRAFT FOR DISCUSSION PURPOSES ONLY
The Context for Possible Changes in Federal Food Safety Structure

The consideration of structural changes in the current federal food safety organizational responsibilities and departmental locations requires evaluation of a number of issues in various contexts. The attached outline of one possible structural shift is premised on the following analysis.

(1) HHS and FDA will continue to be unable to obtain from Congress the resources necessary to strengthen its food safety program. There are a number of reasons for this failure, including organizational weaknesses. First, while food is the first word in FDA, its importance is overwhelmed by other products under FDA's jurisdiction, including pharmaceuticals, veterinary medicines, medical devices, functional foods, and biotechnology. Second, unlike USDA, FDA has no food inspection force that is dedicated to food safety; rather, its inspectors oversee all of the products regulated by FDA. FDA also unfortunately frequently fails to develop persuasive budget justifications for funding increases. While certain parts of its regulated industry are pleased by the fact that it cannot inspect ordinary manufacturing plants more than an average of every 4-8 years, other parts of industry are concerned at its inability to work cooperatively with industry when it embarks on new initiatives.

(2) As HACCP implementation in meat and poultry continues to be successful, there will be increased pressure to reduce USDA's inspection resources from budget sources and from those elements in industry who seek to weaken federal oversight over food safety. These efforts are already underway by a number of entities.

(3) Without a strategic plan that the Administration and the Congress support over the long term, the efforts to cut USDA's food safety resources are likely to succeed while FDA's resources for food safety will not increase. This would result in substantially weakened Federal food safety presence.

(4) The President's Council on Food Safety is unlikely to be able to develop such a strategic plan under the current organization structure. The principal food safety agencies, FDA and FSIS, currently have great difficulty developing simple documents such as a joint budget summary. It may be impossible for the agencies to develop such a complex and sensitive undertaking such as a strategic plan. For example, as long as FDA believes it may be able to obtain funding for its food safety program, FDA has little interest in developing ways to leverage USDA's resources, since doing so would undercut its efforts to gain increased funding or act as a conduit for Federal funds to states. USDA is concerned that the redeployment of its resources must be carefully managed to maintain the base of industry, producer, and consumer group support, and that outside interests may seek to change the pace of USDA's redeployment of its inspectors.

(5) In short, while some may say that structural changes should not be proposed before a strategic plan is developed, it very well may be that structural changes need to be made in order to develop a strategic plan that maintains a strong Federal food safety presence.

(6) Good regulatory programs need a strong scientific base. USDA's research agencies (ARS, CSREES, and ERS) sponsor approximately \$60 million annually in food safety research. These agencies also can rapidly disseminate research results to the private sector through the Cooperative Extension Service in all 50 states.

(7) USDA's reorganization in 1994 laid to rest the criticism from consumer groups that it had a conflict of interest in managing food safety and agriculture promotion programs. The creation of the Office of the Under Secretary for Food Safety and the legislated requirement that the incumbent be experienced in public health and food safety effectively separate the regulatory and marketing functions.

(8) Neither a Democratic nor a Republican Congress will accept moving FSIS from USDA. The agricultural community and food industry would strenuously oppose such a move. It is extremely unlikely any such shift would occur unless there were a terrible food safety catastrophe for which USDA was responsible. Given general industry support for USDA, a Republican Congress may be willing to move FDA functions to USDA.

(9) A Democratic Administration with a strong food safety record would have the credibility to move certain FDA food safety functions to USDA. A Republican Administration would likely be criticized for such a proposal.

(10) Agricultural producer community would likely support such a move.

(11) Consumer community would likely not oppose and may even support such a move. USDA has developed a strong record with consumer groups, many of whom have also been frustrated with recent FDA efforts and also fear that efforts to cut USDA's food safety budget will be successful without a strong strategic plan in place for redeployment.

(12) Parts of the food industry may be supportive, but trade organizations may split as member companies may prefer dealing with a known agency i.e. if an industry sector or company deals predominantly with FDA, it may not want to deal with a new agency. However, company's and trade organizations have expressed interest in replicating USDA's strong federal-state structure in which states that enforce meat and poultry laws may not stray into contrary forms of regulation, so inclusion of preemption in this transfer may generate industry support. In addition, industry would like FDA to have additional resources and staff to address functional foods i.e. foods with new nutritional claims, food additives, and biotechnology. Certainly, some industry groups prefer playing the agencies against one another, while others believe USDA is too consumer or producer focused.

(13) Legislation would be required to accomplish such a transfer, and some additional funds and personnel may be necessary to effectively execute the transfer. However, the proposal contained in the outline would be simple to draft and would not likely require a large amount of additional resources.

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Outline of Possible Changes in Federal Food Safety Structure

Note: Movement of functions from one agency to another would not require opening and negotiating the terms of the underlying statutes. The Secretary that is authorized to implement portions of these acts would be changed, including the delegations for implementation, and USDA's food safety mission area and agency would be modified to ensure protection of public health.

(1) The following functions would be moved from FDA's Center for Food Safety and Applied Nutrition (CSFAN) to USDA: Food inspection, enforcement, and standard-setting/regulation for microbial, viral, and parasitic pathogens, including seafood, eggs, milk, fruits and vegetables. In addition, FDA/state boards on milk and seafood would be moved to USDA, as well as the food code, which is a model food safety code developed by FDA, other Federal agencies, and the states.

The following functions would remain at CFSAN — food additives, dietary supplements, biotechnology, chemical/pesticide/drug residues/standards. In addition, it is possible that food labeling under the Nutrition Labeling Act would remain at CFSAN, including meat and poultry products which are currently under USDA's jurisdiction.

(2) FDA would be provided with funding and staffing increases to address functional foods (i.e. new food products making special nutritional claims), food additives, dietary supplements, and biotechnology. Industry believes FDA lacks resources for these items.

(3) Personnel Resources-- a relatively small number of FDA field personnel with special expertise such as imports would be moved from FDA to USDA. All other inspection personnel would remain for FDA inspections of drugs, medical devices etc. USDA would also need a number of senior level managers and regulatory personnel from CSFAN or FDA to be transferred to USDA in order to ensure a successful transition.

(4) USDA/FSIS would be provided with base increase of XX million to ensure a successful transition of these new responsibilities. Pending full redeployment of USDA's inspection resources, USDA would need increased funding in order to maintain at least the level of inspection currently provided by FDA. As redeployment proceeds over the long term, the need for these additional funds may decrease.

(5) To emphasize the commitment to food safety, the name of USDA would be changed to the U.S. Department of Food and Agriculture, with the current Under Secretary for Food Safety becoming the Under Secretary for Public Health and Food Safety. Given the increased responsibilities, an additional Deputy Under Secretary would be desirable (there is currently one Deputy). All subcabinet positions would require commensurate public health backgrounds.

(6) The underlying statutes governing FDA and USDA (FFDCA, FMIA etc) would remain intact, although one could include a directive that the Administration should develop a proposal to unify

the statutes. This would (1) simplify the legislation, (2) provide general consistency for regulated industries, and (3) avoid possible legislative attempts to weaken any of the relevant statutes. One possible exception should be considered. Under current law, states that implement meat and poultry laws may not stray into contrary forms of regulation, so inclusion of preemption in this transfer may generate industry support. This may be opposed by the states and it is unclear where the consumer community would be on this issue.

(7) While it may perhaps be unnecessary to address consumer concerns, one should consider whether to include additional measures to ensure the independence of food safety from USDA's role of promoting agricultural commodities. Examples include the creation of a statutory advisory board or statutory reaffirmations of this independence.

(8) While this would not likely be included in legislation since it is a Congressional matter, the Administration would support having the Public Health and Agriculture Committees share full jurisdiction over food safety.

(9) Given the increased responsibilities for USDA, there would also likely be a need for increased resources for USDA's Office of General Counsel (perhaps by transfer from FDA) and for USDA's Office of Risk Assessment and Cost Benefit Analysis.