

## IMPORTED FOOD SAFETY ACT OF 1998 SUMMARY

Food Safety  
1998

The Imported Food Safety Act of 1998 complements, and is not a substitute for, the President's food safety initiative. It has a separate source of funding and does not take funds away from the President's food safety initiative.

The legislation responds to the General Accounting Office's recommendations in its recent report that the Food and Drug Administration (FDA) be given stronger enforcement authority over imported food, that FDA needs new detection methods for E coli, salmonella and other pesticide and pathogenic contaminants, and that FDA increase the number of inspections it conducts at the border.

Specifically, the legislation:

- Gives FDA new authority over imported food, including fresh fruits and vegetables, that is comparable to the authority the U.S. Department of Agriculture already has for imported meat and poultry.
  - A. Prohibits imported food from being distributed without prior FDA approval.
  - B. Makes failure to obtain prior approval from FDA and failure to properly dispose of food denied entry subject to criminal penalties.
  - C. Allows FDA to prohibit importation of food if FDA has been refused the right to perform an inspection in a foreign country or if the foreign country does not provide the same level of food safety protection as the U.S.
- Requires FDA to increase the number of inspections of imported food that it conducts at the border. Gives FDA authority to mark any shipment of imported food that is refused entry, so that the product denied entry cannot be re-entered through another port.
- Establishes a "Manhattan Project" for development, over the next 3 years, of "real time" tests that yield results within 60 minutes to detect E coli, salmonella, and other microbial and pesticide contaminants in food.
- Creates a user fee of not more than \$20 per "line item" of imported food. In 1997, there were approximately 2.8 million imported food line items. This would generate \$56 million per year. This money would be used to fund increased border inspections and research and development of "real time" tests for detection of microbial and pesticide contamination.
- Mandates country-of-origin labeling of imported food subject to FDA regulation, at the point such food is offered for retail sale. Restaurants and other prepared-food service establishments are exempted from complying with the country-of-origin requirement.

**STATEMENT OF  
THE HON. JOHN D. DINGELL  
THE IMPORTED FOOD SAFETY ACT OF 1998  
JUNE 17, 1998**

Food is life. But for 9,100 Americans each year, food is death.

The General Accounting Office (GAO) has estimated that as many as 81 million cases of food borne illness occur each year. But only when consumers get sick or die, does the Food and Drug Administration (FDA) try to determine whether the food supply may have contained pathogenic contaminants. The outrageous and wholly intolerable conclusion one must draw is that American consumers are being used as guinea pigs.

Imports now account for 38% of all the fruit and 12% of all the vegetables Americans consume each year. The volume of food imported into the U.S. has almost doubled over the last 5 years, yet the frequency of FDA inspections has declined sharply during the same period of time. FDA acknowledges that it is "in danger of being overwhelmed by the volume of products reaching U.S. ports."

Even if FDA could perform more inspections, FDA does not have the tests it needs to detect E coli, salmonella and other pathogens in imported fruits and vegetables. In addition, all of the microbiological samples that FDA collected and tested in fiscal year 1997 were in response to food borne illness. None were for preventive detection.

GAO has studied this situation and has concluded that the Federal Government cannot ensure that imported foods are safe. In response to this crisis, the President has said FDA needs increased resources, more authority, and improved research and technology.

The Imported Food Safety Act of 1998 addresses each of these points. The legislation provides additional resources in the form of a modest user fee on imported foods, and a "Manhattan Project" to develop "real time" tests that yield results within 60 minutes to detect E coli, salmonella, and other microbial and pesticide contaminants in food. Finally, the legislation gives FDA authority, comparable to that of the U.S. Department of Agriculture with respect to imported poultry and meat, to stop unsafe food at the border and to assure that its ultimate disposition is not America's dinner table.

American consumers deserve better and, as soon as they learn how bad the situation really is, I am confident they will demand better.

I would also note that the current Majority in Congress is clearly not prepared to appropriate funds needed to protect Americans from unsafe food. Funds for the President's food safety initiative were recently zeroed out by a Senate Appropriations Subcommittee, and in the House, only a token amount was appropriated for the food safety initiative. A user fee on imported food, like the user fee in the Imported Food Safety Act, would ensure that FDA has much needed resources to protect American consumers from unsafe imported food.

# IMPORTED FOOD SAFETY ACT OF 1998

## FACT SHEET

- The General Accounting Office's (GAO) April 1998 report on food safety confirms that the Federal government cannot ensure that imported foods are safe.
- According to GAO, the volume of imported food has doubled over the last five years while the number of Food and Drug Administration (FDA) inspections has decreased during this same period of time.
- Thirty eight percent of the fruits and twelve percent of the vegetables consumed annually by Americans are imported. FDA inspects less than two percent of all imported food shipments. Less than two tenths of one percent of imported fruits and vegetables are tested for microbial contamination. FDA's current tests for the presence of microbes in food can take up to two weeks to produce results. Some microbes have developed mutations that allow them to evade detection.
- According to GAO, "up to 81 million cases of foodborne illnesses and as many as 9,100 deaths from these illnesses occur each year." The U.S. Department of Agriculture's Economic Research Service estimates "the costs for medical treatment and productivity losses associated with these illnesses and deaths range from \$6.6 billion to \$37.1 billion."
- Foodborne illness is a hazard to all Americans, but more so for our most vulnerable populations. Examples include people living with HIV/AIDS, persons receiving chemotherapy, young children, pregnant women, and the elderly.
- The GAO reported that FDA's procedures for ensuring that unsafe imported foods do not reach consumers are vulnerable to abuse by unscrupulous importers. In some cases, when FDA decides to inspect shipments, the importers have already marketed the goods.
- According to GAO, some importers ignore FDA's orders to return, destroy or re-export their shipments.
- In fiscal year 1997, **ALL** of the microbiological samples FDA collected and tested were in response to food borne illness outbreaks. **NONE** was for preventive detection.
- In a recent letter, FDA said "FDA has **NO** assignments for monitoring imported fresh fruits and vegetable for presence of pathogenic microorganisms." [emphasis added]
- According to the same letter, FDA stated that there is a "critical need for rapid, accurate methods to detect, identify and quantify pathogens.... the methods for detecting a wide range of bacterial, viral and parasitic pathogens in or on fresh fruits and vegetables are limited..."

**H.R. \_\_\_\_\_, "Imported Food Safety Act of 1998"**

Sponsor: The Honorable John D. Dingell

Original Cosponsors:

Rep. Sherrod Brown  
Rep. Bart Stupak  
Rep. Frank Pallone, Jr.  
Rep. Henry A. Waxman  
Rep. Edward J. Markey  
Rep. Rick Boucher  
Rep. Thomas J. Manton  
Rep. Bart Gordon  
Rep. Elizabeth Furse  
Rep. Bobby L. Rush  
Rep. Ron Klink  
Rep. Albert R. Wynn  
Rep. Gene Green  
Rep. Karen McCarthy  
Rep. Diana DeGette

**CSPI**Center for  
Science in the  
Public  
Interest

Publisher of

**Nutrition Action Healthletter**Date: 11/19Time: 2:10 pm**FAX COVER SHEET**TO: Tom Freedman  
456-7431Food  
Safety

11/19/98

Company: \_\_\_\_\_

Fax Number: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Total Number of pages INCLUDING this cover sheet: 9SENDER: Zoe Enga for Caroline Smith DeWaalSENDER'S Phone Number: X364

This message is intended only for the use of the individual or entity to which it is addressed. It may contain information that is privileged or confidential. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this message is prohibited. If you have received this message in error, please notify us immediately by telephone.

SUBJECT: PR + Speech

COMMENTS:



Center for  
Science in the  
Public  
Interest

Publisher of ***Nutrition Action Healthletter***

**Remarks of Caroline Smith DeWaal  
Director of Food Safety  
at the National Press Club**

**Washington, D.C.  
November 19, 1998**

Exactly one year ago today, I was invited to the National Press Club to talk about holiday food safety. I am delighted to be invited back again today. Clearly, there is no better time to talk turkey about food safety than right before the holidays.

Holidays are a fun time, a family time, with a family feast frequently being the major event. However, if our holiday chefs forget the basics of safe food handling, your family feast could become a family disaster. While no one invites *Salmonella* or *Campylobacter* home for the holidays, consumers must expect these unwelcome guests every time they bring home a turkey. If precautions aren't taken, families could find themselves sharing the misery of food poisoning instead of gathering around the fireplace or the piano. Food poisoning can have particularly severe consequences for the youngest and the oldest members of the family.

Before we talk about the "hows" of preparing safe feasts, let's talk about the "whys." The big name in bad actors this year is "*Campylobacter*," a bacterium primarily associated with poultry products. There is a lot of bad news about *Campylobacter* this year:

- First, *Campylobacter* is present on the vast majority of poultry products. The most complete government survey ever done of turkeys, published by the US Department of Agriculture in August, found that 90 percent of the turkeys tested in 1996 and 1997 were contaminated with *Campylobacter*. It is present in a high proportion of chickens as well.<sup>1</sup> While these data were collected before the new system for minimizing hazards in meat and poultry started in the largest plants, there is little evidence that *Campylobacter* contamination has been reduced. The best data available on that point are from tests conducted by Consumers Union on 1,200 chickens and reported in the October 1998 issue of *Consumer Reports* magazine. The percent of chickens contaminated with *Campylobacter* actually seemed to increase between October 1997 and May/June 1998 even while the

---

<sup>1</sup> U.S. Department of Agriculture, *Nationwide Young Turkey Microbiological Baseline Data Collection Program, August 1996-July 1997*, (Washington, DC: U.S. Department of Agriculture, August 1998); U.S. Department of Agriculture, *Nationwide Broiler Chicken Microbiological Baseline Data Collection Program, July 1994 - June 1995*, (Washington, DC: U.S. Department of Agriculture, April 1996).



prevalence of *Salmonella* was declining.<sup>2</sup> While it is premature to draw any firm conclusions from those data, it is clear that consumers must still take precautions.

- Second, *Campylobacter* is the number one cause of bacterial foodborne illness. It surprised everyone when FoodNet, the Center for Disease Control and Prevention's new surveillance system for foodborne pathogens, identified this bacterium as the most commonly diagnosed cause of diarrheal illness.<sup>3</sup>
- Third, *Campylobacter* can lead to temporary paralysis, similar to polio. *Campylobacter* infections have been linked to a serious neurological disease called Guillain-Barré syndrome. Symptoms include numbness, pain, progressive weakness, and ultimately paralysis.<sup>4</sup>

*Campylobacter* is not the only problem with turkey. The same government survey of turkeys I mentioned earlier also examined how many types of harmful bacteria were carried on turkeys. Over 97% of turkeys in this nationwide survey were contaminated with at least one type of harmful bacteria, and three out of four turkeys carried two or more types of harmful bacteria.<sup>5</sup> Clearly, this is no time to lower the safeguards in the kitchen. While it is imperative that the industry and the government work to ensure safer turkeys, consumers remain the last line of defense against food poisoning. Let me give you some practical tips.

To ensure that dangerous bacteria don't contaminate other foods, keep your turkey double-wrapped in your refrigerator or freezer. Make certain that when you are handling the turkey, your counters are clear. Everything that touches the raw or partially cooked turkey needs to be scrubbed thoroughly with warm, soapy water. This includes your hands, thermometers and any other implements that touch the turkey.

Proper defrosting is critical to ensure thorough cooking. Move your twenty-pound turkey from the freezer to the refrigerator on Sunday. Earlier for a bigger one; later for a smaller one.

Thermometers help take the guesswork out of food safety. In addition, thermometers are getting faster and easier to read. Here are some examples of instant-read dial thermometers or

---

<sup>2</sup> "A Fresh Look at Chicken Safety," *Consumer Reports*, October 1998, pp. 26-27.

<sup>3</sup> Centers for Disease Control and Prevention, "FoodNet: 1997 Surveillance Results," April, 1998, pp. 3-4.

<sup>4</sup> Jean C. Buzby, Tanya Roberts, and Ban Mishu Allos, *Estimated Annual Costs of Campylobacter-Associated Guillain-Barré Syndrome*, (Washington, DC: U.S. Department of Agriculture, Economic Research Service, July 1997), pp. iii, 1.

<sup>5</sup> U.S. Department of Agriculture, *Nationwide Young Turkey Microbiological Baseline Data Collection Program, August 1996-July 1997*, (Washington, DC: U.S. Department of Agriculture, August 1998), p. 8.

instant-read digital thermometers. These are highly reliable and easy-to-use. Oven-safe thermometers are also convenient because they can stay in the oven while the turkey cooks. One new type of thermometer that deserves mention is the T-stick disposable thermometer. They are good for checking hamburgers, though they won't help much with your Thanksgiving turkey.<sup>6</sup>

Don't forget to calibrate before you celebrate. Before you put that thermometer in the turkey, take a minute to calibrate it in a cup of crushed ice topped off with tap water. Put the tip in the ice water at least two inches deep but without touching either the side or the bottom of the cup. Then, check that it reads 32°F after 30 seconds.<sup>7</sup>

The best place to check the turkey is on the thickest part of the thigh, not touching the bone. Checking it in several places is safest. When the thermometer reads 180°F, your turkey is done.<sup>8</sup> We recommend you use a thermometer even if your turkey has a pop-up timer, because the pop-up variety may not always be accurate.

Be sure that your stuffing reaches 165°F.<sup>9</sup> Warm, moist stuffing on the inside of a turkey is a great place for bacteria to grow. If you don't have a thermometer, be sure to thoroughly heat your stuffing on the stove after removing it from the turkey, or better yet, cook it on the stove instead of in the turkey.

All those steps will pay off with a healthy and worry-free holiday celebration. After all, a big serving of delicious, properly cooked turkey, handled with care in the kitchen, is harmless, except maybe for your waistline.

Turkey isn't the only food that could pose a hazard to your holidays. Eggs and unpasteurized cider are still risky, as well. However, things are improving. The Food and Drug Administration's (FDA's) new regulation for juices means that more cider is being pasteurized or otherwise processed to eliminate bacteria.<sup>10</sup> This government action could virtually eliminate food poisoning outbreaks from unpasteurized juices.

---

<sup>6</sup> Food Safety and Inspection Service, U.S. Department of Agriculture, "Kitchen Thermometers," *Technical Information from FSIS*, (Washington, D.C.: U.S. Department of Agriculture, October 1997), p. 4, [hereafter referred to as *Kitchen Thermometers*]. T-Stick disposable thermometers indicate above or below 160°F, and do not reach the high temperature needed to test whether a turkey is done.

<sup>7</sup> *Kitchen Thermometers*, p. 7.

<sup>8</sup> *Kitchen Thermometers*, p. 7.

<sup>9</sup> *Kitchen Thermometers*, p. 7.

<sup>10</sup> Department of Health and Human Services, Food and Drug Administration, "Food Labeling: Warning and Notice Statement; Labeling of Juice Products," *Federal Register*, Vol. 63, No. 130 (1998), pp. 37030-37056.

Raw eggs frequently show up in desserts and eggnog. Shell eggs are still not safe to use in those recipes because they may be contaminated with *Salmonella*. Consumers can avoid those problems by using pasteurized egg products, like Egg Beaters, in recipes that call for raw or partially cooked eggs.

There is a lot that consumers and the food industry can do to make food safer. In addition the government, has a critical role to play.

This year, the revolution in food safety is called HACCP ("hassip"), the acronym for Hazard Analysis and Critical Control Point systems. Last December, the Food and Drug Administration implemented HACCP systems in 3,800 seafood plants.<sup>11</sup> In January, the U.S. Department of Agriculture (USDA) implemented HACCP in the 300 largest meat and poultry slaughter and processing plants.<sup>12</sup> Another 3,000 small and medium-sized meat and poultry plants will start using the new system in January. Let's review how this new system has performed and what it says about the current government programs for ensuring a safe food supply.

There were few surprises with respect to implementing HACCP in large meat and poultry plants. At six months, the industry had a 93% compliance rate.<sup>13</sup> In the six-month progress report, government data showed that *Salmonella* contamination in chicken was cut in half, from 20% to 10%. Other meat and poultry products also showed improvement in *Salmonella* contamination rates following HACCP implementation.<sup>14</sup> *Salmonella* is the only pathogen that is being used to measure HACCP's effect in meat and poultry plants. As I discussed earlier, there is no evidence that *Campylobacter* contamination has declined under HACCP.

In comparison with the large meat and poultry plants, the seafood industry has done a dismal job in implementing the new HACCP systems. Last January, FDA required 3,800 seafood processors, both large and small, to develop and implement HACCP plans. Unlike USDA, FDA doesn't inspect seafood plants daily. Furthermore, the agency chose not to require

---

<sup>11</sup> Department of Health and Human Services, Food and Drug Administration, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule," *Federal Register*, Vol. 60, No. 242 (1995), pp. 65096-65202.

<sup>12</sup> U.S. Department of Agriculture, Food Safety and Inspection Service, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule," *Federal Register*, Vol. 61, No. 144, pp. 38806-38989.

<sup>13</sup> "HACCP Implementation in Small Plants -- The Role of FSIS," Remarks prepared for delivery by Thomas J. Billy, Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, before the Small Plant HACCP Implementation Meeting, September 19, 1998, Raleigh, NC. Available at <<http://www.fsis.usda.gov/OA/specches/smallplant.htm>>INTERNET.

<sup>14</sup> "Clinton Administration's New Food Safety System Reduces Threat of *Salmonella*," U.S. Department of Agriculture News Release No. 0394.98, September 28, 1998.

any pathogen-reduction standards or testing. Within six months of implementing the system in the seafood industry, only 30% of the seafood plants that FDA visited were in compliance with the new HACCP system. The FDA found that 70% of the seafood plants had "serious" or "critical" violations of the HACCP rule. Forty percent of those plants were not even implementing the new requirements. For imported seafood, the record was even worse. Eighty percent of seafood importers had "serious" or "critical" violations.<sup>15</sup>

The lessons from the differing performance of the meat, poultry, and seafood industries are clear. We cannot rely on an industry honor system to ensure the safety of food. For these new HACCP food-safety systems to work, they must be combined with a strong inspection force and standards for the reduction of microbial and other hazards.

Finally, let's review Congress' record of accomplishment in addressing food safety issues. In 1997, we had the largest-ever recall of ground beef. In response, the Clinton administration asked Congress to give USDA the authority to mandate recalls and to fine companies that violate food-safety laws.<sup>16</sup> Congress did nothing.

For two years, imported raspberries contaminated with a parasite made thousands of people sick, and tainted strawberries grown in Mexico showed up in the school lunch program, sickening hundreds of school children. In response, the Clinton administration asked Congress to give FDA the authority to go to foreign countries to see how the imported food was being produced.<sup>17</sup> Again, Congress did nothing.

In August, the National Academy of Sciences issued a scathing report on the condition of the current programs to regulate food safety, saying that the programs are based on laws that are "inconsistent, uneven, and at times archaic."<sup>18</sup> It said that those laws "inhibit use of science-based decision-making."<sup>19</sup> Two forward-thinking members of Congress, Senator Richard

---

<sup>15</sup> "FDA's Reflection on HACCP Implementation," Remarks of FDA Representative before the 85th Annual International Association of Milk, Food and Environmental Sanitarians Meeting, Nashville, TN, August 17, 1998.

<sup>16</sup> "Food Safety Enforcement Enhancement Act of 1997," 105th Cong., 1st Sess., S. 1264.

<sup>17</sup> "Safety of Imported Food Act of 1997," 105th Cong., 1st Sess., HR 3052.

<sup>18</sup> Institute of Medicine, National Research Council, *Ensuring Safe Food From Production to Consumption*, (Washington, DC: National Academy Press, 1998), p. 9.

<sup>19</sup> *Ibid.*

Durbin of Illinois and Representative Vic Fazio of California, proposed legislation to combine the existing food-safety programs into a single food-safety agency.<sup>20</sup> Again, Congress failed to act.

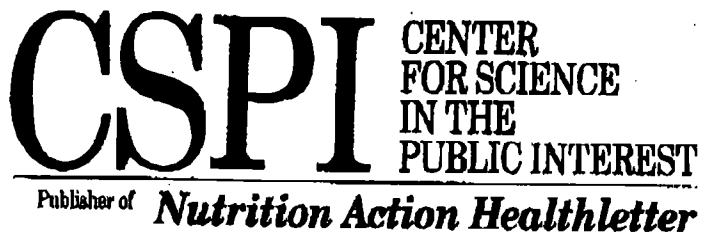
Even the Clinton administration's request for new food-safety funding to enhance inspection, research, and education at first met a tepid response. The House originally approved only \$18 million of the \$101 million request, and the Senate was poised to approve even less, \$2.6 million. After a team of Democratic Senators led by Senator Tom Harkin of Iowa forced a floor vote, the Senate increased the amount of new funding for food safety from \$2.6 to \$68 million.<sup>21</sup> In negotiations over the final budget, the Clinton team demanded even more for consumers, and, in a significant turn around, the final bill provided \$75 million in new food-safety funding.

Food safety is truly a kitchen-table issue for the American public. I hope that the next Congress will complete the work that needs to be done if Americans are to have safe food, not only on Thanksgiving Day, but every day of the year.

---

<sup>20</sup> "Safe Food Act of 1997," 105th Cong., 1st Sess., HR 2801; S. 1465.

<sup>21</sup> *Congressional Record*, 105th Cong. 2d. Sess., July 16, 1998, pp. S8329-S8330.



|                  |
|------------------|
| <b>EMBARGOED</b> |
|------------------|

Not For Release Before:  
November 19, 1998 at 10 a.m.

Contact: Bill Bryant at (202) 332-9110 ext. 370  
Penelope Miller at (202) 332-9110 ext. 358

# How Hazardous Is Your Turkey? CSPI Says 'Handle With Care'

## Thanksgiving 'Guests' May Include *Salmonella* and *Campylobacter*

Washington, DC--Despite recent reports about how new government programs have reduced *Salmonella* contamination on poultry, this Thanksgiving is no time to be lax about food safety. In fact, the best data available indicate that more than nine out of ten turkeys carry bacteria that could cause food poisoning, according to Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest (CSPI).

"While no one invites *Salmonella* or *Campylobacter* home for the holidays," said DeWaal, "consumers must expect these unwelcome guests every time they bring home a turkey."

A leading consumer analyst of laws and regulations governing food safety, attorney DeWaal was the "morning newsmaker" at the National Press Club today. She reviewed recently released data on the contamination rates of turkeys and on the successes and failures of the first year's operation of the new federal food-safety system, called the Hazard Analysis and Critical Control Point (HACCP) system.

DeWaal reported that a major U.S. Department of Agriculture (USDA) survey of turkeys conducted in 1996-1997 found that *Campylobacter* was present in 90 percent of the turkeys tested. USDA's survey found that 97% of turkeys were contaminated with one or more of five types of dangerous bacteria. The data were collected before the HACCP system was implemented in large meat and poultry plants, including many turkey plants, but there is no evidence that *Campylobacter*

## CSPI--Page Two

CSPI recommends the following precautions:

- Keep your turkey double-wrapped in plastic bags in your refrigerator or freezer. Anything and everything that touches the raw or partially cooked turkey needs to be scrubbed thoroughly with warm, soapy water. Move your twenty-pound turkey from the freezer to the refrigerator on Sunday – a day earlier if it's heavier and a day later if it's lighter.
- Use a meat thermometer even if your turkey has a pop-up timer. The best place to check the turkey's temperature is on the thickest part of the thigh, not touching the bone. Checking in several places is safest. When the thermometer reads 180°F, the turkey is done. Stuffing must reach 165°F to assure it is safe, especially if it is cooked inside the turkey or contains raw eggs or oysters.
- Raw eggs -- which may be used in desserts and eggnog -- and unpasteurized cider may be contaminated with dangerous bacteria. Use pasteurized egg products (like Eggbeaters) in recipes that call for raw or partially cooked eggs. Also, avoid unpasteurized juices or heat them to a low boil.

"All those steps," said DeWaal, "will pay off with a healthy and worry-free holiday celebration." She added that, although there is a lot that consumers and the food industry can do to make food safer, the government "has a critical role to play, too."

DeWaal compared the performance of the new HACCP systems in place for meat, poultry, and seafood. Last January, the USDA implemented the new HACCP systems in the 300 largest meat and poultry slaughter and processing plants. Government data for the first six months of the USDA program, said DeWaal, found a 93% compliance rate. Under that program the average *Salmonella* contamination rate in chicken had been reduced by half, from 20% down to 10%. She added that turkey and red meat also showed improvement.

"Compared with the large meat and poultry plants, the seafood industry has turned in a dismal performance," said DeWaal. Last December, the Food and Drug Administration (FDA) implemented HACCP systems in 3,800 seafood plants. FDA chose not to require any pathogen-reduction standards or testing. Within six months of implementing the HACCP system, only 30% of the seafood plants that FDA inspected were in compliance. FDA found that 70% of the domestic seafood plants it inspected had "serious" or "critical" violations. Importers did even worse.

"The lessons from HACCP implementation in the meat, poultry, and seafood industries are clear," said DeWaal. "We can't rely on an industry honor system to ensure the safety of food. For HACCP food-safety systems to work, they must be combined with a strong inspection force and standards for the reduction of microbial hazards."

DeWaal discussed Congress' record on food-safety issues. While Congress did provide \$75 million in new food-safety funding for the National Food Safety Initiative, she noted that it failed to enact mandatory recall legislation, failed to pass a bill to improve the safety of imported food, and failed to create a unified agency to oversee food safety.

contamination has declined.

*Campylobacter* is the number-one cause of bacterial food poisoning, according to the Centers for Disease Control and Prevention (CDC). *Campylobacter* can also cause a serious neurological disease called Guillain-Barré syndrome, which can lead to temporary paralysis, similar to polio.

“The latest government data show that this is no time to lower the safeguards in the kitchen,” she said. “While it is imperative that the industry and the government work to ensure safer turkeys, consumers remain the last line of defense against food poisoning.”

--more--

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

“Food safety is truly a kitchen-table issue for the American public,” said DeWaal. “I hope that the next Congress will complete the work that needs to be done if Americans are to have safe food, not only on Thanksgiving Day, but every day of the year.”

--END--

*The nonprofit Center for Science in the Public Interest (CSPI) focuses on nutrition and food safety. Founded in 1971, CSPI is supported largely by the one million subscribers to its Nutrition Action Healthletter in the United States and Canada. CSPI was a major proponent of recent improvements in meat and poultry inspection. The organization also is well-known for obtaining nutrition labeling on all packaged foods. CSPI accepts no industry or government funding.*

**Visit CSPI on the Internet at [www.cspinet.org](http://www.cspinet.org)**



# FAX TRANSMISSION

UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

OFFICE OF THE ADMINISTRATOR

1400 JEFFERSON DRIVE, SE  
WASHINGTON, DC 20250-3700

TELEPHONE: 202-720-7025

FAX: 202-205-0158

*Food Safety* *EM*

To: *Chris Baldersheim*  
*Tom Friedman*

Date: *1/18/98*

Fax #:

Pages: *11*, including this cover sheet.

From:

*Joan Mordasheer*  
Subject: *Johna Pierce*

COMMENTS:

*Updated talking points and  
Qs + As on the Cox News Story*

*Internal***TALKING POINTS--COX NEWSPAPERS' Story on Meat and Poultry Inspection**

Contact: USDA -- (202) 720-4150

1/18/98

Joan Mondschein -- (202) 244-3397 or Johna Pierce 410-798-8952

- First, it is important to note that the COX story is not based on the new food safety inspection system. In fact, the story is based largely on 1996 events that occurred prior to the implementation of the new food safety requirements.
- Under the old system of inspection, inspectors would ensure food safety by identifying problems and issuing Process Deficiency Reports (PDR's). For the plants that were described in the article, the fact that inspectors issued PDR's means that they were aggressively doing their job to ensure that food safety standards were met.
- The article incorrectly implies that unsafe food was allowed to be produced by these plants and sent to consumers. No contaminated product was allowed to leave the plant. When inspectors issue a critical PDR, either the problem is corrected so that the product is safe and wholesome, or, if it cannot be made safe, then the product is condemned.
- The high number of PDR's indicates that inspectors observed problems, documented them, and took action to ensure that no unsafe food reached consumers.
- The article misleads readers when it stated that "the plant never missed a day of production...because of federal sanctions." In fact, although the entire plant was not shut down, specific lines of production that were in violation were shut down for periods of time on many occasions, as required to ensure safety.
- On January 27, 1997, the first set of requirements of the new food safety system were implemented. Plants were required to develop and maintain Sanitation Standard Operating Procedures (SSOP), a definitive system that the plant must follow to continue to operate.
- Under this approach, if the plant fails to effectively implement their system, or if a plant's system simply does not meet food safety requirements, FSIS can and does take formal action to withhold the mark of inspection and effectively shut down the plant.
- **This is a fundamental change from the old system of regulation:**
  - Previously, plants did not have to maintain effective systems for producing safe food. Where there were problems, inspectors would issue PDRs and direct the plant to make the necessary corrections. And when critical PDRs were issued, no unsafe food was allowed to reach consumers.
  - Under the new approach, however, FSIS can shut down a plant until it makes the changes necessary to ensure that their systems will produce safe food.
- Since January of 1997, FSIS has taken 20 formal actions to withhold the mark of inspection and temporarily close down plants due to SSOP system failures. The plants do

not reopen until they have fixed their systems and food safety standards are met.

- On December 19, 1997, before the Cox reporters visited the plant, FSIS initiated formal action to address repeated SSOP failures in the Tyson plant in Waldron, Arkansas, which led to the plant's closure on January 14, 1998.
- In discussing examples of problems inspectors identified in 1997, the article once again incorrectly implies that unsafe product was allowed to leave the plants. In every instance cited by the article, inspectors took action to prevent unsafe food from reaching consumers and to correct unacceptable practices by the plants.
- On January 26, 1998, the new food safety inspection system, called Hazard Analysis and Critical Control Points (HACCP), will be implemented in all large meat and poultry slaughter and processing plants.
- **The COX article suggests that inspectors will not be documenting and taking action when necessary to address food safety problems. This is wrong.**
  - Non-compliance reports (NRs) will replace PDRs as the inspectors' documentation of violations of HACCP requirements, in addition to SSOPs and other regulatory requirements.
  - FSIS' inspectors will continue to be present day-to-day to verify compliance and take direct action when necessary.
  - In their expanded role under HACCP, inspectors will continue to inspect and will document violations in writing. Inspectors will continue to maintain their authority to prevent unsafe product from leaving the plant. Inspectors will not only continue to document deficiencies, but will document repeated failures, for the purposes of shutting down the plant. In short, FSIS has and will continue to take strong enforcement action for repeated violations of sanitary or food safety requirements.
- **The Clinton Administration has asked Congress for additional enforcement authority to fine companies for violations of food safety standards.**
- Currently, the Department of Agriculture (USDA) can impose fines against people who violate a wide variety of requirements. For example, USDA can fine circuses for mistreating elephants, and can fine people who sell undersized potatoes and people who don't keep the right paperwork on watermelons. But we can't fine companies that violate food safety standards.
- The ability to fine companies that violate food safety standards will make the new food safety system even more effective, and we are working hard to convince Congress to give us this important power.
- Consumers rightfully expect government and industry to improve food safety, and the new food safety system is a revolutionary improvement over the old system.



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

JAN 18 1998

Dear Editor:

As Administrator of the Food Safety and Inspection Service (FSIS), I feel compelled to respond to a recent article which I believe does your readers a disservice by presenting an incomplete picture of our meat and poultry inspection system. First, in every instance cited by the article, inspectors took action to prevent unsafe food from reaching consumers and to correct unacceptable practices by the plants.

It is important to remember that the story was not about the new food safety inspection system, called Hazard Analysis and Critical Control Points (HACCP). In fact, the article is based largely on 1996 events that occurred prior to the implementation of the new food safety requirements. The fact that a plant with over 1,700 regulatory violations was not shut down in 1996 is a fair criticism. It should have been. The reason it wasn't, however, highlights one of the important benefits of the new food safety system, which we began implementing in January 1997.

Under the old system, inspectors would impose corrective actions when there were violations and prevent unsafe food from reaching consumers, but FSIS would allow plants to accumulate large number of deficiencies without taking action to suspend inspection and shut plants down. Under the new food safety system, FSIS has a new tool to stop operations where there is a pattern of deficiencies and insist on preventive measures to improve food safety before a plant can reopen.

Inspectors will use non-compliance reports to document food safety violations. Inspectors will continue to be present everyday to verify compliance and to take direct action when necessary. These actions will lay the groundwork for documenting repeated failures. And where there are repeat failures, FSIS can and will take formal action to shut down the plant.

Your readers should also be aware that the Clinton Administration has asked Congress for additional enforcement authority to fine companies for violations of food safety standards. The Department of Agriculture (USDA) can impose fines against people who violate a wide variety of requirements. For example, USDA can fine circuses for mistreating elephants, and we can fine people who sell undersized potatoes and people who don't keep the right paperwork on watermelons. But we can't fine companies that violate food safety standards. That's just wrong.

Consumers rightfully expect government and industry to do a better job to improve food safety, and the new food safety system is a revolutionary improvement over the old system. The ability to fine companies that violate food safety standards will make the new food safety system

even more effective, and we are working hard to convince Congress to give us this important power.

Sincerely,

Tom Billy  
Administrator

QUESTIONS AND ANSWERS -- COX NEWSPAPERS' Story of Meat and Poultry Inspection  
1/18/98

**1. Why wasn't a plant shut down that had over 1,700 violations?**

First, it is important to note that the COX story is not based on the new food safety inspection system. In fact, the story is based largely on 1996 events that occurred prior to the implementation of the new food safety requirements. The fact that a plant with over 1,700 regulatory violations was not shut down in 1996 is a fair criticism. It should have been. The reason it wasn't, however, highlights one of the important benefits of the new food safety inspection system.

Under the old system of inspection, inspectors would ensure food safety by identifying problems and issuing Process Deficiency Reports (PDR's). For the plants that were described in the article, the fact that inspectors issued PDR's means that they were aggressively doing their job to ensure that food safety standards were met.

**2. Did consumers get any unsafe product?**

The article incorrectly implies that unsafe food was produced by these plants and sent to consumers. No contaminated product was allowed to leave the plant. When inspectors issue a critical PDR, either the problem is corrected so that the product is safe and wholesome, or, if it cannot be made safe, then the product is condemned. The high number of PDR's indicates that inspectors observed problems, documented them, and took action to ensure that no unsafe food reached consumers.

**3. What is an example of a PDR?**

Examples include: unclean equipment, peeling paint, rust, product dropped on the floor.

**4. Did the Tyson's plant continue to operate?**

The article misleads readers when it stated that "the plant never missed a day of production...because of federal sanctions." In fact, although the entire plant was not shut down, specific lines of production that were in violation were shut down for periods of time on many occasions, as required to ensure safety.

**5. What will the new system do?**

On January 27, 1997, the first set of requirements of the new food safety system were implemented. Plants were required to develop and maintain Sanitation Standard Operating Procedures (SSOP), a definitive system that the plant must follow to continue to operate. Under this approach, if the plant fails to effectively implement their system, or if a plant's system simply does not meet food safety requirements, FSIS will take formal action to withhold the mark of inspection and effectively shut down the plant.

On January 26, 1998, the new food safety inspection system, called Hazard Analysis and Critical Control Points (HACCP), will be implemented in all large meat and poultry slaughter and processing plants. HACCP will require plants to meet science-based standards, including testing for microbial contamination, rather than the organoleptic approach of the past 90 years.

## QUESTIONS AND ANSWERS -- COX NEWSPAPERS' Story of Meat and Poultry Inspection 1/18/98

### 1. Why wasn't a plant shut down that had over 1,700 violations?

First, it is important to note that the COX story is not based on the new food safety inspection system. In fact, the story is based largely on 1996 events that occurred prior to the implementation of the new food safety requirements. The fact that a plant with over 1,700 regulatory violations was not shut down in 1996 is a fair criticism. It should have been. The reason it wasn't, however, highlights one of the important benefits of the new food safety inspection system.

Under the old system of inspection, inspectors would ensure food safety by identifying problems and issuing Process Deficiency Reports (PDR's). For the plants that were described in the article, the fact that inspectors issued PDR's means that they were aggressively doing their job to ensure that food safety standards were met.

### 2. Did consumers get any unsafe product?

The article incorrectly implies that unsafe food was produced by these plants and sent to consumers. No contaminated product was allowed to leave the plant. When inspectors issue a critical PDR, either the problem is corrected so that the product is safe and wholesome, or, if it cannot be made safe, then the product is condemned. The high number of PDR's indicates that inspectors observed problems, documented them, and took action to ensure that no unsafe food reached consumers.

### 3. What is an example of a PDR?

Examples include: unclean equipment, peeling paint, rust, product dropped on the floor.

### 4. Did the Tyson's plant continue to operate?

The article misleads readers when it stated that "the plant never missed a day of production...because of federal sanctions." In fact, although the entire plant was not shut down, specific lines of production that were in violation were shut down for periods of time on many occasions, as required to ensure safety.

### 5. What will the new system do?

On January 27, 1997, the first set of requirements of the new food safety system were implemented. Plants were required to develop and maintain Sanitation Standard Operating Procedures (SSOP), a definitive system that the plant must follow to continue to operate. Under this approach, if the plant fails to effectively implement their system, or if a plant's system simply does not meet food safety requirements, FSIS will take formal action to withhold the mark of inspection and effectively shut down the plant.

On January 26, 1998, the new food safety inspection system, called Hazard Analysis and Critical Control Points (HACCP), will be implemented in all large meat and poultry slaughter and processing plants. HACCP will require plants to meet science-based standards, including testing for microbial contamination, rather than the organoleptic approach of the past 90 years.

01-18-98:01:37PM:USDA FSIS OA 72026904437

Non-compliance reports (NRs) will replace PDR's as the inspectors' documentation of violations of HACCP requirements, in addition to SSOPs and other regulatory requirements. FSIS' inspectors will continue to be present day-to-day to verify compliance and take direct action when necessary.

In their expanded role under HACCP, inspectors will continue to inspect and document violations in writing. Inspectors will continue to maintain their authority to prevent unsafe product from leaving the plant.

Inspectors will not only document deficiencies, but will document repeated failures, for the purposes of shutting down the plant. In short, FSIS has and will continue to take strong enforcement action for repeated violations of sanitary or food safety requirements.

**6. How is this different than the old system?**

**This is a fundamental change from the old system of regulation:**

Previously, plants did not have to maintain effective systems for producing safe food. Where there were problems, inspectors would issue PDR's and direct the plant to make the necessary corrections. And when critical PDR's were issued, no unsafe food was allowed to reach consumers. Under HACCP, however, FSIS can shut down a plant until it makes the changes necessary to ensure that their systems will produce safe food.

**7. How often has FSIS shut down plants since January of 1997?**

Since January of 1997, FSIS has taken 20 formal actions to withhold the mark of inspection and temporarily close down plants due to SSOP system failures. The plants do not reopen until they have fixed their systems and food safety standards are met.

On December 19, 1997, before the Cox reporters visited the plant, FSIS initiated formal action to address repeated SSOP failures in the Tyson plant in Waldron, Arkansas, which led to the plant's closure on January 14, 1998.

**8. The COX article quoted an inspector as saying that he won't have to document problems under the new system. Is this accurate?**

Far from it. Non-compliance reports --NRs-- will replace PDR's as the inspector's documentation of violations of HACCP requirements, in addition to SSOPs and other regulatory requirements. FSIS inspectors will continue to verify compliance day-to-day and will take direct action when necessary.

**9. Why has the Clinton Administration asked Congress for additional enforcement authority to fine companies for violations of food safety standards?**

Currently, the Department of Agriculture (USDA) can impose fines against people who violate a wide variety of requirements. For example, USDA can fine circuses for mistreating elephants, and can fine people who sell undersized potatoes and people who don't keep the right paperwork on watermelons. But we can't fine companies that violate food safety standards.

The ability to fine companies that violate food safety standards will make the new food safety

Non-compliance reports (NRs) will replace PDR's as the inspectors' documentation of violations of HACCP requirements, in addition to SSOPs and other regulatory requirements. FSIS' inspectors will continue to be present day-to-day to verify compliance and take direct action when necessary.

In their expanded role under HACCP, inspectors will continue to inspect and document violations in writing. Inspectors will continue to maintain their authority to prevent unsafe product from leaving the plant.

Inspectors will not only document deficiencies, but will document repeated failures, for the purposes of shutting down the plant. In short, FSIS has and will continue to take strong enforcement action for repeated violations of sanitary or food safety requirements.

**6. How is this different than the old system?**

**This is a fundamental change from the old system of regulation:**

Previously, plants did not have to maintain effective systems for producing safe food. Where there were problems, inspectors would issue PDR's and direct the plant to make the necessary corrections. And when critical PDR's were issued, no unsafe food was allowed to reach consumers. Under HACCP, however, FSIS can shut down a plant until it makes the changes necessary to ensure that their systems will produce safe food.

**7. How often has FSIS shut down plants since January of 1997?**

Since January of 1997, FSIS has taken 20 formal actions to withhold the mark of inspection and temporarily close down plants due to SSOP system failures. The plants do not reopen until they have fixed their systems and food safety standards are met.

On December 19, 1997, before the Cox reporters visited the plant, FSIS initiated formal action to address repeated SSOP failures in the Tyson plant in Waldron, Arkansas, which led to the plant's closure on January 14, 1998.

**8. The COX article quoted an inspector as saying that he won't have to document problems under the new system. Is this accurate?**

Far from it. Non-compliance reports --NRs-- will replace PDR's as the inspector's documentation of violations of HACCP requirements, in addition to SSOPs and other regulatory requirements. FSIS inspectors will continue to verify compliance day-to-day and will take direct action when necessary.

**9. Why has the Clinton Administration asked Congress for additional enforcement authority to fine companies for violations of food safety standards?**

Currently, the Department of Agriculture (USDA) can impose fines against people who violate a wide variety of requirements. For example, USDA can fine circuses for mistreating elephants, and can fine people who sell undersized potatoes and people who don't keep the right paperwork on watermelons. But we can't fine companies that violate food safety standards.

The ability to fine companies that violate food safety standards will make the new food safety

system even more effective, and we are working hard to convince Congress to give us this important power.

**10. What has the Clinton Administration done to strengthen food safety? See attached summary.**

01-19-98:01:37PM:USDA FSIS OA 2026904437

## **Clinton Administration Accomplishments In Improving Food Safety**

- \* 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.

**Questions and Answers on Food Safety**  
**January 20, 1998**

Tom - you used a sentence here saying what this money went for.

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

launched a new Presidential FSI. As part of that initiative we succeeded in adding more than \$44M to the FY98 budget.

**A:** Last year we were able to increase spending on food safety by approximately \$40 million. This year, our budget will seek an even more substantial increase in resources 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 expanding CDC's surveillance activities for food-borne illnesses.

Tom - What does this mean? Please rephrase

**Q: Is this a new issue for the Administration?**

**A:** No, our actions are part of a continuing effort that has seen real accomplishment every year:

- \* October, 1997. President announces new initiative to enhance FDA oversight over imported foods and to develop guidance on good agricultural and manufacturing practices for fruits and vegetables; to seek legislation to give FDA the same authority that USDA has to inspect imports; and to seek funds to greatly expand FDA's inspection force.
- \* January, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.
- \* 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.

Food Safety 1.14

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.

Q. A recent story revealed that USDA did not close down a plant despite 1,700 violations. What are you doing to make sure our meat and poultry are safe to eat?

A. We ~~do need to keep doing a better job on~~ <sup>have to keep improving our</sup> food safety <sup>systems.</sup> And I am committing more resources than ever to the problem, and modernizing food safety for meat and fruits and vegetables and the water we drink. There are several important facts to remember in regard to this specific story. First, ~~in every instance cited in the story, inspectors took action to prevent unsafe food from reaching consumers and to correct unacceptable practices by the plant.~~ <sup>Then</sup> Second, ~~the story is based largely on events in 1996. Since that time the Administration has developed the Hazard Analysis and Critical Control Points (HACCP), which we began implementing in January 1997. Under this system, the Food Safety and Inspection Service (FSIS) can insist on preventative measures to improve food safety before a plant can reopen. Under HACCP inspectors will use non-compliance reports to document food safety violations. These actions will lay the groundwork for documenting repeated failures. And where there are repeat failures, FSIS can and will take formal action to shut down the plant. Finally, the Administration has asked Congress for additional enforcement authority to fine companies for violations of food safety standards. Currently, USDA can't fine companies that violate food safety standards.~~ <sup>occurred</sup> <sup>Tom - What</sup> <sup>in the</sup> <sup>would mean?</sup> <sup>see below?</sup> <sup>is that it?</sup> <sup>They</sup>

where there are repeat failures; and they will insist on that the plant take a wide range of measures to prevent any future contamination before plant can open.

although the inspectors did not close the plant - and in my view that was a wrong decision -- They did take actions to correct the plant's bad practices and to prevent unsafe food from reaching the public.

an

**Questions and Answers on Food Safety**  
**January 19, 1998**

**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 will seek an even more substantial increase in resources 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.

**Q. A recent story revealed that USDA did not close down a plant despite 1,700 violations. What are you doing to make sure our meat and poultry are safe to eat?**

**A.** We have to keep improving our food safety systems. And I am committing more resources than ever to the problem, and modernizing food safety for meat and fruits and vegetables and the water we drink. There are several important facts to remember in regard to this specific story. First, although the inspectors did not close the plant -- and in my view that was a wrong decision -- they did take actions to correct the plant's bad practices and to prevent all unsafe food they found from reaching the public. Second, those events occurred in 1996 -- before my Administration began implementing the Hazard Analysis and Critical Control Point (HACCP) system for meat. Under this system, inspectors will document food safety violations; they will shut down the plant where there are repeat failures; and they will insist that the plant take a wide range of measures to prevent any future contamination before the plant can reopen. Finally, the Administration has asked Congress for additional enforcement authority to fine companies for violations of food safety standards. Currently, USDA can't fine companies that violate food safety standards.

**THE WHITE HOUSE**  
**Office of the Press Secretary**

---

Food Safety - EW

For Immediate Release

October 2, 1997

**REMARKS BY THE PRESIDENT  
ON FOOD SAFETY REGULATIONS**

The Rose Garden

10:59 A.M. EDT

THE PRESIDENT: Thank you, Mr. Vice President, Secretary Shalala, Deputy Secretary Rominger, Cathie Woteki, Dr. Friedman, all the representatives of the groups that have helped us come to this day.

Our government made a fundamental promise to the American people of a bountiful and safe food supply way back at the beginning of this century. It is a promise that we have had to renew our commitment to periodically over the years, and a promise that needed a lot of work when I became President. From the day I took office, I worked very hard to honor that commitment, to make our food supply -- the world's safest -- even safer.

In 1993, the Vice President's national performance review recommended an overhaul of our food safety procedures so that we could use the best scientific technology available in inspection methods, to make sure that we had put in the best preventive controls to keep our food supply the world's safest.

Since then, we have taken major steps. We first put in place rigorous new safety standards for seafood, meat and poultry products, throwing out archaic and ineffective methods of inspection that had not been updated for nearly a century. We've required slaughterhouses to test for deadly E. Coli and salmonella bacteria. We've begun developing new safety standards for fruit and vegetable juices. We've strengthened our system of guaranteeing that our drinking water will remain safe, and improved public health protections for pesticide uses on food. And we brought a host of federal agencies together to boost food safety research, education and surveillance efforts around our nation. In so doing, we're using the world's best science to help prevent food contamination tragedies before they happen, to make sure our supply of food is as safe as it can be.

Today, our food supply remains the world's safest, but we can't rest on those accomplishments. We have to do more. At the time when Americans are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply from whatever source.

Today, I want to tell you the new steps we're taking to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards. First, I'm asking Congress to give the Food and Drug Administration the power and the obligation to ban the importation of fruits, vegetables and other foods from countries whose safety precautions do not meet American standards. This new law would be similar to a law that already requires the United States Department of Agriculture to keep meat and poultry

from countries with inferior food safety systems out of our stores.

In my next budget, I will provide enough funds to ensure that the FDA can fully implement this new legislation by dramatically expanding its international food inspection force. 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. Our food safety system is the strongest in the world, and that's how it's going to stay.

I'm also directing 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 specific safety standards for the growing, processing, shipping and selling of fruits and vegetables. These standards will address potential food safety problems throughout the production and distribution system, and they'll improve the sanitation and safety practices of all those seeking to sell produce in the United States market.

I'm asking Secretary Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year. I'll also ask them to submit a comprehensive plan to improve the monitoring of food safety programs abroad, to help foreign countries upgrade their safety precautions and toughen food inspections at the border.

Being a parent is perhaps the toughest job in the world. Our parents deserve the peace of mind that comes from knowing the food they set before their children is safe. With today's new actions, we can help make their jobs much easier.

And, again, let me thank all of those who were involved in this effort as I sign this order. Thank you very much.

(The order is signed.)

THE PRESIDENT: Thanks. (Applause.)

Q Mr. President, will you be using the line item veto

THE PRESIDENT: Excuse me?

Q Will you be using the line item veto on any of the appropriations bills that you've just passed -- that you've just signed?

THE PRESIDENT: Well, let me say, I have received only -- I've received one memorandum for my staff on one bill. And that came in late last night, so I haven't read it. But I will consider it -- as the bills come in. I will ask for a review of the potential uses by specific bill and make judgments as we go along. I have nothing to report at this time, because I have received only one memorandum and I haven't read it.

Q What about the census, sir? Do you have any concerns concerning the Commerce bill and the particular ways that the money will be used for the census?

THE PRESIDENT: Well, my feeling is that we ought to do the census as well as we can. I don't think this is a complicated issue. The National Science Foundation has recommended this statistical sampling method. The man who did President Bush's census says that it's the only way to get the most accurate count. I just want to do whatever the Census Bureau believes, the full-time professionals, believe is the most accurate thing to do.

I think that's a heavy constitutional responsibility we have, to conduct a census that is as

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

(OVER)

2

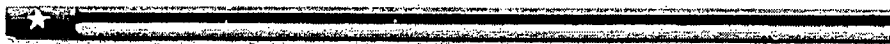
First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for 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

# # #



accurate as possible based on what the professionals say. This ought to be a professional, not a political judgment. And that's the position I will take throughout.

Q Mr. President, did the Democratic Party send money to the states because of federal election law restrictions?

Q Mr. President, there are fresh fruit and vegetables producers that are saying --

THE PRESIDENT: Well, wait a minute. I'll take both of them. Go ahead first.

Q There are fresh fruit and vegetable producers that are saying that you're acting with this action as the world food police and that your actions here today are unwarranted and that's going to complicate the trade environment.

THE PRESIDENT: Well, I hope it doesn't complicate the trade environment. But, you know, it seems to me that we have no higher responsibility than to protect the health and safety of our citizens, and everyone who has been following all of your reporting over the last four or five years knows that we have had continuing challenges in food safety. We have millions of people who get sick every year. And we're not trying to unfairly target foreign producers of food into our market; we don't ask them to meet any standards we don't meet. And indeed, if you look at the actions of this administration over the last four years, when we started, I think you can make a compelling case that we started working on things that were problems coming out of the American market first. So I just don't think that's right.

I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick.

Q Mr. President, did the Democratic National Committee send money to the states in order to get around the federal spending limits that went along with accepting federal money for the national campaign, sir?

THE PRESIDENT: It's my understanding that everything the Democratic National Committee did had the prior approval of the lawyers. If they cleared it all in advance, then it was perfectly legal. And when this issue was raised about a year ago, the exact issue, I believe that that was clarified at that time. I'm sure that they had legal advice that they followed, and I believe the Republicans said that they did some of the same things and also had prior legal clearance.

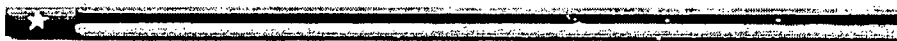
Q Mr. Clinton, do you think that Mrs. Reno -- she's been advised to go forward with the 90-day investigation into the fundraising calls of the Vice President -- and perhaps Mr. Gore would like to comment, too --

THE PRESIDENT: I think that --

Q -- do you feel that the 90-day investigation would be helpful?

THE PRESIDENT: Well, if you read the statute, she can consider certain things in the 90-day period that are not permitted in the 30-day period. But I think this is a legal question and it should be done based on an independent legal review with no pressure from the outside, from me or from anyone else. And that's the way I intend to keep it, at least on my part.

Thank you.



TO : TOM F. 65581

FROM SUSAN C.

See my comments, including  
number changes.

I'm checking on your OFAP question.

8 page follow.

Kroger

Food Safety

EW

THE PRESIDENT HAS BEEN  
1-5-92

Food Safety & Inspection Service

Part of Govt. are need a  
\* globalisation which deals w/  
prohibitions and threats w/  
govt. Chem? Bio? Warfare  
\* Biotech -

Need to make  
sure we have enough  
in bugs or ~~enough~~  
and spreading food safety  
ex. - Malaria problems

FC

Copied  
Feed  
Sperling

Tim -

Please write something in the  
weekly on the budget increase  
in food safety. You don't have to  
worry about malaria - Chris is  
taking care of this.

Eric

1-5-98

# Deadly Bacteria a New Threat To Fruit and Produce in U.S.

A1

By CHRISTOPHER DREW and PAM BELLUCK

Continued From Page 1

Anna Grace Glimmestad, 18 months old, was just beginning to put her infant stamp on the world. She would parrot the whirr of a helicopter, pause on each stair step to kiss her parents through the banister.

And every time her mother wheeled her past the grocery-store cooler, she would point excitedly to her favorite: the colorful, fruity juices made by a California company, Odwalla, that promoted its products as some of the nation's freshest and healthiest.

To Christy and Chad Glimmestad, who live in Evans, Colo., these fresh-squeezed juices seemed natural and nutritious. But in late 1996, Anna became so ill after drinking Odwalla apple juice that, within two weeks, her kidneys gave out, part of her brain became clogged with dead

## FRESH HAZARDS

First of three articles.

blood cells, her heart faltered and she died.

Health authorities say Anna's body collapsed so fast because the juice had been contaminated with an increasingly troublesome hazard in America's food system: a strain of bacteria known as E. coli O157:H7. The authorities say that while Odwalla was marketing its products as premium sources of nourishment, the fast-growing company had significant flaws in its safety practices — weaknesses that may have allowed tainted apples to contaminate some of its juice and caused 70 people to become sick.

Interviews with former Odwalla managers and company documents show that in the weeks before the outbreak, Odwalla began relaxing its standards on accepting blemished fruit and relying in the authority of its own safety officials, culminating in tense, dramatic moments on the morning of Oct. 7, 1996, the day the contaminated juice was pressed.

By these accounts, production managers brushed aside warnings from a young company inspector that a batch of apples was too rotten to use — some were highly decayed and one had a worm in it — without taking special precautions against contaminants. These issues are being examined by a Federal grand jury in Fresno, Calif., that could bring

criminal charges.

Odwalla officials acknowledge that their safety systems failed to keep out the E. coli, but they deny that the company took any undue risks and insist no lives were broken. Top company executives say that, like many others in the industry, they simply did not realize that E. coli O157:H7 could be in something as acidic as apple juice and they still are not sure how it got into the outbreak. Odwalla has begun pasteurizing many of its products, including apple juice, a sure-fire method of killing bacteria with heat.

What happened at Odwalla (pronounced ode-WALL-a) is more than just a tale of one company and a one-time breakdown in safety precautions. This case and similar outbreaks across the country illustrate one of the least understood new currents in food safety: this dangerous strain of E. coli has begun to infiltrate fresh fruit juices and vegetables, the very foods that Americans are buying more of to be healthy.

Since 1993, when hundreds of people got sick from undercooked hamburgers, the public has associated the biggest hazards with ground beef. Yet a small but growing portion of food-poisoning cases — some stunning in their severity — now arise from E. coli, salmonella and other pathogens in fresh juice and produce.

The nation's food supply remains one of the world's safest. But the emphasis on freshness and nutrition is placing a greater burden on companies to insure that their products are as free of harmful bacteria as other foods that have undergone processes like pasteurization. And while the food industry responds to the changing American palate with a jazzy array of new products, from exotic juices to convenient packs of fancy premixed salads, the Odwalla case shows how some growers and processors are failing to meet the rigorous safety standards needed to keep out dangerous pathogens.

It has also become clear that as more companies expand distribution of their products, unsanitary conditions in even the smallest corners of the industry can cause widespread harm. In another striking example, Federal and state health authorities say they believe a small lettuce producer — operating under conditions cited as blatantly unsanitary — was responsible for an outbreak of E. coli O157:H7 that sickened at least 61 people in Illinois, Connecticut and New York in May and June 1996.

After the outbreak, a team of investigators found that the lettuce had been washed and packaged less than 100 feet from a cattle pen. Although E. coli O157:H7 originates in animals and cattle (feces is the most common source), there were virtually no measures to protect the lettuce.

Until recently, the Government had shown little leadership in dealing with the problems, and there are deep flaws in the system that regulates much of the nation's

food industry. It is a patchwork of weak agencies and a lumbering federal bureaucracy, centered at the Food and Drug Administration, that has focused more on reacting to outbreaks than on preventing them.

The F.D.A. is responsible for the safety of all foods except meat, poultry and eggs. But for an agency that must also regulate pharmaceutical drugs and medical devices, food has never been a high priority, and the F.D.A. has given little guidance to the industry.

In fact, the agency inspected Odwalla's plant just three months before the E. coli outbreak. But Government reports indicate its inspector focused on minor issues and missed signs that the company had failed to build the kind of safeguards that the F.D.A. now contends it should have had.

The emergence of this mysterious strain of E. coli points up how the food chain is becoming more vulnerable to microscopic threats. Millions of Americans suffer some sort of illness each year from something they eat. But Government officials say that less than 5 percent of food illnesses are ever reported to authorities, so they rely heavily on estimates.

All told, the Centers for Disease Control and Prevention estimates that E. coli O157:H7 infects as many as 20,000 Americans a year through meat, produce and other means and kills up to 500. It first began to appear in food in 1980, and the outbreaks have gotten more frequent. Since mid-1995, the C.D.C. has confirmed that more than 300 people had severe diarrhea and other illnesses in nine outbreaks of the E. coli in lettuce, alfalfa sprouts and fresh apple juice or cider.

But what alarms food experts is how devastating the E. coli can be, especially for children. In the Odwalla case, 14 children were hospitalized with a severe blood and kidney disorder, hemolytic uremic syndrome. Anna Glimmestad was the only one who died, but doctors say some of the others are likely to have permanent kidney damage and other lasting problems.

"The biggest problem in the food system right now is the new hazards like E. coli O157:H7," said Caroline Smith DeWaal, a consumer advocate in Washington. "And the most surprising thing is the number of outbreaks linked to fresh fruits and vegetables."

Food contamination, she added, "isn't just a stomachache anymore."

Dr. Michael A. Friedman, the acting commissioner of the Food and Drug Administration, agreed that the hazards are growing. Regulators need "to be more vigilant and to be, honestly, more aggressive," he said.

Many food companies, especially the largest ones, have taken steps to improve safety, and the Clinton Administration recently unveiled several safety initiatives. The F.D.A. has begun to draft new rules for juice production, though it faces opposition from some juice and cider makers who maintain that unpasteurized products taste better and can still be made safely.

Odwalla now says it would never have sold unpasteurized apple juice if it had understood the dangers. "The bottom line is that you would have to say we failed," said Stephen C. Williamson, Odwalla's chief executive. "And those are hard words." Od-

Continued on Page 14

# The New York Times

Sunday, January 4, 1998

1  
3

Odwalla also criticized the roughly 1,500 companies, mostly farms and roadside operations that make fresh apple juice and cider, as failing to heed this lesson.

A close look at the Odwalla case shows there is little margin for error in dealing with fresh products. While Odwalla had told growers it wanted only tree-picked apples, the authorities suspect the bacteria got into its plant on decayed apples that had fallen on the ground and come into contact with feces, possibly from deer.

But former Odwalla managers see another lesson as well: the company, they say, was growing so rapidly that it did not pay enough attention to safety.

"In terms of safety, it could have been improved greatly if we had spent a little more time on it instead of just focusing on production," said Douglas A. Dobbs, a former company planning official.

## The Backdrop

### Quality Standards Vs. Production

Nearly all the giant juice companies, like Tropicana, and some mid-sized upstarts, like Nantucket Nectars, rely on pasteurization. Analysts estimate that 98 percent of the nation's juice goes through this process.

But when Odwalla's chairman, Greg A. Steltenpohl, started the company in 1980, he saw absolute freshness as his entrée into a highly competitive business.

Inspired by his father's habit of squeezing his own orange juice, Mr. Steltenpohl borrowed \$200 from a girlfriend, started making juice at home and delivered it to restaurants in Volkswagen vans. He took the name Odwalla from a character in a jazz song who guided the lost "people of the sun" out of the "gray haze."

Over the years, Odwalla worked hard to build up its brand name, and it now markets more than 20 flavors of juice, smoothies and vitamin-packed drinks in the West and Southwest. Mr. Steltenpohl kept the folksy philosophy, even as Odwalla became a public company in 1993 and its sales soared, to \$59 million in its 1998 fiscal year from \$9 million in 1991. It studied its labels with whimsical sunbursts, gave its products names like Mo' Beta and Femme Vitale and threaded its mission statements with phrases like "Nourishing the Body Whole."

This approach created an enthusiastic following, particularly among professionals. It also turned Odwalla into one of the nation's largest fresh-juice companies, along with a few other regional outfits. And before the E. coli outbreak, Odwalla officials never considered pasteurization, fearing that it would kill nutrients and make their juices taste bland.

"If it's not fresh-squeezed, then it's not part of Odwalla — and that's truly the way we thought," Mr. Steltenpohl said at the company's headquarters in Half Moon Bay, a seaside town south of San Francisco.

But if a juice company does not pasteurize, it is placing a huge strain on the rest of its safety processes. Even the least harmful bacteria, like food-spoilage organisms, multiply so fast that they can render fresh juices undrinkable within a couple of weeks.

This means that the companies have to rely on several lines of defense, from sorting out bad fruit to washing the usable pieces with sanitizing chemicals.

Company documents reviewed by The New York Times show that Odwalla had been grappling with these problems since it opened a \$1 million plant in Dinuba, Calif., in 1993. Tests on samples of its juices then found high readings of general bacteria, yeast and mold that could cause them to spoil. A contractor later warned in a memorandum that Odwalla's citrus-processing equipment was so poorly maintained it was breeding bacteria in "black rotten crud" and "inoculating every drop of juice you make."

After customers complained of illnesses in early 1995, tests found low levels of *Listeria monocytogenes*, a pathogen that can harm pregnant women, in samples of Odwalla's apple and orange juice. Federal law bans the sale of any food or drink with this strain of *Listeria*. But Odwalla officials say the levels in the juice were far too low to cause any health risk.

Mr. Steltenpohl and Mr. Williamson said the company spent several million dollars over the last several years to upgrade plant equipment and install new safety devices, and it reduced the general bacterial counts to relatively low levels. "We thought we were doing a good job," Mr. Williamson said.

But in mid-1995, juice makers in Florida were hit by an outbreak of salmonella in orange juice served at Walt Disney World that sickened more than 60 children and adults.

The cause was odd: authorities believe the disease came from a toad that crawled onto a juice plant's processing equipment. But this was the first time that a toxic bacteria had been discovered in orange juice. It shook much of the industry with the realization that pathogens could survive in highly acidic products.

Before this, there had been two small outbreaks of E. coli O157:H7 in fresh apple juice and cider made on farms in Canada in 1980 and Massachusetts in 1991. But the incidents had received little attention at Odwalla or in the industry, and even the C.D.C. suggested that such contamination was likely to occur at only the crudest operations.

After the Disney World outbreak, the State of Florida drafted new rules, which took effect in early 1996, that required larger fresh-juice companies to add more protections. The regulations prohibit using split or decayed fruit. They also require a two-step fruit-cleaning process, including both an acid-based detergent and chlorine.

As a California company, Odwalla was under no obligation to follow these rules, and few juice companies outside of Florida did.

But Odwalla had just hired two managers from the Florida juice industry. One of them, Dave Stevenson, who oversaw quality assurance as Odwalla's technical services director, contended that Odwalla should add a chlorine rinse as a crucial backup against bad fruit, company documents show. But Chip Bettie, a former Tropicana executive who became Odwalla's senior vice president, feared chlorine would leave an aftertaste and decided that only an acid wash was needed.

By the summer of 1996, as Odwalla's plant pushed hard to keep up with rapidly rising sales, some former company officials say production demands began to overshadow safety concerns.

At the end of August, Steve Kock, Odwalla's quality assurance manager, sent an E-mail to Mr. Bettie saying he planned to start testing for *Listeria* again.

But on Sept. 2, Mr. Bettie wrote back: "why are we doing it, why now, what do we want to PROVE... If the data is bad, what do we do about it. Once you create a body of data, it is subpoenaable."

Mr. Bettie declined to be interviewed. He said in a statement that he was mainly concerned that any testing be based on "a sound plan" to identify corrective measures.

Mr. Kock dropped the testing plan. And by mid-September, he asked to be relieved of his management duties, demoting himself, in effect, to a quality technician. Mr. Kock, who still works at Odwalla, did not return calls for comment.

But former associates said he had grown tired of battling with production officials over safety issues, like how often to sanitize the juice tanks. He was also concerned that Mr. Stevenson was leaving at the end of September to take a sales job with Odwalla in New Mexico.

In a company report on Oct. 4, Mr. Kock described how his department's authority was being cut back. "Philosophically," he wrote, "the department is moving towards

## THE PRESIDENT HAS SEEN

1-5-98

an audit function as compared to one of controlling or policing."

## The Crucial Day

### A Plant Struggles With a Basic Tenet

Interviews and documents suggest that the tensions reached a climax three days later at Odwalla's plant, located about 200 miles from the company's headquarters in the main agricultural belt of Central California.

No time disputes that Oct. 7, 1996, was when the contaminated apple juice was made: the genetic markings on the E. coli in the victim's matched bacteria found in a product bottled that day. On that day, according to a new account provided to Federal investigators, production workers used decayed fruit over the objections of a quality-control inspector and resisted taking extra steps to weed out the rotten pieces.

So in the end, health authorities say, the E. coli outbreak may have occurred simply because the plant violated one of the most fundamental tenets of fresh juice production: Do not use rotten fruit.

The new account comes from Mr. Stevenson, who told investigators last month about the face-off between the quality inspector, Anita Velasquez, and production officials. According to people familiar with his account, Ms. Velasquez described this to Mr. Stevenson in early November 1996, shortly after health authorities had traced the first E. coli illnesses to Odwalla.

Mr. Stevenson had returned to the plant to help, and he asked Ms. Velasquez if anything unusual had happened. She responded, he told investigators, by relating the trouble she had run into on Oct. 7.

Ms. Velasquez then repeated that account, without citing that date, in a two-page handwritten note on Nov. 4, 1996.

In the note, Ms. Velasquez said that the disagreement with the production officials began on a Friday, when she saw "a couple of apple bins that had high decay." She added that she cut open one apple and found a worm in it.

Around this time, Odwalla had received several loads with poor-quality apples because of a seasonal switch from prized Washington fruit to less expensive California varieties. Company documents show that its policy was to stretch its standards for fruit quality at such times — and add extra sorters to pick out bad pieces.

While Odwalla often had accepted only loads in which no more than 5 percent of the fruit was defective, it had lifted that to 10 to 15 percent. In the three weeks before the bad juice was made, the documents show, some loads of apples came in with 25 to 30 percent defective fruit.

Ms. Velasquez wrote that on that Friday, she "didn't want to accept the rest of the bins" in the load. But her objection was overruled by an official who told her "we had to use them since we had the load here."

Ms. Velasquez wrote that the production staff used half of that load on Friday and decided to use the other half on Monday. That meant the apples would sit in a cooler for two days, and she was worried that bacteria would spread among them.

So she got the leader of the apple press line to agree to assign three or four people on

Monday to sort out bad apples, instead of the usual one or two.

When Ms. Velasquez came in on Monday morning, she saw only one sorter picking out rotten apples as they rolled by to be pressed into juice. She also spotted 10 to 15 decayed apples that the sorter had missed.

She suggested slowing the line and was told a second sorter would be added. But when she checked 10 minutes later, there was still only one sorter, and she asked again to slow down the line. "At this point, everyone was upset at me," she wrote. She added that the tensions had risen this high "only because I wanted to reject it but couldn't due to higher power."

In her note, Ms. Velasquez did not indicate that she or the production officials took further action.

In a brief telephone interview, she said, "What I wrote is true." She said that she did not know if these problems were connected to the illnesses, but added, "It was an incident that happened at that time."

But Ms. Velasquez, who is being represented by a lawyer for Odwalla, declined to comment further. Chris Gallagher, an Odwalla spokesman, said Ms. Velasquez had told company lawyers that she could not recall the dates when the incidents occurred.

"Obviously, the 'Friday' and the 'Monday' could well be dates other than October 4 and 7," Mr. Gallagher wrote in a statement. "Indeed, there are a number of inconsistencies suggesting that the incident referred to in the memo may not have occurred over that precise weekend."

Mr. Gallagher said one inconsistency was that Odwalla's records indicate that the company used three sorters on the morning of Oct. 7. He also said that Ms. Velasquez had told company lawyers that on the day she described, she ended up halting the production line until extra sorters were added.

"This is an indication of good quality management, not a failure," Mr. Gallagher wrote.

But Federal and state inspection reports confirm that the company used apples from two loads with relatively high defect levels on the day the tainted juice was made. Moreover, Warren Hayes, a former Odwalla production supervisor, said there may have been a similar incident that day. Mr. Hayes said a production team leader told him that he had objected to using rotten fruit but others had "made the decision to run it."

Mr. Hayes added: "Generally if it's that bad, you shouldn't be running it."

## The Reaction

### A Broad Debate Over Safety Rules

Right after the outbreak, new regulatory inspections also found other flaws in Odwalla's safety programs. And the problems at Odwalla have since sparked a broad debate

over what rules are needed to insure the safety of fresh juices and cider.

The F.D.A. cited Odwalla for having an "inadequate" program to test for food-poisoning bacteria. Odwalla's chemical supplier said the brand of acid wash Odwalla was using had killed all the E. coli O157:H7 in only 8 percent of lab tests and should not have been used without chlorine.

And while Odwalla now has one of the most extensive bacteria-testing programs in the industry and has expanded its fruit-washing, it also has become one of the most vigorous champions of a solution it once disdained: pasteurization.

The company hired safety consultants, then identified every point where bacteria could slip in and devised measures to kill them. This systematic approach, known as a Hazard Analysis Critical Control Point plan, is what Federal regulators are starting to require as the best answer to the new threats in other types of foods, from seafood to meat. The F.D.A. said it would draft a similar rule for juices.

With apples, where the skin gets mashed right into the juice, Odwalla says this has inevitably meant a shift to pasteurization. But given that orange juice can be extracted without touching the rind, Odwalla's tests show it is still safe to sell it without pasteurizing.

But a bitter debate is shaping up. Many doctors now caution against giving children fresh apple juice or cider, and small cider makers fear that more regulations could put them out of business. Other companies think the F.D.A.'s move will lead to pressure to pasteurize all fresh juices. And they say this is too sweeping a conclusion to draw from Odwalla's failure.

"The perception I've got is that it was just a breakdown in good manufacturing practices," said Marc Isaacs, co-chairman of the American Fresh Juice Council.

But Mr. Williamson, Odwalla's chief executive, said his company has "a more sensitive perspective on safety" than it used to. He added: "Having Anna die was unquestionably an horrifically awful, terrible thing to go through. You can't imagine worse."

Next to Anna Gimmestad, 4-year-old Amanda Berman was perhaps the child most severely injured by Odwalla's apple juice. She drank it at a Starbucks in Seattle and was catapulted into a maze of medical tubes and machines — 17 days of kidney dialysis, vomiting and blood transfusions. After her illness, she had trouble sleeping for months.

The Berman's are suing Odwalla, which has paid an undisclosed sum to the Gimmestads and settled 5 of 10 lawsuits by other victims.

For most of these families, the big worry is that their children will experience problems as they grow older. Of the children who got hemolytic uremic syndrome in the 1993 E. coli outbreak involving hamburgers, some developed diabetes, and one has needed a kidney transplant.

"You just got to wait and see," said Amanda's father, Adam.

NEXT: Tracing a three-state food poisoning outbreak to one small lettuce producer.

THE PRESIDENT HAS SEEN

1-5-98

Food Safety

## EXECUTIVE SUMMARY

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year--mostly the very young and elderly--die as a result. The threats are numerous and varied, ranging from *Escherichia coli* (*E. coli*) O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water--and most recently, to hepatitis A virus in frozen strawberries.

In his January 25, 1997 radio address, President Clinton announced he would request \$43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify specific steps to improve the safety of the food supply. He directed them to consult with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days. This report responds to the President's request and outlines a comprehensive new initiative to improve the safety of the nation's food supply.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that the public and private sectors should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Six agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)--the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public-health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies

It will use the \$43.2 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

The actions in this report build on previous Administration steps to modernize our food-safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review (NPR), the agencies have encouraged the widespread adoption of preventive controls. Specifically, the NPR report urged implementation of Hazard Analysis and Critical Control Point (HACCP) systems to ensure food manufacturers identify points where contamination is likely to occur and implement process controls to prevent it. Under HACCP-based regulatory programs there is a clear delineation of responsibilities between industry and regulatory agencies: Industry has the primary responsibility for the safety of the food it produces and distributes; the government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action if necessary.

The Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995, the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulations to modernize the nation's meat and poultry inspection system. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. Additional actions outlined in this report will encourage the use of HACCP principles throughout the food industry.

The need for further action is clear. Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food for there to be a risk of illness; for others, we do not have the ability to detect their presence in foods. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state, and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource constraints increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can go by before some plants receive a federal inspection.) Increasing quantities of imported foods flow into this country daily with limited scrutiny. Some food processors, restauranteurs, food-service workers, supermarket managers, and consumers are unaware of how to protect food from the threat of foodborne contaminants. These and other deficiencies will be addressed by key Administration actions outlined in this report and described below.

### **Enhance Surveillance and Build an Early-Warning System**

As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY98 funds, the Administration will:

**Enhance Surveillance.** The Administration will expand from five to eight the number of FoodNet active surveillance sentinel sites. Personnel at these sentinel sites actively look for foodborne diseases. Existing sites are in Oregon, Northern California, Minnesota,



---

**October 2, 1997**

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

Message Creation Date was at 2-OCT-1997 11:39:00

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

Final



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Office of the Assistant Secretary  
for Legislation

Washington, D.C. 20201

January 9, 1998

The Honorable Tom Bliley  
Chairman, Committee on Commerce  
U.S. House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

In response to your letter, dated November 21, 1997, to Secretary Shalala concerning additional questions submitted by members of the Commerce Committee, the Secretary asked me to provide you with the enclosed responses.

Thank you for the opportunity to complete the Committee's hearing record.

Sincerely,

Richard J. Tarplin  
Assistant Secretary for Legislation

Enclosure

In all Medicaid recoveries, the federal share is based on the individual state's match rate (the percentage of its Medicaid costs paid for by the federal government). On average, the federal government pays about 57 percent of Medicaid expenditures for services. Therefore, the federal government will recover about 57 percent of the Medicaid-related share of the total settlement. The federal government also pays half of the administrative and litigation costs related to Medicaid, including those incurred by the states in recovering funds from liable third parties.

At present, it is difficult to estimate exactly the Medicaid-related share of the total settlement. We believe most state suits were primarily based on Medicaid expenditures, though some may be related, in varying degrees, to state programs other than Medicaid. We expect states to credit us with the federal share whenever the state receives payment from the tobacco industry. In these tobacco settlements, HCFA will work with each state involved to determine the appropriate amounts. The 11/3/97 letter from HCFA to state Medicaid directors invites them to discuss this with us.

***Questions submitted by MR. DINGELL***

1. Madam Secretary, the President's proposal includes an element related to increasing the price per pack of cigarettes, up to \$1.50 per pack over the next 10 years. You know there will be an argument that such a price increase will penalize adult smokers and, further, that a price increase of this magnitude or higher could result in destroying the American tobacco industry. This argument is extended to point out that such a result would be counter-productive, because it could mean that the agreed-on financial contributions could not be made by the tobacco industry and, therefore, the expected public health activities could not be undertaken. How do you respond to these arguments?

**RESPONSE:** The President called for a combination of industry payments and penalties to increase the price of cigarettes by up to \$1.50 in the next decade, as necessary to meet youth smoking reduction targets of 30 percent in 5 years, 50 percent in 7 years, and 60 percent in 10 years. We have proposed this because increasing the price of cigarettes is the most effective method of reducing underage smoking. Youth smokers are far more price sensitive than adult smokers, which means that price increases should disproportionately reduce youth smoking — our primary goal in this initiative. Although price increases may reduce adult smoking as well, we believe the tobacco industry will be able to meet its obligations.

The President's fundamental intent in this initiative is to focus on this historic opportunity to significantly reduce the use of tobacco among young people. Raising the price of tobacco products is a critical element in achieving that goal.

2. In discussing the need for international tobacco control, your testimony stated that American embassies and missions should not be taking actions or be involved in activities that promote the demand for tobacco, especially among young people. What specific kinds of activities are you referring to? What activities should Congress and the administration be attempting to curtail?

**RESPONSE:** Congress approved an amendment to the FY 1998 appropriations bill for Commerce, Justice, State and the Judiciary (Section 618 of P.L. 105-119) which stipulates that funds provided under the appropriations act cannot be used to promote the sale or export of tobacco products, or to seek the reduction or removal by any foreign country of restrictions on the marketing of tobacco products, except for restrictions that are not applied equally to all tobacco products of the same type. An Interagency working group is now preparing comprehensive guidance on tobacco-related issues for distribution to all overseas posts.

The United States should increase its commitment to the efforts of the international health community to reduce tobacco use abroad, particularly as it affects the health of children and youth especially in developing countries. This can be accomplished by improving training, surveillance, research, and education. To reach out to foreign countries, the U.S. should act either to initiate multilateral and bilateral collaborations, or to invigorate our involvement in already existing collaborations, such as the WHO's Tobacco or Health Plan of Action (1996-2000).

3. In talking about an enhanced research agenda, you emphasized in your testimony the need for a comprehensive approach that includes a whole spectrum of activities, from basic biomedical research and disease-specific studies to epidemiological and other research. What level of research funding are you envisioning? How does this future research agenda compare with what is going on already, funded by NIH, CDC, SAMHSA, and others?

**RESPONSE:** Tobacco use is our nation's leading cause of premature death and preventable illness. It is responsible for 30 percent of the cancer incidence, one-third of cardiovascular disease deaths and 90 percent of chronic obstructive pulmonary disease, taking the lives of 400,000 Americans each year and consuming \$50 billion in medical expenditures to treat. Each year, work by the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies identify additional diseases (SIDS, low-birth weight babies, miscarriage, and birth defects such as cleft lip and palate, and periodontal disease) where tobacco use is implicated.

Targeted funding to support a broad spectrum of tobacco-related research could help take advantage of the many promising scientific opportunities that could

reduce the toll of tobacco-related illness. To make significant progress in preventing illness and addiction, improving treatments, and better understanding the causes of tobacco-related diseases, we should support a robust and comprehensive research portfolio. Such a portfolio should examine tobacco's impact on health, disease, and quality of life, and include studies from seven broad research categories: biomedical, clinical, behavioral, health services, public health, product design, community-based and surveillance/epidemiologic research. Research must address issues at the national, state and local levels and include studies of tobacco use among both youth and adults. While most tobacco-related research is currently funded through the NIH, significant research in this field also is conducted by the other PHS agencies. In addition to these current activities, there are other important areas of tobacco-related research to explore. For example-

- ▶ Research directed toward ensuring that young people do not start using tobacco;
- ▶ Research to identify and test the most effective interventions for helping current users to stop use of tobacco with emphasis on special populations (especially children);
- ▶ Research to prevent disease in former smokers;
- ▶ Research to assess baselines and monitor trends in incidence and prevalence of tobacco use behaviors and exposures to tobacco smoke (including appropriate use of biomarkers);
- ▶ Research to definitively characterize the environmental and biobehavioral underpinnings of nicotine addiction in both children and adults;
- ▶ Research on non-addictive and reduced risk tobacco products;
- ▶ Research on health effects of tobacco smoke in the environment;
- ▶ Research to characterize all tobacco and combustion products (including those of newly-introduced tobacco products) and their health consequences;
- ▶ Research to evaluate the success of approaches to limit access by children and youth to tobacco products;
- ▶ Scientific review of tobacco industry research and other information that has been released and that will be released. This would include work on product design, marketing strategies (especially youth-oriented strategies), and health research. The review will help us determine our future research priorities and enhance the development of technologies and products to reduce the adverse health effects of tobacco products.

4. I was pleased to note the Administration's concern about the impact of the tobacco settlement, and any related legislation, on the variety of interests that were not involved in the settlement negotiations, such as tobacco farmers, retailers, vending machine companies, and others. What proposals is the Administration developing that will try to minimize adverse impact on tobacco farmers and others?

**RESPONSE:** The President made it clear that any tobacco legislation must protect tobacco farmers and their communities. Most tobacco farmers live and work on small family farms; in many cases, their families have been growing tobacco for generations. In some states, entire communities rely on income from the tobacco crop. The Administration is committed to working with Congress in a bipartisan fashion to protect the financial well-being of tobacco farmers, their families and their communities. As I mentioned in my testimony, there are several active proposals before Congress and there will be more to come. Secretary Clinton and I will continue to work with Congress to develop effective solutions.

**Questions submitted by MR. STUPAK**

1. What are the public health ramifications of not approving the proposed settlement or some variation?

**RESPONSE:** Each day, nearly 3,000 young people in the United States become regular smokers. Almost 1,000 of those young people will have their lives cut short by diseases caused by their use of tobacco. In fact, 5 million young people alive today will die prematurely because of tobacco use. We must act now to prevent this terrible tragedy from continuing, and the President's five principles lay a strong foundation for congressional action on meaningful, comprehensive tobacco legislation in 1998.

2. Under current law, if a plaintiff is awarded a judgment against a state's Medicaid program, is the federal government responsible for paying its pro-rata share of the judgment?

**RESPONSE:** HCFA will match all court-ordered state Medicaid expenditures, as long as the payment falls within the parameters of Title XIX. The federal government will pay all pro rata shares of the judgment arising from proper operations of the Medicaid program. However, if the state is taking actions not permitted by the Medicaid program, or is sued for a non-Medicaid issue, HCFA will not participate.

3. Is it your understanding that current law would have to be amended to allow the states to keep 100 percent of the settlement?

**RESPONSE:** Yes. Section 1903(d) of the Social Security Act clearly states, "(2)(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party

*pursuant to the provisions of its plan in compliance with section 1902(a)(25)...."*

Since Medicaid's inception, the statute has mandated that the federal government share in any recoveries just as it shares in payment of Medicaid costs. To excuse states from sharing Medicaid-related tobacco recoveries would require specific statutory authority.

4. Does the Administration believe that the Health Care Financing Administration should be allowed to recoup the federal share of the judgment?

**RESPONSE:** As noted in question 3, current law requires that HCFA pursue recovery of the federal share of any settlement or judgment. With respect to the proposed legislation, on December 5, the President sent a letter to the National Governors' Association and to the National Association of Attorneys General indicating his desire that the allocation of funds between state and federal government be "resolved through legislation."

5. If changes to current law are required to allow the states to keep the settlement proceeds, does the Administration support such a change?

**RESPONSE:** The President stated in his December 5 letter that he "would prefer to see the allocation of tobacco funds resolved through legislation" and he "looks forward to working with the States and with Congress to find a mutually agreeable purpose for the funds generated by tobacco legislation."

6. Should the litigation in Minnesota, which is scheduled to go to trial in January, delay Congressional action on the settlement?

**RESPONSE:** Minnesota's lawsuit against the tobacco industry is currently scheduled to begin on January 20, 1998. If it proceeds, this trial could last for months. Consideration of comprehensive tobacco legislation, which can begin once the Congress reconvenes, does not have to interfere with that litigation. Both can take place at the same time.

7. Why should states be allowed to recover the costs they spent treating tobacco related illness, but private insurance plans and union plans will not?

**RESPONSE:** There is nothing to prevent the Congress from considering claims by private insurance plans and union plans in its deliberations on comprehensive tobacco legislation.

**Questions submitted by Mr. KUSH**

1. The *Chronicle of Higher Education* has reported that African American scholars received less than one percent (0.4%) of the National Institutes of Health (NIH) research that was awarded by NIH in 1991. These rates have not improved significantly since then.

Although minority medical schools and educational institutions receive little federal assistance for minority health research, they continue to commit significant funds to this vital area.

Researchers at minority institutions are most likely to be familiar with the community resources needed to develop effective tobacco control programs in this community.

Therefore, what steps will the Administration take to use funds from the settlement to support effective public health programs?

**RESPONSE:** Despite significant progress in the overall health of the Nation, there are continuing disparities in the burden of death and illness experienced by minority populations as compared to the U.S. population as a whole. These disparities are noteworthy in the area of tobacco. Minority groups and other special populations suffer a disproportionate burden of tobacco-related disease and are often among the greatest users of tobacco products.

Given these trends, the Administration is currently considering ways to target resources to address these health disparities in a host of health areas (e.g., heart disease, HIV/AIDS, diabetes, and infant mortality). We look forward to working with Congress in crafting innovative ways to address these public health problems.

2. Several studies on reducing tobacco use, including the Department of Health and Human Services (DHHS) report, "Strategies to Control Tobacco Use in the United States: A blueprint for public health action in the 1990s" by Dr. Louis Sullivan (1991), have argued that innovative strategies will have to be developed to operate effective education and cessation campaigns in the minority community.

In light of these studies, what types of efforts does the Administration feel DHHS and other agencies can have in designing and overseeing the types of extensive community-based measures that will be required to truly reduce tobacco use in the minority community?

**RESPONSE:** Public health studies of tobacco use and the incidence of tobacco-related death and disease are necessary to determine accurately the scope of this problem within minority communities. Many of these issues will be addressed in the upcoming Surgeon General's Report on *Tobacco Use among Minority Populations*. However, significant data gaps must be closed before we can be sure that effective measures to prevent and control tobacco use among minority youth are successful.

Culturally appropriate strategies are created through partnership and collaboration with members of minority population groups. This collaboration promotes a sense of ownership, enhances receptivity, and elevates the impact of tobacco control messages to minority youth. The experience of the Department of Health and Human Services is extensive. For example, the Centers for Disease Control and Prevention (CDC) fund 32 states, the District of Columbia and several national organizations to ensure participation by diverse community groups, coalitions and leaders to strengthen tobacco control initiatives nationwide. NIH's National Cancer Institute (NCI) funds 17 states for tobacco control. NCI initiated a Multicultural Committee which seeks to address diversity issues in tobacco control programming. The Indian Health Service also reduces tobacco use through cessation programs and several policy efforts. The Health Resources and Services Administration researches the effectiveness of medical care delivery systems which treat nicotine addiction and provide training programs that reach many minority communities.

Building on this experience, the Administration will continue to work with Congress to make sure that the health research and tobacco control programs that result from this legislation are responsive to our minority communities.

3. In addition to research for effective prevention and cessations programs for minorities, there are a number of minority health issues related to tobacco use that require further research. For example, 76 percent of African Americans smoke menthol cigarettes compared with 23 percent of whites.

This is particularly disconcerting since menthol cigarettes can be inhaled more deeply, and therefore, cause more damage to the lungs. However, most admit that research on menthol cigarettes is severely lacking. What kinds of research efforts can be undertaken on menthol cigarettes and other tobacco-related public health issues that are specific to the minority community?

**RESPONSE:** Research that examines the causes and ultimate effects of tobacco use is being conducted by several Public Health Service (PHS) agencies, particularly the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). While this research has not focused on additives in cigarettes,

important strides are being taken in understanding the role of tobacco among youth and adults in minority communities.

**CDC's National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health:** Smoking patterns differ significantly between African American and white youth. In 1995, white high school students had double the smoking prevalence of black high school students. To better understand these large differences in youth smoking among racial groups, CDC is sponsoring multisite collaborative qualitative research among teenagers. This research has revealed striking differences in teen attitudes and determinants of smoking by race. For example, African American girls report particularly negative perceptions of smoking and the potential impact of smoking on their reputations and future; these attitudes correspond to the lower smoking rates experienced among African American girls as compared to white girls.

The upcoming Surgeon General's Report on tobacco use among minority populations will review the latest research findings on the health consequences of tobacco use, including use of mentholated products, among minority populations. The report also will review patterns of use, factors influencing tobacco use, and tobacco control and education efforts among minority populations.

**National Cancer Institute (NCI):** Minority smoking interventions have remained a strong focus of NCI-supported smoking control research. For example, in the 17 state ASSIST demonstration projects, all participating sites are required to address minority smoking issues. More than 10 million African Americans and seven million Hispanics or members of other ethnic groups are affected by ASSIST cessation and prevention interventions.

Additionally, NCI supports a broad portfolio of behavioral and intervention research related to tobacco use among African American, Hispanic and Native Americans. For example, NCI continues to support two broad-based community-oriented cancer prevention and control initiatives aimed specifically at Black and Hispanic populations which have significant smoking control components. The National Black Leadership Initiative on Cancer and the National Hispanic Leadership Initiative on Cancer represent grassroots efforts to reduce cancer incidence and mortality by modifying environmental and lifestyle factors which have been associated with increased cancer risk.

An NCI-supported project conducted at Stanford University (entitled *Community-Based Approaches to Tobacco Control*) is designed to provide postdoctoral training in community-based intervention strategies, including interventions focused on minority groups. Investigators at Columbia University are testing intervention strategies suitable for community sites to reduce cancer risks associated with

tobacco and alcohol use. These interventions emphasize parent-family member involvement in such issues. Investigators at Duke University are focusing on techniques related to cancer risk communication among African-Americans in order to develop cost-effective interventions to improve decision-making about cancer related behaviors such as smoking reduction and increased use of mammography. NCI-supported investigators at San Diego State University have recently begun a project entitled, "Reducing Cancer Risk in Migrant Hispanic Adolescents," designed specifically to reduce tobacco use among Hispanic youth ages 12 to 15.

Lastly, NCI has developed and funded a variety of innovative tobacco intervention programs for Native Americans. These projects have dealt with a variety of techniques to reduce habitual tobacco use among both adolescents and adults. For example, investigators at the Center for American Indian Research and Education and the University of California-Berkeley targeted fourteen rural and four urban northern California Indian clinics to increase long-term smoking cessation through health-provider-based investigations. At the University of New Mexico, investigators included Indian children in grades 5-7 in fourteen schools in New Mexico and Arizona to compare the effectiveness of a school-based curriculum versus curricula augmented with family/community interventions. Other investigations among Native Americans are being conducted.

**National Heart, Lung, and Blood Institute (NHLBI):** Menthol cigarettes pose a number of questions for basic science, clinical science, and public health that can only be answered by further research. In particular, it is not clear whether a preference for menthol cigarettes among blacks and Asians is culturally derived or the result of selective advertising. However, understanding racial and cultural differences in smoking patterns and brand preferences is critical to the success of a public health effort to reduce consumption of tobacco products.

In the area of smoking prevention, NHLBI research is seeking to understand race-specific reasons for habitual smoking. For example, one project is examining national survey data to uncover attitudes and practices that lead to acquisition of smoking habits among African American teenagers.

A number of studies are attempting to identify effective ways of encouraging and facilitating smoking cessation among minorities. For example, interventions are being delivered through prevention coordinators in the primary care setting, churches and other African American community organizations, public health nurses providing care to maternity patients, and pediatric clinics serving low-income young mothers.

**National Institute on Drug Abuse (NIDA):** NIDA research spans many areas from prevention to treatment. Many of the observed differences in drug use behaviors

among various populations, including tobacco use among ethnic/racial groups, were identified as the result of NIDA-sponsored research. For example, the *Monitoring the Future* Survey tracks changes in the beliefs, attitudes, and drug use of young people in the United States. The Community Epidemiology Work Group provides descriptive and analytical information regarding the nature and patterns of drug abuse, emerging trends, characteristics of vulnerable populations and social and health consequences.

In addition to analyzing and monitoring trends in smoking behavior, NIDA sponsors research into effective prevention programs to meet the specific needs of minority populations, including African Americans. For example, NIDA is currently funding the Tri-Ethnic Center for Prevention Research at Colorado State University to study drug abuse prevention among minority youth as well as several other grants specifically addressing prevention issues among minority youth. All of these studies have tobacco use as a major target of prevention efforts.

To better understand the root causes of the observed racial and ethnic differences, NIDA also is sponsoring research to examine nicotine sensitivity in minority populations. For example, an investigator at the San Francisco General Hospital, has an ongoing grant exploring individual and racial/ethnic differences in susceptibility to tobacco addiction and its health consequences focusing on nicotine pharmacokinetics and metabolism. Another grant, "Biobehavioral Nicotine Dependence in Black Women," is examining smoking behavior, nicotine metabolism and the effect of menthol-containing cigarettes on smoking behavior specifically in African American women. As a better understanding of the underlying biochemical mechanisms of these differences is developed, treatment programs can be designed to address the needs of the African American community.

Food Safety weekly ita

1/17/98

## FOOD SAFETY IN BUDGET <sup>will fund</sup> ~~continued~~

The new budget contains a significant new commitment to improving food safety programs in HHS and <sup>USDA</sup> FDA. The \$101 million increase goes to a variety of <sup>that were</sup> initiatives, including: implementing our aggressive fresh produce plan to hire FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; increasing the risk assessment on beef, chicken and pork to better determine the source of the greatest risk of contamination; developing <sup>better</sup> more tests for meat and poultry for federal inspectors and others to detect food borne illnesses; improving educational outreach on proper food handling, especially to the elderly and poor; and expanding <sup>the new national early warning system</sup> CDC's surveillance activities for food-borne illnesses. These increase come after an increase of <sup>more than</sup> approximately \$40 million last year. We are looking into ways to highlight this effort in the State of the Union speech. In addition to mentioning the specific new programs in your speech, you could note that on the day before the speech <sup>USDA</sup> commenced ~~implementation of your our new science based enforcement system for meat and poultry and that we are bringing food safety technology into the next century.~~

programs that are part of  
the Presidential Food Safety  
Initiative <sup>you</sup> ~~was~~ announced  
last year

<sup>science-based</sup>  
USDA's new system for ensuring meat safety <sup>takes</sup> ~~took~~ effect.

As you may recall this new <sup>preventive</sup> approach to enforcing our nation's food safety law (known as HACCP - Hazard Analysis <sup>and</sup> Critical Control Point) was recommended by the VP in ~~1993~~ in response to the <sup>foodborne</sup> outbreak ~~of~~ that occurred in the northwest ~~center~~ in 1993.



DEPARTMENT OF AGRICULTURE  
OFFICE OF THE SECRETARY  
WASHINGTON, D.C. 20250

Food Safety SW

January 6, 1998

Honorable Franklin D. Raines  
Director  
Office of Management and Budget  
Room 252 Old Executive Office Building  
Washington, D.C. 20503

To -  
Tom

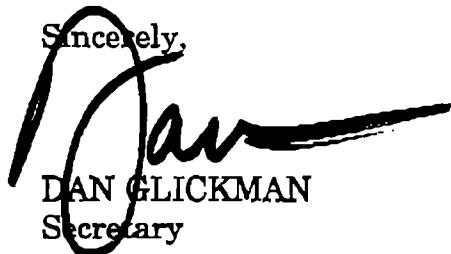
Dear Frank:

My staff advises me that OMB has decided to change the presentation of the meat and poultry inspection user fee proposal in the budget. They tell me that our "current law" appropriations request will anticipate enactment of the user fees, and therefore will request only \$150 million rather than the full \$620 million which would be required to operate the program under current law.

I am writing to urge you to reconsider this decision. I realize that there are budgetary reasons for this sort of presentation, but it really creates some problems from a policy perspective. It will allow some in Congress to accuse the Administration of having under funded the meat and poultry inspection program and raise questions about the seriousness of our overall commitment to food safety. It also sets the stage for a crisis later in the year if the Congress does not enact user fee legislation, and we have to find a way to fund the appropriations requirements of the program or shut it down.

We intend to work hard to secure enactment of the user fee legislation. I do not think our cause is helped, however, by a budget presentation which raises questions about our commitment to food safety.

Sincerely,

  
DAN GLICKMAN  
Secretary

Page Two  
December 30, 1997

If you agree, I would appreciate your sending word to the participants at our December 16 meeting that follow-up meetings with WGU staff are appropriate and desirable. I intend to request that WGU staff work to convene these meetings as soon as possible, preferably before the end of January.

My further proposal, Tom, would be to reconvene a larger meeting with all the players from the "working group" once WGU and the departments have had an opportunity to access specific department and program linkages. If you are amenable, I think a second meeting with the group might take place in late February or March. At this meeting, I am hopeful that WGU staff would be prepared to offer specific proposals that are cross-cutting for the federal government. It would also be useful to tie up loose ends so that we all have a full understanding of the federal government's more comprehensive response to the potential of WGU.

Again, many thanks for your leadership in setting up the meeting on December 16. I look forward to hearing your response to my proposal for next steps.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Roy", with a large, sweeping flourish extending from the end of the name.

Roy Romer  
Governor

cc: Jeff Livingston, WGU  
Bob Albrecht, WGU  
Tom Freedman, Domestic Policy Council

Food Safety 2w

Dear Editor:

As Administrator of the Food Safety and Inspection Service (FSIS), I feel compelled to respond to a recent article which I believe does your readers a disservice by presenting an incomplete picture of our meat and poultry inspection system. First, in every instance cited by the article, inspectors took action to prevent unsafe food from reaching consumers and to correct unacceptable practices by the plants.

It is important to remember that the story was not about the new food safety inspection system, called Hazard Analysis and Critical Control Points (HACCP). In fact, the article is based largely on 1996 events that occurred prior to the implementation of the new food safety requirements. The fact that a plant with over 1,700 regulatory violations was not shut down in 1996 is a fair criticism. It should have been. The reason it wasn't, however, highlights one of the important benefits of the new food safety system, which we began implementing in January 1997.

Under the old system, inspectors would impose corrective actions when there were violations and prevent unsafe food from reaching consumers, but FSIS would allow plants to accumulate large number of deficiencies without taking action to suspend inspection and shut plants down. Under the new food safety system, FSIS has a new tool to stop operations where there is a pattern of deficiencies and insist on preventive measures to improve food safety before a plant can reopen.

The article suggests that inspectors will not be documenting and taking action when necessary to address food safety problems under HACCP. This is wrong. Inspectors will use non-compliance reports to document food safety violations. Inspectors will continue to be present everyday to verify compliance and to take direct action when necessary. These actions will lay the groundwork for documenting repeated failures. And where there are repeat failures, FSIS can and will take formal action to shut down the plant.

Your readers should also be aware that the Clinton Administration has asked Congress for additional enforcement authority to fine companies for violations of food safety standards. The Department of Agriculture (USDA) can impose fines against people who violate a wide variety of requirements. For example, USDA can fine circuses for mistreating elephants, and we can fine people who sell undersized potatoes and people who don't keep the right paperwork on watermelons. But we can't fine companies that violate food safety standards. That's just wrong.

Consumers rightfully expect government and industry to do a better job to improve food safety, and the new food safety system is a revolutionary improvement over the old system. The ability to fine companies that violate food safety standards will make the new food safety system

even more effective, and we are working hard to convince Congress to give us this important power.

Sincerely,

Tom Billy  
Administrator



# U.S. DEPARTMENT OF AGRICULTURE

## OFFICE OF THE SECRETARY

Telephone (202) 720-3631 Fax (202) 720-5437

FOOD  
SAFETY  
FED

### FAX COVER SHEET

DATE: \_\_\_\_\_

NUMBER OF PAGES \_\_\_\_\_, INCLUDING COVER SHEET

PLEASE DELIVER TO: Tom

FAX NUMBER: ( ) \_\_\_\_\_ PHONE NUMBER: ( ) \_\_\_\_\_

- FROM:
- ☐ DAN GLICKMAN, SECRETARY
  - ☐ JOHN GIBSON, SPECIAL ASSISTANT
  - ☐ GREG FRAZIER, CHIEF OF STAFF
  - ☐ KOFI DEGRAFT-JOHNSON, EXECUTIVE ASSISTANT
  - ☐ REBA PITTMAN EVANS, DEPUTY CHIEF OF STAFF, INTERNAL AFFAIRS
  - ☐ PATRICK STEEL, DEPUTY CHIEF OF STAFF, EXTERNAL AFFAIRS
  - ☐ JOSE VENZOR, ASSISTANT TO THE DEPUTY CHIEFS OF STAFF
  - ☐ PAUL DRAZEK, SPECIAL ASSISTANT FOR POLICY
  - ☐ ANNE KENNEDY, SPECIAL ASSISTANT FOR POLICY
  - ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
  - ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: My Home # is 332-3570. I will be checking voice mail at work 720 3808.

Press Secretary's: Tom AmmanWee 703 370 9816, pager 888 378 5193

FSES Administrator Tom Bily, 301 649 2066, cell phone 202 531 1353

Am

I am leaving Sunday am for Chicago. AmmanWee leaves around noon.

Also sending Sec. speech on Sunday fig.

JAN 16 '98 15:55 FR 10-ADM

202 775 9861 TO 581

P.05/05

\_\_ Don't defrost meat and poultry on your countertop. Use the refrigerator, microwave or cold water.

\_\_ Do wash your hands after handling raw meat, poultry or eggs. \_\_ Don't use the same plates, cutting boards or utensils for cooked foods that you've already used for raw meat and poultry.

\_\_ Do use a meat thermometer to ensure internal food temperatures are high enough to kill dangerous bacteria

\_\_ Don't truss the drumsticks when cooking whole poultry; heat needs to penetrate the joints.

#### ^FAST FACTS<

##### Minimum internal temperatures.

- \_\_ For ground beef \_ 160 degrees Fahrenheit.
- \_\_ For roasts, steaks, and chops \_ 145 degrees.
- \_\_ For fresh pork \_ 160
- \_\_ For ground poultry \_ 165.
- \_\_ For poultry breasts \_ 170.
- \_\_ For fresh ham \_ 160.

##### Maximum storage time for fresh foods:

- \_\_ For red meat \_ 3-5 days in the refrigerator.
- \_\_ For poultry \_ 1-2 days in the refrigerator.
- \_\_ Cooked, perishable foods \_ 2 hours at room temperature.

^For use by clients of The New York Times News Service@<



REMARKS OF SECRETARY DAN GLICKMAN  
5TH ANNIVERSARY OF PACIFIC NORTHWEST OUTBREAK  
CHICAGO, ILLINOIS -- JANUARY 18, 1997

Good afternoon. We are here to remember Celina, Lauren, Michael and Riley, and to pay our respects to the many more -- Alex, Eric, Florence, and the others all of whom I cannot name -- those who are gone, those who are left behind, those who have survived.

In my faith, we have a saying: 'The only truly dead are those who have been forgotten.' I carry with me today a very simple message from President Clinton: America will never forget.

We have heard today words of remembrance. We have heard about the meaning of respect. I am here -- as your Secretary of Agriculture -- to talk about resolve.<sup>1</sup> This church provides a fitting backdrop because I most certainly am preaching to the choir. But our refrain echoes across this nation. Every American family is with us in our effort to improve the safety of our nation's food.

You know, this afternoon as I got on a plane to come here, I thought to myself:

We hear so much these days about how people just want government to get out of the way. Yet no one would ever question government's role in ensuring our planes are safe. If you asked people what should government do about aviation safety? The answer would be nearly unanimous -- *more*.

The American people feel equally strongly about food safety. Everywhere I go, it is the *first* question on people's minds. Is my food safe? Is my family at risk at the dinner table or a restaurant? How can I be sure?

People look to their government to protect them in ways that they cannot protect themselves. That is why, as Secretary of Agriculture, there's *nothing* I take more seriously than the safety of America's food. This is the one that keeps me up at night.

At the dawn of this century, Chicago was home to a great national hero by the name of Upton Sinclair. By the simple act of telling the American people the truth, he pushed government and meatpackers to do what was *right* -- to take *basic* steps to protect the public health.

More than 90 years later, names like Nancy Donley, Roni Rudolph, and Mary Heersink may not be as familiar, but the impact that *all* of you in this organization have had on our nation is at *least* as lasting and profound.

Unlike Mr. Sinclair, you did not choose this calling. I'm sure that many of you would much

---

<sup>1</sup>'Remember, Respect, Resolve' is the theme.

rather be serving on the PTA, or as a Little League coach, or the head of a Girl Scout troop. Instead, you found one another through *unspeakable* tragedy, and found *in* each other a powerful devotion to seeing that other families *never* experience what you have.

President Clinton had just taken office when your nightmare began. Your experiences and the voice and face you gave to some very somber statistics galvanized this Administration and our nation behind a food safety revolution.

We started by creating a separate Food Safety and Inspection Service at USDA -- run by independent public health experts at an arm's length from the interests of agriculture.

We declared E. coli 0157:H7 an adulterant in meat, *banning* the sale of any product with which it was contaminated. This decision -- which has kept *millions* of pounds of bad meat away from good people -- was bitterly resisted at the time.

We established FoodNet -- a state-of-the-art, nationwide monitoring system to speed our ability to identify and contain outbreaks. In the Pacific Northwest, *700* people were sick before the outbreak was under control. During the Hudson outbreak, that number was down to 16.

Last year, Nancy, Roni and other parents stood with President Clinton as he announced an historic leap into the 21st century for America's meat and poultry inspections. For the first time, there will be regular tests for E. coli and salmonella. For the first time, plants and processors will be required to not just *catch* contamination, but *close* the safety gaps that invite it in the first place. For the first time, the focus is on *prevention*. For the first time, America's public policy makes it crystal clear that industry is *responsible* for producing safe food.

Our new meat and poultry inspection system will begin to take effect next week. I can think of no greater way to show our respect and our resolve on the 5th anniversary of this tragedy than to launch America's second great food safety revolution for meat and poultry.

And I want to make one thing perfectly clear -- "We will be watching." If you're out there producing dirty product what we would call a "repeat violator." From now on -- don't expect a thousand chances to get it right! USDA will make sure the plant knows what it needs to do to fix the problem, but again -- we will not hesitate to close down those plants that refuse to take their food safety responsibilities seriously.

I also strongly believe that USDA needs new enforcement tools. As the law stands today, USDA cannot *order* a recall of unsafe food. We cannot *fine* a company that puts the public health at risk. Most Americans are stunned to find this out. After all, government can recall unsafe toys, cars and other products. It can fine airlines and manufacturers with lax safety standards. Why treat unsafe food differently? We need to trade in this double standard for one high standard of protection for our people. I could certainly use STOP's resolve in this fight. It's an uphill battle right now, but I have no doubt that a strong voice for America's families would refocus this

debate, and breathe new life into this important effort.

I have several food safety folks from USDA with me here today, people who have worked on these issues for many years, some of the best scientists in their field. I think I can speak for all of them, and many more in the government and public health arenas, in saying that *all* of these accomplishments I have just laid out -- which this Administration counts among its greatest -- would likely not have been possible without all of you.

Alexis du Tocqueville, the great French observer of American democracy, once asked Alexander Hamilton: What is so *great* about America? Hamilton answered: 'Here, sir, *the people govern.*' Looking around me today, I know exactly what he meant.

We should not forget that it was just a few years ago when government told consumers that contamination was *unavoidable*; that it was *their* problem. Fortunately for America, STOP *refused* to accept that answer. Instead, you became a powerful, morally *unstoppable* force for change.

For decades, every time a major food safety reform was pushed. Advocates were told to forget it. They were told that their ideas were out there; that they would devastate a vibrant part of the U.S. economy; that they didn't have a chance. Five years ago, everything changed, and there was a parting of the waters. Industry, consumer groups, government and public health officials sat down together at the table, and time after time, we didn't get up until we'd done the right thing.

Without a doubt, the difference was each of you, and this wonderful organization. You shared your stories. We listened, and we *all* knew what we had to do.

What about all that economic doom and gloom that the naysayers predicted? It never came to pass. In fact, America's high food safety standards are one of agriculture's great assets today. Look at the major world food scares of 1997: During the avian flu scare in Hong Kong -- where they killed all the chickens -- Hong Kong consumers cut their poultry purchases in *half*. With the mad cow scare in Europe, beef sales there dropped *40%*. Those countries' industries were devastated. Here at home, what was the economic impact of the Hudson beef recall? Zero. People *trusted* that their government was putting their safety first. That confidence is rare around the world.

I don't believe in talking about food safety in terms of the economic numbers, except to point out a very encouraging trend: The *economic* interests of agriculture and the *public* interest in food safety are rapidly becoming one and the same, as the market -- in an educated, empowered consumer environment -- recognizes a simple overriding fact: safe food sells.

As much as America has needed your resolve these past 5 years, we will need it even more as we face up to the food safety challenges of a new century. We need more research to help us understand a complex enemy: What causes E. coli's presence in farm animals? Why does our foe

change its stripes, creating new, more virulent strands?

... You know, I'm a Kansan, and Kansans don't make a habit of walking around speaking Latin to one another, but I want to share with you our state motto -- ad astra per aspera, to the stars through difficulties. It seems to translate particularly well today.

It would be all too easy to stand here -- especially on this day -- and think only of death, despair and loss. You must forgive me if I look around this room today, and see life, hope and all that America has gained through your tireless, selfless advocacy.

From great personal tragedy, this organization has risen up to lead the nation toward higher ground on one of the most critical public health debates of our time.

Standing here in a church that reaches further up into the heavens than any other on earth,<sup>2</sup> I hope that you continue to challenge me and all Americans to reach higher.

Beyond that, *I* have nothing to teach any of *you* about resolve. You have turned the tide on food safety. You have focused the nation on what really matters -- the difference between a happy and a heartbroken family. You have made America stronger.

The only advice that I can give you today is never, ever stop.

On behalf of a grateful president and a grateful nation, thank you.

###

---

<sup>2</sup>This church is listed in the Guinness Book of World Record as the world's tallest church.

JAN 16 '98 15:59 FR NY-ADM

202 776 9861 TO 581

P.04/05

But the day-to-day monitoring of these so-called "critical control points" will be done not by federal inspectors, but by plant employees.

The new system, known as HACCP (for Hazard Analysis and Critical Control Points) is touted by Agriculture Department officials as a science-based system with objective standards. Skeptical meat inspectors, however, privately joke that HACCP actually stands for "Have A Cup of Coffee and Pray."

Caroline Smith DeWaal, director of the food safety program at the Center for Science in the Public Interest, was surprised by the findings in the database and said they "don't bode well for the HACCP system."

"If the plants aren't cleaning up these basic problems," she said, "why should we expect them to act any faster if the messenger is a plant employee rather than a government inspector who theoretically has the power to shut them down?"

Charlie Limoges, a veteran inspector stationed in Iowa, said he doesn't trust the new system either. "The packers are going to have it made," he said. "The only thing they had going against them was the PDRs, the stuff I documented. Now, there won't be the documentation."

Parts of the HACCP program were put in place a year ago. But at a pork plant operated by IBP Inc. in Columbus Junction, Iowa the new program has failed to halt contamination of hams, records show. IBP is the second largest meat processor in the country earning more than \$12 billion last year.

But the contaminated ham was a problem throughout 1997.

The HACCP system is supposed to target "repetitive deficiencies," but according to inspection reports, that's not what happened when machine oil was found dripping directly onto hams moving down the Columbus Junction production line.

Beginning in January 1997, inspectors began tagging the plant with "criticals" because machine oil or grease was found contaminating hams at one particular spot on the production line.

Even though the inspectors noted the precise location of the contamination, and even though plant managers promised each time to solve the problem, the oil was found again and again throughout the year.

Two weeks ago, a full year after oil first was found on the hams, the plant was cited again for the problem. On Jan. 5, an inspector wrote plaintively: "This has been a very on-going problem at (the plant) and it has never been corrected. There are approximately 47 PDRs out for this now. The IBP plant is not correcting the problem."

A company spokesman for IBP issued a written statement saying "Most of the deficiency reports... were filed by the same inspector and did not involve finished product." The statement also says IBP "is considered by many in the meat business as having the cleanest, most well operated plants in the industry."

According to the Agriculture Department database, the Columbus Junction plant was second only to Tyson's Waldron plant in collecting critical violations in 1996. In that year, the plant was cited 1,517 times.

< END OF STORY. Following is material for a box/graphic:

#### ^TIPS FOR SAFE FOOD^

Some do's and don'ts for handling food safely in the kitchen:

JAN 16 '98 13:55 FR WCH:AM

202 776 9861 TO 581

P.03/05

The administration says it is responding to the public's alarm over the safety of the nation's food supply. The Centers for Disease Control in Atlanta estimates that contaminated foods make more than 30 million Americans sick every year -- and cause over 9,000 deaths.

Agriculture Department records show President Clinton's concerns hit close to home. Arkansas, where Clinton was governor, led the nation with 15,269 critical violations in 1996, even though there are far fewer processing plants there than in states such as California and New York.

While the Cox computer analysis was limited to 1996, inspection records obtained by Cox show the food safety problems were not

On Feb. 4, 1997 a plant inspector in the Midwest found approximately half the carcasses being processed peppered with "feces, bile, hair."

On March 17, 1997 inspectors at another plant noted Kosher slaughtered beef was "completely covered with blood" and there was "commingling of blood (of) several animals" heightening the danger of cross-contamination

On May 28, 1997 a plant was discovered preparing scores of carcasses for sale that had dropped on the plant floor

"It's horrendous. It's horrendous," said Felicia Nestor, the food safety expert at the Government Accountability Project, a non-profit organization that has supported whistle-blowers among federal food inspectors

"The part I feel worst about," Nestor said after learning details of the computer analysis, is that the vast majority of people would never guess that that's the situation."

Nestor scoffed at inspection chief Billy's explanation that the high volume of critical violations at some plants shows the Agriculture Department has been doing its job. She said inspectors are not catching every instance of food contamination.

"It's totally ludicrous to think that they are," she said.

<  
STORY CAN END HERE. OPTIONAL ADD FOLLOWS<

<  
Billy also said the inspection records dramatize the need for the new inspection program that is coming into place Jan. 26.

The old method of assigning inspectors to catch problems is being replaced with a program where companies will monitor their own operations and inspectors will double-check the work.

But the new system has drawn criticism from consumer groups and many federal inspectors themselves who say it gives meat packing companies too much authority to police their own operations.

Under the system being phased out, government inspectors visually inspect meat and poultry as it is being processed, and write up citations known as Process Deficiency Reports, or PDRs, when meat and poultry packing laws are violated. Plant managers must respond to PDRs by either appealing them or explaining the steps being taken to ensure cited problems will be corrected

Under the new program, PDRs will be eliminated and plants have been asked to identify points in their production processes where contamination is most likely to occur and then design programs for controlling it. Plants also will be required to test for bacteria and halt production if bacterial levels exceed specified limits.

JAN 16 '98 15:57 FR WIL-ALM

202 776 9661 TO 581

P.02/05

While most of the nation's approximately 6,000 processing plants had only a handful of violations, there were 299 that were cited weekly. Although Agriculture Department officials can close or curtail operations at plant, they rarely do so, even in the most extraordinary circumstances.

The database showed a poultry plant in Waldron, Ark., operated by Tyson Foods Inc., amassed 1,753 "critical" violations in 1996, the most of any plant in the nation. On some days it averaged one critical violation every two hours.

A "critical" violation is defined by the Agriculture Department as a plant condition that is "certain" to cause contamination of food, which is "certain" to reach consumers, and is "certain" to have a detrimental effect upon the consumer."

Yet the plant never missed a day of production in 1996 because of federal sanctions.

By comparison, the ground beef plant in Nebraska that made headlines last August for its 25 million pound meat recall and for being shut down by an Agriculture Department "swat team" of inspectors, had only 90 critical violations during 1996.

It was difficult to get Tyson's response to the findings late last week because its chief spokesman, Archibald L. Schaffer III, a company vice president, said he was "distracted" by his indictment Thursday by the special prosecutor investigating illegal corporate gifts from Tyson to former Agriculture Secretary Mike Espy. The company already has pleaded guilty to some charges.

On Friday he released a statement blaming the high number of violations at the Waldron plant on the "subjectivity" of the federal inspectors.

While the computer database notes categories of violations, it does not include inspectors' specific descriptions of the unsanitary conditions being reported.

A Cox Newspapers reporter who visited the Waldron plant recently was refused access to the actual inspection reports kept in an Agriculture Department office at the plant.

"That [examining the reports] is not something that we are going to allow you to do," Schaffer told the reporter at the time.

Although the documents are public record, both Schaffer and the government inspector in charge at the plant said journalists could see the records only after filing a Freedom of Information Act request in Washington. Such requests often can take months to process.

Last Wednesday, six days after the reporter visited the plant, Agriculture Department officials finally closed the Waldron operation for repeatedly violating sanitation regulations. A department spokesperson said they had amassed 4,100 violations in 1997. It could not be determined how many of those were critical.

Still, the Arkansas plant's track record on critical violations was not unique.

While 299 plants had 100 or more critical violations, seven plants topped 1,000 or more in 1996, the last year for which there are complete records. But the Agriculture Department told Congress that in 1996 it only shut down six plants.

Department spokesperson Jacque (CQ) Knight would not disclose the names of the plants, and in December referred a request for those details to the Freedom of Information Act office. A month later, that office has still not supplied the names of the six plants.

The Clinton administration said late last month that it was planning to ask Congress for significantly more money in the next federal budget to, among other things, increase the number of food inspectors.

JAN 16 '98 15:55 FR 100-011

202 776 9821 TO 581

P.01/05

**COX**  
**NEWSPAPERS****WASHINGTON BUREAU**

1000 15TH ST. N.W.  
 WASHINGTON, D.C. 20004  
 TEL: 202/680-2119  
 FAX: 202/680-2119  
 WWW: COXNEWS.COM

ANDREW ALEXANDER  
 Editor

Alaska: Anchorage  
 Arizona: Phoenix  
 Atlanta: Atlanta  
 Austin: Austin  
 Baltimore: Baltimore  
 Boston: Boston  
 Butte: Butte  
 Chicago: Chicago  
 Cincinnati: Cincinnati  
 Cleveland: Cleveland  
 Dallas: Dallas  
 Denver: Denver  
 Detroit: Detroit  
 El Paso: El Paso  
 Fort Worth: Fort Worth  
 Fresno: Fresno  
 Hartford: Hartford  
 Houston: Houston  
 Indianapolis: Indianapolis  
 Jackson: Jackson  
 Jacksonville: Jacksonville  
 Kansas City: Kansas City  
 Las Vegas: Las Vegas  
 Little Rock: Little Rock  
 Los Angeles: Los Angeles  
 Louisville: Louisville  
 Madison: Madison  
 Miami: Miami  
 Milwaukee: Milwaukee  
 Minneapolis: Minneapolis  
 Mobile: Mobile  
 Montgomery: Montgomery  
 Nashville: Nashville  
 New Orleans: New Orleans  
 New York: New York  
 Norfolk: Norfolk  
 Oklahoma City: Oklahoma City  
 Omaha: Omaha  
 Orange County: Orange County  
 Orlando: Orlando  
 Phoenix: Phoenix  
 Portland: Portland  
 Raleigh: Raleigh  
 Richmond: Richmond  
 Sacramento: Sacramento  
 St. Louis: St. Louis  
 Tampa: Tampa  
 Tulsa: Tulsa  
 Utah: Salt Lake City  
 Virginia: Virginia  
 Wichita: Wichita

For questions on this story:

Elliot Jaspin: 202-887-8346

Scott Montgomery: 202-887-8328

# **^EXCLUSIVE: MEAT, POULTRY PLANTS REMAIN OPEN DESPITE THOUSANDS OF FEDERAL SAFETY CITATIONS<**

^EDS: Material for a box/graphic on food safety tips is at the bottom of this story.

^For use on or after Sunday, Jan. 18<

^By ELLIOT JASPIN and SCOTT MONTGOMERY<

^c 1998 Cox News Service@=

**WASHINGTON** \_ The U.S. Department of Agriculture has permitted hundreds of meat and poultry plants to operate virtually uninterrupted even while federal inspectors file tens of thousands of citations against them for unsanitary conditions and food contamination, department records show.

Cox Newspapers analyzed an Agriculture Department computerized database of meat and poultry inspection records for 1996 and found 138,593 instances in which inspectors said food being prepared in packing plants was "certain" to sicken consumers. The database was obtained under the Freedom of Information Act.

Experts can't estimate how much contaminated meat and poultry makes its way to America's dinner tables from these plants. Officials at the Centers for Disease Control and Prevention have long argued that food-borne illness is a far bigger problem than public reports would suggest, and that food processing plants play a major role.

But even a CDC doctor was surprised by the extent of the situation detailed in the Agriculture Department database.

"Heavens," said Dr. Paul Mead, an epidemiologist at the center in Atlanta, when told by reporters that some plants have been allowed to operate after being cited 1,000 or more times for the most serious of unsanitary conditions.

"The burning question is why is a plant with that many violations.. why has the (federal) inspector not been pulled from that plant?" he asked. "And I have no idea."

Thomas J. Billy, head of the Agriculture Department's Food Safety Inspection Service, said the high number of violations shows that his inspectors did their job in catching contaminated food before it left the plant. He dismissed as "speculation" the idea that frequent violators might be shipping contaminated food that inspectors missed.

done, the food is condemned.

The Cox article implies that unsafe product was allowed to leave the plants. This is incorrect.

In instances where critical violations were cited by the inspector for plant conditions that were certain to cause contamination of product, the food was deemed adulterated or unsafe and not allowed to leave the plant.

In instances where FSIS found that plants prepared carcasses for sale that had fallen on the plant floor, FSIS inspectors identified and addressed the unacceptable practices.

In instances where product was found to be adulterated by unacceptable conditions, e.g., dripping oil in plant machinery, FSIS' inspectors addressed and corrected the situation by preventing the product from leaving the plant.

On January 26, 1998, FSIS will implement HACCP requirements in all large meat and poultry slaughter and processing plants. The article suggests that inspectors will not be documenting and taking action to prevent food safety problems. This is incorrect.

Non-compliance reports (nr's) will replace pdr's as the inspectors' documentation of violations of HACCP requirements, as well as SSOPs and other regulatory requirements. FSIS' inspectors will continue to be present day-to-day to verify compliance and take direct action when necessary.

In their expanded role in HACCP implementation, inspectors will continue to inspect carcasses and will document violations in writing. Inspectors will maintain their authority to prevent adulterated product from leaving the plant. Inspectors will not only continue to document deficiencies, but will lay the groundwork for documenting repeated failures, for the purposes of shutting down the plant.

FSIS has and will continue take strong enforcement action for repeated violations of sanitary or food safety requirements.

The Administration has asked Congress for additional enforcement authority to fine companies for repeated violations of food safety standards. USDA can fine circuses for abusing elephants, but we can't fine companies that violate food safety standards.

First, it is important to remember that the Cox story is not based on the new food safety inspection system. For the most part, the story is based on 1996 data that occurred prior to the implementation of the requirements for the new food safety inspection system.

Under the old system of inspection, inspectors would ensure food safety by identifying problems and issue Process Deficiency Reports (PDR's). The fact that inspectors issued PDR's means that they were aggressively doing their job to ensure that food safety standards were met.

The high number of plant deficiency reports (pdr's) indicates that inspectors observed problems, documented them and took action. A pdr that is cited as critical requires that action must be taken to 1) ensure that the problem with the product is corrected so that the product is safe and wholesome or 2) the product is condemned.

In short, no contaminated product cited in a critical pdr is allowed to reach consumers. Although the entire plant was not shut down, specific lines that were in violation were shut down for periods of time on many occasions. This brings into question the premise of the Cox reporter's story.

The Cox article suggests that contaminated food was allowed to leave the plants. This is incorrect. The critical point to remember is that the food was not allowed to leave the plant unless the plant corrected the problem and made the food safe and wholesome, if possible. If this was not possible, the product was condemned.

On January 27, 1997, FSIS implemented the first set of requirements of the new food safety system. Plants were required to develop and maintain Sanitation Standard Operating Procedures (SSOP). SSOP's are a system that the plant must follow to continue to operate. FSIS employs a systematic process to enforce SSOP requirements and holds plants accountable for effectively implementing their plans.

The new system enables FSIS to take formal action to withhold the mark of inspection and effectively shut down the plant due to the failure of the system to produce safe food. This is a watershed change from the old "command and control" system of regulation. Previously, plants did not have to make corrections in their systems until the inspector noticed a problem. Now, USDA can shut down a plant until it make the necessary changes in their system that will ensure safe food.

Since January of 1997, FSIS has taken 20 formal actions to withhold the mark of inspection and temporarily close down plants due to SSOP system failures.

On December 19, 1997, before the Cox reporters visited the plant, FSIS initiated formal action to address repeated SSOP failures in the Tyson plant in Waldron, Arkansas which led to the plant's closure on January 14, 1998.

Even under the new system, where inspectors find problems that make food unsafe, that food is not allowed to leave the plant unless it can be reprocessed so that it is safe. If this cannot be

Food Safety - gw  
Total Pages: 13

LRM ID: RJP177

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

**URGENT**

Friday, January 2, 1998

**LEGISLATIVE REFERRAL MEMORANDUM**

**TO:** Legislative Liaison Officer - See Distribution below  
*Janet R. Foragren*  
**FROM:** Janet R. Foragren (for) Assistant Director for Legislative Reference  
**OMB CONTACT:** Wendy A. Taylor  
**PHONE:** (202)395-4815 **FAX:** (202)395-6974  
**SUBJECT:** HHS/USDA Report on Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables

**DEADLINE:** 10 AM Thursday, January 8, 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/USDA draft report to the President is in response to his October 2, 1997, Directive on the progress made to date on ensuring the safety of imported and domestic fruits and vegetables.

**DISTRIBUTION LIST****AGENCIES:**

7-AGRICULTURE - Marvin Shapiro - (202) 720-1516  
25-COMMERCE - Michael A. Levitt - (202) 482-3151  
29-DEFENSE - Samuel T. Brick Jr. - (703) 697-1305  
32-ENERGY - Bob Rabben - (202) 586-6718  
33-Environmental Protection Agency - Chris Hoff - (202) 260-5414  
52-HHS - Sondra S. Wallace - (202) 690-7760  
61-JUSTICE - Andrew Fois - (202) 514-2141  
62-LABOR - Robert A. Shapiro - (202) 219-8201  
76-National Economic Council - Sonyia Matthews - (202) 456-6630  
84-National Science Foundation - Lawrence Rudolph - (703) 306-1060  
95-Office of Science and Technology Policy - Jeff Smith - (202) 456-6047  
114-STATE - Paul Rademacher - (202) 647-4463  
118-TREASURY - Richard S. Carro - (202) 622-0650  
128-US Trade Representative - Fred Montgomery - (202) 395-3475

**EOP:**

Joshua Gotbaum  
T J. Glauthier  
Sally Katzen  
JENNINGS\_C

Sarah A. Bianchi  
Donald H. Gips  
✓Toby Donentfeld  
Phillip Caplan  
✓Thomas L. Freedman  
Barbara D. Woolley  
Jerold R. Mande  
Barry T. Clendenin - 7025  
Richard J. Turman - 7002  
Jim R. Esquea - 7002  
Mark A. Weatherly - 8013  
Adrienne C. Erbach - 8013  
Daniel D. Heath - 8013  
Donald R. Arbuckle - 10201  
Wendy A. Taylor - 10235  
K. Lisa Grove - 10202  
Pamula L. Simms - 6236  
David J. Haun - 9002  
Lori Schack - 8202  
Alicia K. Koleian - 6001  
✓Sanders D. Korenman -  
Clifford J. Gabriel  
erickson\_audrea  
Margaret A. Malanoski - 10202  
Ronald K. Peterson  
James C. Murr  
Janet R. Forsgren  
Robert J. Pollicci  
✓Mary L. Smith  
OMB LA



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

### **Background**

While American consumers enjoy the safest food supply in the world, in the last several years there have been increasing incidents of foodborne illness outbreaks associated with both domestic and imported fresh fruits and vegetables. On October 2, 1997, President Clinton announced an "Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables". The initiative specified that FDA seek legislation to extend its existing authority to provide increased coverage of imported foods, that future budget requests include activities in this initiative, and that FDA and USDA develop a series of activities focused on assisting the domestic and foreign produce industries to improve the safety of fresh fruits and vegetables.

FDA and USDA have identified the funding necessary to carry out the domestic and international activities associated with the fresh fruits and vegetables initiative. Full implementation in FY99 is contingent upon receiving adequate funds. As part of the overall food safety initiative, the agencies are making plans for the most efficient use of funds, for example, by participating in a research coordination working group organized by Dr. John Gibbons, Science Adviser to the President, under the auspices of the National Science and Technology Council.

*Status of the Legislation:* A bill, the Safety of Imported Food Act of 1997 (H.R. 3052), was introduced in the House of Representatives on November 13, 1997. No comparable bill has yet been introduced in the Senate. If enacted, this proposed legislation would amend the Federal Food, Drug, and Cosmetic Act to expand FDA's authority to assure the safety of imported foods by providing FDA with authorities more comparable to those of USDA.

### **This Report**

The President directed the Secretaries of HHS and Agriculture to submit a report on progress made in development of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), as well as other elements of the initiative. GAPs and GMPs guidance are interrelated in that some procedures may overlap. GAPs/GMPs primarily focus on production practices including growing, harvesting, handling, and transportation. GMPs can include harvesting and transportation, but also include other practices such as processing and packaging. Because of this overlap, the terms "GAP/GMP" and "GAPs/GMPs", as appropriate, will be used throughout the document.

The United States produce industry, as well as some 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 development of GAP/GMP guidance, recognize this effort and build on it.

This report discusses the progress made on development of GAPs/GMPs and plans to accomplish the other elements of the initiative. This report also describes interdependent activities that will enhance the successful adoption of GAP/GMP guidance by the industry. For example, effective adoption of GAP/GMP guidance will depend on U.S. agencies providing technical assistance to the domestic industry and to countries exporting produce to the U.S. Education and outreach efforts will be provided to both the domestic and foreign industry and all of these activities will be based on a strong, underlying, accelerated research program. The cooperative efforts described in this report represent a comprehensive approach to improving the safety of fresh fruits and vegetables. Current resources have been redirected to these efforts, however, the overall level of effort will be determined by the resources provided in the FY 99 budget and thereafter.

### 1. Good Agricultural Practices/Good Manufacturing Practices Guidance

**Status:** FDA, working with USDA, is preparing a general GAP/GMP guidance document. FDA plans to publish the document as proposed voluntary guidance. This guidance, titled "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables", describes 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, 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 other 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.

FDA and USDA sponsored 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 Guide and to 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 draft guidance document. The revised document was subsequently used as the basis of discussion at a series of meetings targeted to 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.

**Timeline:** FDA will publish draft GAP/GMP guidance, incorporating comments and information from the public meetings, in the Federal Register by early March, 1998. A 45-day comment period will be provided for public review and further comment. A public meeting may also be held. It is anticipated that finalized GAP/GMP guidance will be available at the end of July, 1998.

**Supporting Information:** The draft guidance represents the best advice of FDA and USDA, builds on current industry and scientific practice, and will incorporate information provided by the agricultural community, consumers, academicians, individuals involved in international trade, states' representatives, and other interested parties. Development of the final guidance will draw on fundamental information that describes the fresh fruit and vegetable industry domestically and in countries exporting products to the U.S.

**Timeline:** To complement data and information being developed domestically, comparable data and country information, such as copies of food safety legislation and regulation affecting production, handling, and storage of produce for selected countries which export produce to the U.S. will be compiled by mid-July, 1998.

## **II. Technical Assistance and Education and Outreach**

**Technical Assistance:** GAP/GMP guidance alone cannot be effective in improving the safety of fresh fruits and vegetables if technical resources to adopt all or even parts of the guidance do not exist. The guidance is most effective when all the essential components that apply to a particular commodity or production operation are adopted, ensuring use of practices that bolster safety 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 adoption of the GAPs/GMPs by the produce industry. Working with foreign and U.S. agencies to provide assistance is not only beneficial to the industry but also to the health of American consumers. 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 fruit and vegetables or when, in order to provide requested technical assistance, it

becomes necessary for FDA investigators or scientists to visit foreign operations to ascertain the source of problems that may pose a safety hazard in produce exported to the U.S., USDA and the State Department overseas personnel will collaborate as necessary to facilitate these visits.

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 adoption of GAPs/GMPs 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. 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 standards. 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:** During FY'98 the groundwork is being laid for providing technical assistance, pending finalization of the GAP/GMP guidance.

**Education and Outreach:** Education and outreach programs are essential to foster adoption of GAP/GMP guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to industry's understanding of the essential principles of GAP/GMP guidance, as well as the scientific and practical reasons for adoption 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.

CSREES, 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 and FDA will plan a national food safety scientific and education conference for early 1998 to share current scientific and educational information on fruits and vegetables, to apprise scientific experts and extension professionals with the voluntary general guidance document, and to discuss methods. States may want to consider incorporation of the President's directive into ongoing State extension programs. State and local extension agents can play a vital role in the successful adoption 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.

CSREES will also disseminate the guidance and incorporate it into ongoing federal food safety extension programs.

To reach the produce industry workforce, the GAP/GMP 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 GAP/GMP 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 produce industry to ancillary industries, such as wholesale and retail, and to the consumer. Expanded education efforts will be directed to increasing awareness of public health concerns about fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce.

The information provided at the GAP/GMP 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, FAS will be instrumental in facilitating the development of education and training programs, either through their staff or the State Department. The FAS' International Cooperation and Development group can facilitate development of cooperative training programs on the GAP/GMP guidance, in collaboration with other agencies capable of providing funding for these activities. FAS will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the FAO and the Inter-American Institute for Cooperation of 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.

**Timeline:** Preliminary steps have been taken to determine mechanisms for providing information and assistance to the domestic industry in adopting GAP/GMP guidance. Likewise, preliminary steps will be taken to develop a program targeted to foreign producers.

### **III. Specific Guidance**

The general GAP/GMP guidance is a requisite to ensure the safety of all produce. This general guidance is essential as a foundation for a host of more specific guidance for various commodities, hazards and pathways of contamination, or pathogens. As we consider the broad spectrum of a food safety system, general guidance is usually the first consideration. However, specific GAPs/GMPs are very appropriate and often essential for those foods or systems where individual HACCP programs are not warranted. Specific guidance for individual commodities can provide tailored guidance for reducing the potential for microbial contamination, e.g., the minimum time between manure application and produce harvest, appropriate manure treatment technologies to eliminate or significantly reduce levels of pathogens in manures, the best type of irrigation system to use, specific harvesting practices (e.g., picking berries or melons), or recommendations for transporting specific commodities. Likewise, specific guidance can be designed for minimizing 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. Some pathogens may be appropriate subjects for specific guidance that would apply to all foods in which the risk of contamination with that pathogen exists.

**Supporting Information:** Domestic commodity data provided by USDA includes specific commodities produced, the form (whole or processed) and the quantities produced. FAS has available, as part of its ongoing trade reporting system, data on fruits and vegetables imported into the U.S. and some commodity specific reports for selected countries. Information about the current agricultural practices, about currently used handling and transportation practices, processing and packaging techniques, and about products associated with foodborne illness outbreaks will also be used. Both USDA and FDA have some data on current agricultural and manufacturing practices which they will provide. Country information (such as copies of food safety legislation and regulation affecting production, handling, and storage of produce) useful in identifying current production and processing practices in foreign countries will be provided by FAS. This information will be used to direct and support decisions to develop more specific guidance documents, as appropriate.

**Selection of commodities, or hazards, or pathways of contamination, or pathogens:** Options are being explored for the most efficient way to provide the industry with guidance that is effective and that yields the most benefit from the resources expended. Among the options under consideration are:

- Industry organizations could voluntarily work with FDA and USDA to develop specific guidance for commodities produced by their members.
- The subject of specific guidance for a commodity, or hazard, or pathway of contamination, or pathogen could be determined through a public process. FDA could publish a notice in the Federal Register announcing our intention to develop more specific guidance and proposed criteria to be used in the selection. This notice could ask for information to guide the selection of subjects.
- The competitive grant mechanism available through CSREES could be used to fund development of commodity-specific GAPs/GMPs by academic institutions in different regions of the country.
- Other approaches that could provide targeted guidance to the produce industry in a timely manner, including a combination of the options listed here, a combination of these options with other options.
- A decision not to develop any type of specific guidance.

Whichever options are chosen, some basic factors will be considered in selecting the subject of the guidance. These include the potential hazards associated with the commodity and whether or not microbe-specific methods (e.g., identification, detection, enumeration, and/or sampling technique) exist to ensure an appropriate level of public health protection. The potential public health impact of the commodity, based on the volume of the commodity produced and the primary consumer group (e.g., young children, the elderly, the population in general), are other factors that will be considered. A careful analysis will be conducted in selecting the subject of specific guidance (i.e., a commodity, or hazard, or pathway of contamination, or pathogen). This analysis will consider the value of any public health improvements that may result from specific guidance. It will also consider the total cost to society of foodborne illnesses (e.g., medical costs and productivity losses) associated with the subject, and the costs to the industry or consumers of implementing specific guidance that will reduce human health risks. On the basis of this information, a cost/benefit ratio can be estimated to assist in determining future actions. Another approach is to use epidemiological data, specifically data about the severity of illnesses, the potential magnitude of an outbreak of foodborne illness, and the frequency of occurrence of outbreaks. A combination of these two approaches may be most useful.

In any event, a FDA/USDA committee will oversee and direct development of the specific guidance documents which will undergo scrutiny in the FDA public review process. This process entails publication of the draft documents in the Federal Register, receipt and evaluation of comments, revision of the documents incorporating information from the comments, and publication as a final guidance document.

**Timeline:**

It is anticipated that proposed specific guidance will be available to the produce industry during 1998. If the CSREES grant process is used for development of the specific guidance documents, it is anticipated that the grant process will begin in May, 1998 and conclude with grant awards in October, 1998. Draft documents will be developed during 1999 and will undergo the FDA public review process beginning in 2000.

**IV. Focused Inspections and Monitoring Adoption Of GAP/GMP Guidance**

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

FDA will continue its fresh fruit and vegetable inspection and testing program at current levels 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 GAP/GMP guidance has not been adopted.

**Monitoring:** Monitoring and evaluating the effectiveness of GAP/GMP guidance and/or specific guidance will provide assurances to consumers, producers, and processors that following the guidance will result in reducing risks. The USDA and FDA will use survey techniques to determine the effectiveness of the GAP/GMP program and the extent of adoption of the guidance by both the domestic and foreign industry. 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 GAP/GMP 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 thorough, survey on practices will be conducted at a later date. This information — from the surveys and other sources — will be used to monitor adoption of the GAP/GMP guidance and to make necessary adjustments in the GAP/GMP program, including the guidance.

**Timeline:**

FDA's inspection and sample collection and analysis activities are ongoing. Increased inspection and testing efforts are budget dependent and would be desirable to help monitor the effectiveness of general and specific GAP/GMP guidance. The monitoring activity may begin in FY98.

## **V. Accelerated Food Safety Research**

Successful implementation of this initiative relies heavily on adequate scientific research targeted to assessment of risk to public health posed by microbial contamination. The overall research goal identified in this initiative is development of 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. These methods will be used to conduct long-term surveillance and monitoring of both domestic and imported produce, to support development of control and prevention strategies that augment use of GAP/GMP, and to develop guidance that accommodates specific needs imposed by environmental factors (e.g., water quality, manure management including development of appropriate manure treatment technologies to eliminate or significantly reduce pathogens in manure, worker hygiene).

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 ambient water and potential subsequent contamination of fruits and vegetables through irrigation practices.

FDA and USDA are individually and collectively reviewing their respective FY98 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 EPA, DoD, the Department of Energy, the National Science Foundation, and 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 on preventive technologies and intervention strategies to reduce or eliminate microbial contamination is a high 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.

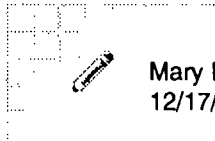
**Timeline:** The process of reviewing research related to safety of fresh fruits and vegetables was initiated in September, 1997. A research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research.

#### **VI. Participants in this Initiative**

The following agencies are contributing to this initiative: the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS); the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), the Animal and Plant Health Inspection Service (APHIS), the Cooperative State Research, Education, and Extension Service (CSREES), the Economic Research Service (ERS), the Foreign Agricultural Service (FAS), the Food Safety and Inspection Service (FSIS), the National Agricultural Statistics Service (NASS), the Natural Resources Conservation Service (NRCS), and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA) in the U.S. Department of Agriculture (USDA); the Environmental Protection Agency (EPA); the Department of Labor's (DoL) Occupational Safety and Health Administration (OSHA); and the Department of Defense's U.S. Army-Natick Research Development and Engineering Center are also working on segments of the initiative.

December 22, 1997

Food Safety



Mary L. Smith  
12/17/97 03:06:24 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP  
cc: Laura Emmett/WHO/EOP  
Subject: Principals' Meeting on Food Safety at USDA

I attended the principals' meeting on Food Safety at USDA today. There were three basic topics: (1) reports from public meetings; (2) timing of the report to the President; and (3) meeting on the Hill scheduled for Monday.

1. **Reports from public meetings.** The comments in the 6 public meetings with the growers and the state health departments were pretty favorable. In fact, it was emphasized that not one of the growers was opposed to the development of the guidance in general. The comments were just that the timing seemed like it was happening very quickly; that the growers hoped that they could actively participate and that it would be a bottom-up process rather than a top-down process; and that, to the extent that we develop product-specific guidance, that they want to contribute to this process. It seems that the concern regarding the product-specific guidance is addressed adequately, at this initial stage in the process, in the draft report.

On the international front, there was a public meeting in Washington that staff of many of the embassies attended. The international community seems fine with it as well, but, again, they would like to participate and would like to conduct more research.

One other item that growers asked about was the President's position on country of origin labeling.

2. **Report to the President.** The report on the progress of the development of the Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) is due to the President on January 2, 1997. I am sending you an outline of the report as well as a draft to the report. It looks like HHS, FDA, and USDA are on track to get this to the White House by January 2, 1997. However, there were some rumblings that because of holidays, etc., they might not be able to send over the final draft until January 3 or 4. I emphasized that they should keep on track for the January 2, and that is the plan now. The timing could be emphasized again in the Food Safety meeting you have scheduled for tomorrow at 5 p.m.

3. **Hill Briefing.** Some Senate staff want a briefing on the entire food safety initiative, including the legislation and the guidance. This meeting is scheduled for Monday, December 22 at 1 p.m. HHS, USDA, and FDA are sending people to the meeting.

Thanks, Mary,

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

## **I. Introduction**

## **II. Good Agricultural Practices Guidance**

### **A. Status**

1. Preparation of draft guidance: "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables"
2. Public meeting, National Advisory Committee on Microbiological Criteria for Foods meeting, grassroots meetings, international meeting

Timeline: FDA will publish draft GAP guidance, incorporating comments and information from the public meetings, in the Federal Register at the end of February or in early March, 1998. A 45-day comment period will be provided for public review and further comment. A public meeting may also be held. It is anticipated that finalized GAP guidance will be available at the end of July, 1998.

### **B. Supporting information**

1. Data/ information describing fresh fruit and vegetable industry domestically and in countries importing into U.S.

Timeline: Data and information covering up to 40 country/commodity combinations will be compiled by mid-July, 1998. These data will provide a profile of each country's current growing, harvesting, handling, and transportation practices for the variety of products offered for import into the U.S.

## **III. Technical Assistance and Education and Outreach**

### **A. Technical Assistance to support adoption of GAPs/GMPs - application**

1. FDA and USDA work with appropriate government public health and agricultural agencies; WHO, FAO, and subsidiaries; and industry and exporter groups abroad and in the U.S.; landgrant colleges and universities.

Timeline: During FY'98 the groundwork is being laid for providing technical assistance, pending finalization of the GAP guidance. FY99 funding will determine the extent of the program.

**B. Education for industry, consumers - understanding principles**

**1. Domestic**

- a. Producers and processors
- b. CSREES will be the primary domestic source of GAP/GMP outreach and educational activities for producers.

National food safety scientific and education conference for early 1998 to provide colleges and universities background on GAP guidance for incorporation into their academic programs.

- c. Expanded education efforts to ancillary industries, such as wholesale and retail, to the consumer - budget dependent
- d. Other agencies and industry to provide education and outreach

**2. Multi-lingual materials for domestic and foreign use**

FDA and USDA will work with industry and foreign governments to provide translations - budget dependent

**3. International:**

- a. FAS will be instrumental in facilitating the development of education and training programs, either through their staff or the State Department.

Timeline: Preliminary steps have been taken to determine mechanisms for providing information and assistance to the domestic industry in adopting GAP guidance. Likewise, preliminary steps will be taken, as funding permits, to develop a program targeted to foreign growers.

**IV. Good Agricultural and Good Manufacturing Practices Guidance for Specific Commodities**

- A. Purpose: Augment general guidance with guidance tailored to unique aspects of a commodity to reduce the potential for microbial contamination

**B. Supporting Information**

**C. Selection of Commodities**

- 1. Options are being explored

- a. Industry organizations will voluntarily work with FDA and USDA to develop specific GAPs/GMPs as guidance for commodities produced by their members.
- b. Use public process. FDA will publish a notice in the Federal Register announcing our intention to develop guidance for specific commodities and the criteria to be used in the selection. This notice will ask for information to guide the selection of commodities.
- c. CSREES competitive grant mechanism to fund development of commodity-specific GAPs/GMPs by academic institutions in different regions of the country.
- d. Other approaches

D. Factors to consider in selecting commodities:

- 1. Health-related factors and availability of methods to ensure an appropriate level of public health protection.

E. Process

- 1. FDA/USDA committee will oversee and direct development of the guidance documents
- 2. Documents undergo public review process

Timeline: It is anticipated that development of the specific guidance by the agencies will be available to the produce industry during 1998. If the CSREES grant process is used for development of the specific guidance documents, it is anticipated that the grant process will begin in May, 1998 and conclude with grant awards in October, 1998. Draft documents will be developed during 1999 and will undergo the FDA public review process beginning in 2000.

**V. Focused inspections of production and processing operations and testing on areas of highest risk and monitoring adoption of GAP/GMP guidance.**

A. Inspection and Testing

FDA will continue its fresh fruit and vegetable inspection and testing program at current levels for domestic and imported produce.

B. Monitoring

- 1. Initial and follow-up survey to determine effectiveness and extent of adoption of guidance - USDA and FDA - budget dependent

Timeline: FDA's inspection and sample collection and analysis activities are ongoing. Increased inspection and testing efforts are budget dependent. The monitoring activity may begin in FY98, dependent on funds available.

**VI. Accelerated food safety research.**

- A. FDA and USDA reviewing current research to identify projects for fast-track

Interagency meetings and meetings with industry and consumer representatives

- b. Coordinated research plan being developed

1. Scheduled to be available in early 1998
2. Focus: Research on preventive technologies and to develop intervention strategies

Timeline: The process of reviewing research related to safety of fresh fruits and vegetables was initiated in September, 1997. A research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research .

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

## **Introduction**

While American consumers enjoy the safest food supply in the world, in the last several years there have been increasing incidences of foodborne illness outbreaks associated with fresh fruits and vegetables from both domestic and imported sources. On October 2, 1997, President Clinton announced an "Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables". The initiative specified that FDA seek legislation to increase its authority over imported foods, that budget requests include activities in this initiative, and that FDA and USDA develop a series of activities focused on assisting the domestic and foreign produce industries to improve the safety of fresh fruits and vegetables.

The United States (U.S.) produce industry, as well as some countries importing fresh fruits and vegetables into the U.S., have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly development of good agricultural practices and good manufacturing practices guidance, recognize this effort and build on it.

A bill, the Safety of Imported Food Act of 1997 (H.R. 3052), was introduced in the House of Representatives on November 13, 1997. No comparable bill has been introduced in the Senate. If passed by Congress, this proposed legislation will amend section 402 (adulterated food) of the Food, Drug, and Cosmetic Act to expand FDA's authority to assure the safety of imported foods. This will provide FDA with authorities more comparable to those of USDA over imported foods. FDA's and USDA's budget requests for FY99 includes funding for activities associated with the fresh fruits and vegetables initiative. The budget requests have been submitted to the Office of Management and Budget. As part of the overall food safety initiative, the agencies are making plans for the most efficient use of funds, for example, by participating in a research coordination working group organized by Dr. John Gibbons, Science Adviser to the President, under the auspices of the National Science and Technology Council.

The President directed the Secretaries of HHS and Agriculture to submit a report on progress made in development of Good Agricultural (GAPs) and Good Manufacturing Practices (GMPs) and other elements of the initiative. GAPs and GMPs guidance are interrelated in that some procedures may overlap. GAPs primarily focus on production practices and include growing, harvesting, handling, and transportation. GMPs can include harvesting and transportation, but also include other practices such as processing and packaging.

This report discusses the progress made on development of GAPs/GMPs and plans to accomplish the other elements of the initiative. This report also describes interdependent activities that will

enhance the successful adoption of GAP/GMP guidance by the industry. As an example, effective adoption of GAP/GMP guidance will depend on U.S. agencies providing technical assistance to the domestic industry and to countries importing produce. Education and outreach efforts will be provided to both the domestic and foreign industry and all of these activities will be based on a strong, underlying, accelerated research program.

Agencies contributing to this initiative are: the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS). U.S. Department of Agriculture (USDA) agencies include: the Agricultural Marketing Service (AMS), the Agricultural Research Service (ARS), the Animal and Plant Health Inspection Service (APHIS), the Cooperative State Research, Education, and Extension Service (CSREES), the Economic Research Service (ERS), the Foreign Agricultural Service (FAS), the Food Safety and Inspection Service (FSIS), the National Agricultural Statistics Service (NASS), the Natural Resources Conservation Service (NRCS), and the Office of Risk Assessment and Cost Benefit Analysis (ORACBA). The Environmental Protection Agency (EPA) and the Department of Labor's (DoL) Occupational Safety and Health Agency (OSHA), and the Department of Defense's Natick Labs (get full name) are also working on segments of the initiative.

## **I. Good Agricultural Practices Guidance**

**Status:** FDA, working with USDA, is in the process of preparing a general Good Agricultural Practices (GAP) guidance document to be published as a proposal. This "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables" describes 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 transportation and handling. The guide also describes use of producer identification and information on the flow of the product through distribution channels. This information facilitates 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 GAP guidance will be consistent with World Trade Organization guidelines and will not impose undue restrictions or barriers on either domestic or foreign producers.

A series of public meetings were held from mid-November to mid-December, 1997 in which the agricultural community, the international trade community, consumer, and the scientific community participated. The purpose of these meetings was to give these parties the opportunity to offer their perspective on the working draft Guide and to provide pertinent information, comments, technical information, and suggested modifications of the draft guidance. The first public meeting was held with the National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (an USDA/FDA advisory committee) in attendance. The

Subcommittee provided recommendations that were incorporated into the working draft guidance document used as the basis of discussion at a series of meetings targeted to the agricultural community. Six "grassroots" meetings were held around the country in December. The agencies also presented the proposed guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting.

**Agencies Responsible:** Lead: FDA  
Support: USDA (CSREES, AMS, ARS, FSIS, ERS, NASS, FAS), EPA, DoL (OSHA), CDC

**Timeline:** FDA will publish draft GAP guidance, incorporating comments and information from the public meetings, in the Federal Register at the end of February or in early March, 1998. A 45-day comment period will be provided for public review and further comment. A public meeting may also be held. It is anticipated that finalized GAP guidance will be available at the end of July, 1998.

**Supporting Information:** The draft guidance represents the best advice of FDA and USDA which builds on current industry and scientific practice and will incorporate information provided by the agricultural community, consumers, academicians, individuals involved in international trade, states, and other interested parties. Development of the final guidance will draw on fundamental information that describes the fresh fruit and vegetable industry domestically and in countries importing products into the U.S.

**Agencies Responsible:** Lead: USDA (ERS, NASS, FAS) and FDA  
Support: USDA (CSREES, AMS),

**Timeline:** Data and information covering 40 country/commodity combinations will be compiled by mid-July, 1998. These data will provide a profile of each country's current growing, harvesting, handling, and transportation practices for the variety of products offered for import into the U.S.

## **II. Technical Assistance and Education and Outreach**

**Technical Assistance:** GAP/GMP guidance, alone, cannot be effective in improving the safety of fresh fruits and vegetables if a lack of technical resources to adopt all or even parts of the guidance exists. The guidance is most effective when all the essential components of the guidance that apply to a particular commodity or production operation are adopted, ensuring use of practices that bolster safety at every step in the process from in-field operations to distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with the appropriate public health and agricultural government agencies abroad and in the U.S. to provide technical assistance needed to support adoption of the GAPs/GMPs by the produce industry.

Working with foreign and U.S. agencies to provide assistance is not only beneficial to the industry, but to the health of American consumers. Successful adoption of GAP guidance by the industry will greatly enhance the safety of fresh fruits and vegetables. When it becomes necessary for FDA investigators or scientists to visit foreign operations to ascertain the source of problems that may pose a safety hazard in produce imported into the U.S., FAS and State Department officials will facilitate these visits. (The FY99 budget request includes funding for additional resources to carry this program out.)

USDA and FDA will work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S.. These include officials from the health and agriculture agencies in foreign countries, the World Health Organization and the Food and Agriculture Organization and subsidiary organizations (e.g., PAHO), as well as exporter associations. In the U.S., the agencies will work with appropriate landgrant colleges and universities, state agencies, and industry associations. In working with these groups, it is critical that we not only provide technical assistance but that they have a clear understanding of the requirements for importing foods into the U.S. and meeting U.S. legal requirements. Equally important, is an appreciation for the U.S. consumers' perception of food safety. With this understanding, these groups can guide industry's determination of what, if any, modifications of current practices are needed for industry to satisfy U.S. legal and consumer expectations. FDA and USDA will provide technical advice and assistance to the domestic industry and to governments of countries importing products into the U.S. to aid in the adoption of GAPs/GMPs, as well as to improve production and processing practices in any other way. 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, post-harvest treatments to reduce or eliminate pathogen levels on produce.

**Agencies Responsible:** Lead: FDA and USDA (FAS, FSIS, APHIS)

**Timetable:** During FY'98 the groundwork is being laid for providing technical assistance, pending finalization of the GAP guidance. FY99 funding will determine the extent of the program.

**Education:** Education and outreach programs are essential to successful adoption of GAP/GMP guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to the industry understanding the essential principles of GAP/GMP guidance, as well as the scientific and practical reasons for adoption 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 in these programs in order to assure that the care taken to prevent microbial contamination in growing, harvesting, processing, and transporting is not thwarted by mishandling later. (The extent of efforts in this area will be

contingent on additional funding in the FY99 budget.)

CSREES, through its existing network of agricultural extension service agents located in the U.S. farming community, will be the primary domestic source of GAP/GMP outreach and educational activities for producers. USDA and FDA will plan a national food safety scientific and education conference for early 1998 to provide colleges and universities background on GAP guidance for incorporation into their academic programs. The Extension agents play a vital role in the successful adoption of GAPs because they are knowledgeable about on-farm assessments and can provide advice to individual farmers on potential problem areas in their operations and how to improve practices. CSREES will disseminate the GAP guidance and incorporate it into the ongoing programs for domestic fruit and vegetable growers. Where necessary and funding is provided, the existing Extension Service-farm infrastructure will be strengthened to facilitate communication in the agricultural community.

In reaching the produce industry workforce, the GAP guidance and associated educational materials must be available in native languages and terms understood by this diverse community. Multi-lingual materials are also needed for use in foreign countries. To meet these needs, the GAP/GMP guidance documents, as well as associated training and information materials will be translated into appropriate languages as quickly as possible as they are finalized and funding permits.

We anticipate that education and outreach activities will reach beyond the immediate needs of the produce industry to ancillary industries, such as wholesale and retail, to the consumer. Expanded education efforts (contingent upon additional FY99 funding) will be directed to increasing awareness of public health concerns about fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce vegetables.

The information provided at the GAP 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, FAS will be instrumental in facilitating the development of education and training programs, either through their staff or the State Department. The FAS' International Cooperation and Development group can facilitate development of cooperative training programs on the GAP guidance, in collaboration with other agencies capable of providing funding for these activities. FAS will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the FAO and the Inter-American Institute for Cooperation of Agriculture in order to facilitate discussions on produce safety issues. FDA and USDA will

provide governments and organizations in foreign countries with multilingual GAP/GMP education programs and materials (as funding permits) for presentation to their industries.

**Agencies Responsible:** Lead: FDA and USDA (CSREES, NAPLAP, NRCS, FSA)  
Support: EPA, OSHA

**Timetable:** Preliminary steps have been taken to determine mechanisms for providing information and assistance to the domestic industry in adopting GAP guidance. Likewise, preliminary steps will be taken in late FY98 to develop a program targeted to foreign growers.

### **III. Good Agricultural and Good Manufacturing Practices Guidance for Specific Commodities**

The general GAP guidance that is being developed cannot be expected to provide the specificity needed to ensure safe produce. This general guidance is essential as a foundation for more specific GAP/GMPs for various commodities. As we consider the broad spectrum of a food safety system, general guidance is usually the first consideration. However, specific GAPs/GMPs are very appropriate and often essential for those foods where individual HACCP systems are not warranted. GAP/GMPs for individual commodities can provide tailored guidance for reducing the potential for microbial contamination, e.g., the minimum time between manure application and harvest, the best type of irrigation system to use, specific harvesting practices (e.g., picking berries or melons), or recommendations for transporting specific commodities. So, additional GAP/GMP guidance documents will be developed that are tailored to reducing the risk of specific commodities.

**Supporting Information:** Domestic commodity data provided by USDA includes specific commodities produced, the form (whole or processed) and the quantities produced. FAS has available, as part of its ongoing trade reporting system, data on fruits and vegetables imported into the U.S. and some commodity specific reports for selected countries. Information about the current agricultural practices, about currently used handling and transportation practices, as well as processing and packaging techniques, and information about products associated with foodborne illness outbreaks will also be used. Both USDA and FDA have some data on current agricultural and manufacturing practices which they will provide. Country information (such as copies of food safety legislation and regulation affecting production, handling, and storage of produce) useful in identifying current production and processing practices in foreign countries will be provided by FAS. This information will be used to direct and support decisions to develop specific GAP/GMP guidance documents.

**Selection of Commodities:** Options are being explored for the most efficient way to provide the

industry with guidance that is effective, and yields the most benefit from the resources expended. Among the options under consideration are:

- Industry organizations will voluntarily work with FDA and USDA to develop specific GAPs/GMPs as guidance for commodities they represent.
- Commodities for which specific GAPs/GMPs will be developed will be selected through a public process. FDA will publish a notice in the Federal Register announcing our intention to develop guidance for specific commodities and the criteria to be used in the selection. This notice will ask for information to guide the selection.
- The competitive grant mechanism available through CSREES will be used to provide funding for academic institutions in different regions of the country to develop commodity-specific GAPs/GMPs.
- Other approaches that will provide targeted guidance to the produce industry in a timely manner.

Whichever option is chosen for development of specific GAP/GMP guidance, some basic factors will be considered in selecting the commodities. These include the potential hazards associated with the commodity and whether or not microbe-specific methods (e.g., identification, detection, enumeration, and/or sampling technique) exist to ensure an appropriate level of public health protection. With these criteria, *Cyclospora* is not an appropriate choice for a specific GAP. The potential public health impact of the commodity, considering points such as the volume of the commodity produce, and the primary consumer group (e.g., young children, the elderly, the population in general).

Regardless of the option chosen for selecting commodities for which to develop individual GAP/GMP guidance, a FDA/USDA committee will oversee development of the documents which will undergo scrutiny in the FDA public review process. This process entails publication of the draft documents in the Federal Register, receipt and evaluation of comments, revision of the documents according incorporating information in the comments, and publication as a final guidance document.

**Agencies Responsible:**   Lead:     FDA  
                                  Support:  USDA (CSREES, AMS, ARS, NRCS, NASS, ERS),  
                                                  EPA, DoL (OSHA), CDC

**Timeline:**               It is anticipated that development of the specific guidance by the agencies will be available to the produce industry during 1998. If the CSREES grant process is used for development of the specific guidance documents, it is anticipated that the grant process will begin in May, 1998 and conclude with

grant awards in October, 1998. Draft documents will be developed during 1999 and will undergo the FDA public review process beginning in 2000.

#### **IV. Focussed inspections of production and processing operations and testing to areas of highest risk and monitoring adoption of GAP/GMP guidance.**

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

FDA will continue its fresh fruit and vegetable inspection and testing program at current levels for domestic and imported produce. Additional resources (additional funding from the FY99 budget) will be focussed on sampling products from producers that have not adopted GAP/GMP guidance, domestic or foreign.

***Monitoring:*** The USDA and FDA will use survey techniques to determine the effectiveness of the GAP/GMP program and the extent of adoption of the guidance in both the domestic and foreign industry. 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 GAP 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 thorough, survey on practices will be conducted at a later date. All of this information - from the surveys and other sources - will be used to monitor adoption of the GAP/GMP guidance and to make necessary adjustments in the GAP/GMP program, including the guidance. (The extent of this work is contingent on additional funding in the FY99 budget.)

**Agencies Responsible:**      Lead:      FDA  
                                         Support:    USDA (ORACBA, ERS, FSIS, ARS, AMS, FAS),  
                                                              EPA, CDC

**Timetable:**      FDA's inspection and sample collection and analysis activities are ongoing.  
                         Increased inspection and testing efforts are budget dependent. The monitoring activity will begin in FY98, dependent on funds available.

#### **V. Accelerated food safety research.**

Successful implementation of an initiative, such as this, relies heavily on scientific research to develop intervention and prevention strategies to prevent foodborne illness. Research will

support development of improved detection methods useful in a variety of environments to conduct longterm surveillance and monitoring of both domestic and imported produce, development of control and prevention strategies to augment use of GAP/GMP, and to develop GAP guidance that accommodates specific needs imposed by environmental factors (e.g., water quality, manure management, worker hygiene).

FDA and USDA both have extensive 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 also have research programs underway focused on water quality and manure management.

FDA and USDA are individually and collectively reviewing their respective FY98 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 Department of Defense, the Department of Energy, the National Science Foundation, and the National Institutes of Health. In addition, the agencies have met with industry and consumer representatives to determine what food safety research outside the government is currently ongoing or in the developmental stages and, from this outside perspective, identify research needs.

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, in particular manure management and maintenance of water quality; and use of post-harvest treatments, such as antimicrobial agents in wash water, to reduce levels of unavoidable microbial contamination. NIH will put out a call for research proposals in these and other related areas.

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

**Agencies Responsible:** Lead: FDA and USDA (ARS, CSREES, ERS)

Support: EPA, NIH, DoD (Natick Labs)

**Timetable:** The process of reviewing research related to safety of fresh fruits and vegetables was initiated in September, 1997. A research plan delineating fresh fruit and vegetable-related research being accelerated, will be available in early 1998 .

| Federal Food Safety Agency: Agencies Currently with Food Safety Activities                             |                                                                                                                                                                                                                                 |                                                                                                                                                                   |                                                                                                                                                                                                                                                                         |                                              |                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Agency                                                                                                 | Current Food Safety Responsibility                                                                                                                                                                                              | Authorizing Statute/<br>Relevant Cmtes.                                                                                                                           | FY 1998<br>Budget (in<br>millions)                                                                                                                                                                                                                                      | Recommendation                               | Rationale                                                                                                                                                                                                                                                                |
| <div>15</div> <b>HHS/FDA:<br/>Center for<br/>Food Safety<br/>and Applied<br/>Nutrition<br/>(CFSAN)</b> | <i>Franks/Vegh</i><br>Regulates all food (except meat, poultry, and egg products) to ensure that it is wholesome, unadulterated, and properly labeled.<br><br>Also responsible for the safety and proper labeling of cosmetics. | <i>Statute:</i> Food, Drug, and Cosmetic Act<br><br><i>House:</i> Commerce<br><br><i>Senate:</i> Labor and Human Resources, Agriculture Appropriations Committees | \$220 M in appropriated BA and 2,342 FTEs.<br><br>\$3.6 M in user fees for the certification of color additives.<br><br>Note: Total FDA appropriated BA is \$925 M and 8,503 FTEs. Total program level is \$1,038 M and 9,288 FTEs which includes \$113 M in user fees. | Include as part of a new food safety agency. | <i>aw</i><br>The agency's primary responsibility is food safety inspections, food research and risk assessment, and education. These activities, along with the safety standards and inspections of meat and poultry, would comprise the core of any food safety agency. |
| <b>HHS/FDA:<br/>Center for<br/>Veterinary<br/>Medicine<br/>(CVM)</b>                                   | Regulates the manufacture and distribution of drugs and feed additives intended for animals.                                                                                                                                    | <i>Statute:</i> Food, Drug, and Cosmetic Act<br><br><i>House:</i> Commerce<br><br><i>Senate:</i> Labor and Human Resources, Agriculture Appropriations Committees | \$44 M in appropriated BA<br><br>403 FTEs.                                                                                                                                                                                                                              | Include as part of a new food safety agency. | The agency's primary responsibility is the approval of animal drugs and feeds, a major component of food safety.<br><br><i>does drug research / consumer groups would like</i>                                                                                           |

\* GAO also includes activities of the Treasury's Bureau of Alcohol, Tobacco, and Firearms, Treasury's Customs Service, and the Federal Trade Commission in their list of Federal food safety agencies.

like FDA  
for animal.

Perhaps leave drug approval  
for FDA or FDA pass this

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

| Agency                                                                              | Current Food Safety Responsibility                                                                                                                                                                                                                                                                  | Authorizing Statute/<br>Relevant Cmtes.                                                                                                                                                            | FY 1998<br>Budget (in<br>millions)                                      | Recommendation                              | Rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>USDA: Food<br/>Safety<br/>Inspection<br/>Service<br/>(FSIS)</b>                  | Regulates meat, poultry, and egg products to ensure that they are wholesome, unadulterated, and properly labeled<br><br><i>Inspector in slaughter house &amp; products</i>                                                                                                                          | <i>CFR 92</i><br>Statutes: Federal Meat Inspection Act, Poultry Products Inspection Act, Egg Products Inspection Act<br><br>House/Senate: Agriculture<br><br>Agriculture Appropriations Committees | \$589 M in appropriated BA<br><br>\$94 M in user fees<br><br>9,895 FTEs | Include as part of a new food safety agency | Setting standards and performing food safety inspections are the agency's primary responsibility.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>USDA:<br/>Agricultural<br/>Research<br/>Service<br/>(ARS)</b>                    | Performs food safety research, such as developing ways to detect and control bacterial contamination of foods<br><br>→ home part                                                                                                                                                                    | Statute: Organic Act of 1862, Research and Marketing Act of 1946<br><br>House/Senate: Agriculture<br><br>Agriculture Appropriations Committees                                                     | approx. \$50 M in appropriated BA<br><br>150 FTEs                       | Include as part of a new food safety agency | <i>NPR - inspection</i><br>This funding, in addition to the research funding provided through FDA's programs, would support the pre- and post-harvest research necessary to support the agency's regulatory and education activities.<br><br><i>Data confusion</i>                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Commerce:<br/>National<br/>Oceanic and<br/>Atmospheric<br/>Admin.<br/>(NOAA)</b> | Provides voluntary inspection and certification services for fish and fishery products on a fee-for-service basis. Services address safety, wholesomeness, quality, and proper labelling of fishery products. Inspected products can carry a DOC mark indicating compliance with Federal standards. | Statute: Agricultural Marketing Act<br><br>House: Resources<br><br>Senate: Commerce<br><br>Commerce Appropriations                                                                                 | \$700,000 in appropriated BA<br><br>\$13M in user fees<br><br>190 FTE   | Include as part of a new food safety agency | The agency contains the seafood inspection/products expertise that FDA needs to meet HACCP requirements. In order to gain efficiencies, NOAA and FDA are currently developing a legislative proposal to transfer NOAA'S National Marine Fisheries Service (NMFS) to FDA (as a PBO). The voluntary inspection program would continue, but NMFS inspectors would also be available for use by FDA to conduct inspections within its mandatory/regulatory program. NMFS' seafood expertise would be important to a new food safety agency, and inclusion in the new agency would avoid duplicative programs on labelling, wholesomeness, etc. |

→ could mandate close down.  
→ civil penalties

→ OSTEP + want to add.  
quick to kill  
RF - think should have R&D adm.

*Seafood*

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

| Agency                              | Current Food Safety Responsibility                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Authorizing Statute/<br>Relevant Cmtes.                                                                                                                                                                                                                                                                                                                               | FY 1998<br>Budget ( in<br>millions)                                                                                                                                                                                  | Recommendation                                      | Rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>EPA –<br/>Drinking<br/>Water</b> | <p>Regulates drinking water to ensure that it is safe to drink. Conducts research to support standards.</p> <p>Regulates injection of contaminated water into underground wells to protect drinking water wells.</p> <p>Provides Drinking Water State Revolving Funds (DW SRFs) capitalization grants to states for infrastructure upgrades and state programs.</p>                                                                                                                  | <p><i>Statute:</i> Safe Drinking Water Act</p> <p><i>House:</i> Commerce, Science and Transportation (partial), Infrastructure (partial)</p> <p><i>Senate:</i> Environment, Public Works</p> <p>VA/HUD Appropriations subcommittees</p>                                                                                                                               | <p>\$149 M in BA for regulation, research and enforcement, \$105 M of which goes to States as grants to run drinking water and related programs.</p> <p>\$725 M for DW SRF capitalization grants.</p> <p>941 FTE</p> | Do not include as part of a new food safety agency  | <p>The Administration and Congress just reformed this program, with passage of the 1996 SDWA Amendments, and the reforms seem to be working. Program implementation is very different from the other programs under consideration because the drinking water program is primarily implemented by the States with EPA grant money. There is also a large Federal assistance component in the DW SRF. EPA would lose significant economies of scale in the administration of the Drinking Water and Clean Water SRFs if they were separated. At the same time, the DW SRF needs input from the drinking water program on project prioritization based on public health goals. Protection of drinking water sources is an environmental issue and has synergies with EPA's Clean Water Act programs.</p> |
| <b>EPA –<br/>Pesticides</b>         | <p>Evaluates the risks to public health and the environment from pesticide active and inert ingredients.</p> <p>Sets the terms and conditions for the sale, use, and labeling procedures for food/feed-use and nonfood-use pesticides.</p> <p>Sets pesticide worker protection standards, provides certification and training, works with USDA, FDA, and pesticide users to reduce pesticide risk and use, and promotes international harmonization and regulatory coordination.</p> | <p><i>Statute:</i> Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal Drug, and Cosmetic Act. (FFDCA), and Food Quality Protection Act of 1996 (FQPA) amending FIFRA and FFDCA.</p> <p><i>House:</i> Agriculture, Commerce</p> <p><i>Senate:</i> Agriculture, Labor and Human Resources</p> <p>VA/HUD and Agriculture Appropriations Committees</p> | <p>\$118 M<br/>(Total for all pesticide program activities)</p>                                                                                                                                                      | Do not include as part of a new food safety agency. | <p>how pesticide effect environment &amp; food.</p> <p>It would be difficult to separate EPA's tolerance setting activities for food-use active ingredients from other registration, reregistration, and cross-cutting activities. EPA is currently implementing the requirements of the new law.</p> <p>FDA does monitoring.<br/>Dobin's bill does include.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                      |

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

| Agency                                                                      | Current Food Safety Responsibility                                                                                                                                                                                                                                                                                                                                                                   | Authorizing Statute/<br>Relevant Cmtes.                                                                                                                                   | FY 1998<br>Budget ( in<br>millions)                                                                                                             | Recommendation                                                                  | Rationale                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>HHS: Center<br/>for Disease<br/>Control and<br/>Prevention<br/>(CDC)</b> | <p>Gives grants to State and Local Health Departments to conduct surveillance and investigate causes of human foodborne disease.</p> <p>Funds help link 8 "FoodNet" state laboratories via computer technology with CDC labs to conduct "digitized" fingerprinting of foodborne pathogens.</p> <p>Conducts research, trains epidemiologists and coordinates investigations of disease outbreaks.</p> | <p><i>Statute:</i> Public Health Service Act</p> <p><i>House:</i> Commerce</p> <p><i>Senate:</i> Labor and Human Resources</p> <p>L/HHS Appropriations Subcommittees.</p> | Of the \$115 million appropriated for infectious disease activities, <b>\$15 million</b> is designated for <b>Foodborne Disease</b> activities. | Do not include as part of a new food safety agency.                             | <p>As part of its overall infectious disease program activities, CDC awards grants to States to conduct surveillance and epidemiology of a variety of diseases including foodborne diseases, emerging infections and waterborne diseases. States conduct foodborne disease surveillance in concert with these other related surveillance activities. We recommend maintaining these functions within CDC given this structure and its longstanding relationship with State and local health departments.</p> <p><i>hard to split out</i></p> <p><i>does good job.</i></p> |
| <b>USDA:<br/>Agricultural<br/>Marketing<br/>Service<br/>(AMS)</b>           | <p>Pesticide data program (PDP) determines residue levels in food</p> <p><i>Stark</i></p> <p><i>W. J. 1/1/97</i></p>                                                                                                                                                                                                                                                                                 | <p><i>Statute:</i> Agricultural Marketing Act of 1946</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>                            | PDP: \$10M in appropriated BA                                                                                                                   | <p><i>Include</i></p> <p>Do not include as part of a new food safety agency</p> | <p><i>include M.C.D. - halogen</i></p> <p>Pesticide programs are not recommended for inclusion in new agency</p> <p><i>Survey max level</i></p> <p><i>Sample work (5/12/97)</i></p> <p><i>RT</i></p>                                                                                                                                                                                                                                                                                                                                                                      |
| <b>USDA:<br/>Grain<br/>Inspection</b>                                       | <p>Determines levels of aflatoxin and vomitoxin as part of inspection process</p>                                                                                                                                                                                                                                                                                                                    | <p><i>Statute:</i> Agricultural Marketing Act of 1946, U.S. Grain Standards Act</p> <p><i>House/Senate:</i> Agriculture</p> <p>Agriculture Appropriations Committees</p>  | Aflatoxin and vomitoxin testing is funded through user fees, as one of several charges to users                                                 | Do not include as part of a new food safety agency                              | <p>This is an integral part of the overall activities of this agency, and is only one of many tests that are given.</p> <p><i>eg. us. applied</i></p> <p><i>get authority on food aspect not ag.</i></p>                                                                                                                                                                                                                                                                                                                                                                  |

**Federal Food Safety Agency: Agencies Currently with Food Safety Activities**

| Agency                                                                              | Current Food Safety Responsibility                                   | Authorizing Statute/<br>Relevant Cmtes.                                                                                                                                               | FY 1998<br>Budget ( in<br>millions)         | Recommendation                                           | Rationale                                                    |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------------------------------|--------------------------------------------------------------|
| <b>USDA:<br/>Animal and<br/>Plant Health<br/>Inspection<br/>Service<br/>(APHIS)</b> | Ensures safety of animal and<br>plant resources from<br>infestations | <i>Statute:</i> many,<br>including the Organic<br>Act of 1944 and the<br>1990 Farm Bill<br><br><i>House/Senate:</i><br>Agriculture<br><br>Agriculture<br>Appropriations<br>Committees | \$0 for direct<br>food safety<br>activities | Do not include as<br>part of a new food<br>safety agency | There is no immediate direct connection with food<br>safety. |

## Clinton Administration Food Safety Accomplishments

- 1993    USDA proposes **Safe Food Handling Labels** for meat and poultry products.
- 1993    Administration announces **Safe Drinking Water Act** reauthorization principles.
- 1993    **NPR recommends creating a single food safety agency**
- 1994    Administration proposes **Pesticide Reform Act of 1994**. This reform initiative was developed collaboratively by an interagency policy group including EPA, USDA, FDA, and other stakeholders to address the Delany Clause problem and the recommendations of the 1993 National Academy of Sciences report on procedures to improve pesticide regulation to better assure that children are fully protected from pesticide risk.
- 1994    USDA proposes **Pathogen Reduction Act**, which includes authority for mandatory recall, traceback, civil penalties, and the designation of foods not handled in a way to destroy pathogens as adulterated.
- 1995    **EPA reinvents Drinking Water Program** to reorient to the highest public health risks, using administrative authorities and renegotiating consent decrees.
- 1995    **FDA Seafood HACCP** final rule is published.
- 1996    Administration and Congress reauthorize the **Safe Drinking Water Act**. The new law includes most of the Administration's principles and reinvention activities to address highest risks.
- 1996    **The Food Quality Protection Act of 1996 (FQPA)**, unanimously passed by Congress, is signed.
- 1996    **USDA Meat and Poultry HACCP program** final rule is published.
- 1997    **President's Food Safety Initiative** is announced. USDA, HHS, and EPA draft a report to the President with a plan to improve food safety that includes budget, regulatory and legislative proposals.
- 1997    FDA publishes **Substances Prohibited from Use in Animal Feed, Animal Proteins Prohibited in Ruminant Feed (Mad Cow Disease Rule)**; final rule.
- 1997    FDA publishes the **Fruit and Vegetable Juice Beverages HACCP program**, Interim Warning Statement, and Educational Program; notice.
- 1997    USDA proposes "**The Food Safety Enforcement Enhancement Act of 1997**" to strengthen its enforcement authority by allowing for mandatory recalls and civil penalties in response to the voluntary recall of 25 million pounds of hamburger.
- 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.

## **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.

By JEFFREY KLUGER

**T**AMMY LOWERY COULDN'T SEE THE BLOOD vessels rupturing in her gut, but the way she was feeling, she didn't have to. Lowery had been sick for five days, growing steadily worse as the week wore on. First had come the stomach pains. Then the bloody diarrhea. Then the paralyzing cramps. She had laid off food for a while, figuring the problem would pass. It didn't. Finally, as July 4 approached—when Lowery should have been at the Alpine, Wyo., gift shop where she works, preparing for the crush of campers and tourists who make the Independence Day weekend such a busy one—she noticed that her son Sean, 5, had come down with the same symptoms.

That did it. Struggling to get to the car, Lowery drove Sean to the office of Dr. Donald Kirk, a physician who serves many of Alpine's 470 year-round residents. She got there just in time; shortly after she walked into Kirk's waiting room, Lowery passed out on the floor.

On Friday of the same weekend in late June that Lowery started feeling wobbly, a young motorcyclist who lives in a nearby town was passing through Alpine. Dropping in on some friends, he gulped two glasses of water drawn straight from an Alpine tap. Before too many more days had passed, he realized that he was falling seriously ill.

**DON'T DRINK THE WATER**  
CDC sleuth Breuer tests  
a suspect spring for  
the mutant *E. coli*

# ANATOMY OF AN OUTBREAK

There's a deadly microbe loose on  
the land, and medical detectives  
are hot on its trail.

PHOTOGRAPHS FOR THIS ARTICLE BY E. LISS

# KILLER BACTERIA/E. COLI O157:H7

of Alpine, members of the Scott family were driving in from all over the northwest. The Scotts had been planning a reunion in Alpine for months, and on June 26, a Friday, 43 of them showed up. They spent the weekend picnicking, playing touch football and rafting on the Snake River. Like most families planning a weekend outdoors, they brought their own food along. The Scotts didn't like Wyoming water, so they brought their own water too. But the kids filled their squirt guns from a faucet and took a few sips from the barrel ends of their water pistols, and the adults began to drink from the tap when they ran out of bottled water. If there was something seriously wrong with Alpine water, they couldn't tell by the taste.

**R**EGARDLESS OF HOW ALPINE'S water tasted, there was in fact something grievously—perhaps lethally—wrong with it. That something was a particularly dangerous strain of the *E. coli* bacterium called *E. coli* O157:H7, or O157 for short. Ordinarily a benign organism found in the intestines of human beings and animals, *E. coli* has a nasty ability to mutate and proliferate. Lately it has been proliferating with a vengeance. Five years ago, the fast-food industry was rocked when four children died and 500 other people fell ill after eating *E. coli* O157-contaminated hamburgers at Jack in the Box restaurants across the Pacific northwest. Massive as that outbreak seemed at the time, it was, for the bacterium, merely a shot across the bow.

In the half-decade since, there have been as many as 30 *E. coli* outbreaks each year in the U.S., resulting in thousands of very ill people and hundreds of lost lives. In the past seven months, new outbreaks have been reported in Indianapolis, Ind.; Milwaukee, Wis.; Washington; and Chicago. Americans have grown sick after eating ground beef, coleslaw, cheese and various fruits. Just last week California-based Odwalla Inc. pleaded guilty to violating federal food-safety laws and agreed to pay a \$1.5 million fine for selling a batch of contaminated apple juice that sickened 70 people and killed a 16-month-old girl in 1996. With the country sweating through one of the hottest summers on record, such problems are likely to grow, as more people cook outside, eating too rare hamburger, unwashed fruit and other foods that have been mishandled or badly prepared.

Making matters worse, some people are getting *E. coli* infections without eating any food at all. In Spokane, Wash., last winter, seven children in a day-care center

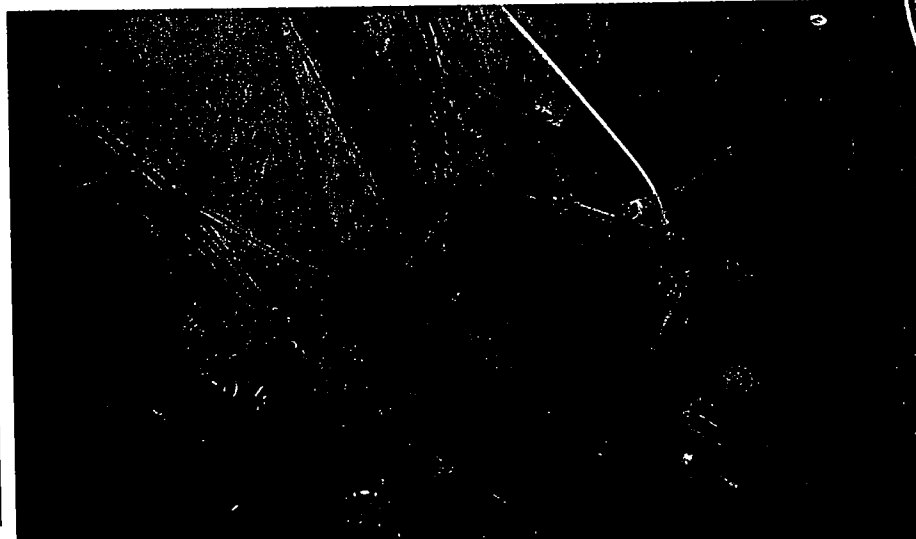
ed sand, soil and modeling clay. In June, 26 kids, including the three-year-old son of Atlanta Braves shortstop Walt Weiss, contracted the bug in a pool at a Georgia water park. Brody Weiss recovered in time to watch his dad play in the All-Star game. One of the other children in the water park that day, two-year-old McCall Akin, developed kidney complications and died last week. In all, some 20,000 people in the U.S. suffer *E. coli* infections each year, 250 of them fatally.

If there is any seawall against the spread of *E. coli*, it's the epidemiologists from the Centers for Disease Control and

who make it their business to monitor all serious disease outbreaks, from swine flu to salmonella to HIV. It's the job of those scientists to track the pathogen back to its source, where it can be eradicated or—at the very least—studied, and to spot weaknesses in the public health system that will help them prevent future outbreaks. The medicine these doctors practice is less academic than it is forensic, relying on both high-tech hardware and old-fashioned shoe leather. When the size of the epidemic grew beyond the money and staff available to the Wyoming experts, they called the CDC for reinforcements.



A downed fence may have allowed animals into the Alpine springs



Traces of contamination may have been left in the pumping station

ery collapsed in his waiting room that he had a problem on his hands. A cursory examination of the Lowerys told him two disturbing things: he had never seen symptoms like these before; and, unfamiliar as he was with the symptoms, he was pretty sure *E. coli* was to blame. Kirk dispatched Tammy to the hospital in nearby Afton and then began to work the phone.

Canvassing the other doctors who serve the area, he learned that in the past few days, six people in Alpine had come down with the same symptoms. In Jackson Hole, also close by, two other Alpine residents had been hospitalized. Only mo-

re Jackson Hole patients confirmed that the victims were carrying not only *E. coli* but also the deadly—if prosaically named—O157:H7 strain. With that, Kirk made one more call, to Donn Wooden, the mayor of Alpine. “We have a real potential health problem in the community,” Wooden recalls Kirk telling him.

A problem indeed. Of all the bacteria that bloom in the body, *E. coli* is usually one of the most beneficial, helping to metabolize food in the intestine. In 1982, however, scientists discovered that *E. coli* wasn’t always so benign. That year 26 people in Oregon were felled by a violent in-

doctors analyzed the bug behind the illness, they found that it was all but indistinguishable from ordinary *E. coli*, with but a small exception: this breed of the bacterium contained a few strands of genetic rewiring that cause it to produce a powerful toxin its less potent kin can’t.

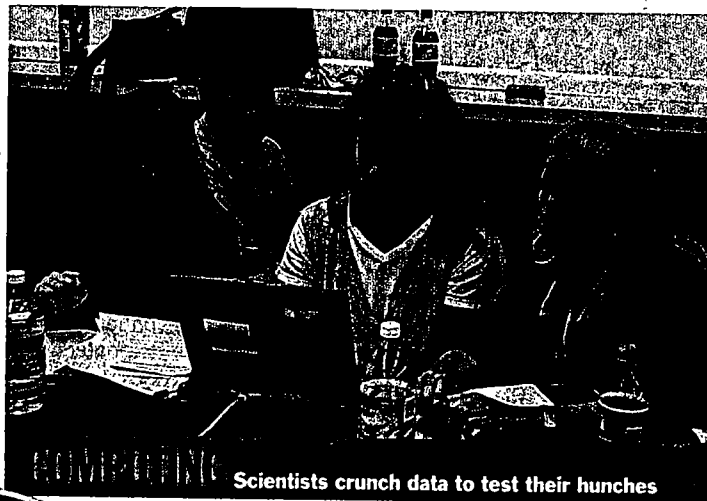
When this fortified *E. coli*, which researchers dubbed the O157:H7 strain, takes hold in the body, it behaves savagely. Doctors believe the bacterial toxin first destroys blood vessels in the intestines, which accounts for the bloody diarrhea that is the signature symptom of the infection. The toxin then passes into the bloodstream, where it probably damages vessels throughout the body. This produces gummy clots that clog organs like the kidneys. Up to 5% of all people with O157 infection develop a kidney condition known as hemolytic uremic syndrome; up to 5% of all HUS cases are fatal. The clotting caused by *E. coli* can also damage the heart, the lungs and even the central nervous system.

Certainly, O157 *E. coli* is not an easy bug to pick up. It’s not an airborne pathogen like a flu virus, and it can have an ill effect only if it’s ingested. The vast majority of people who do come down with the infection survive if they are kept hydrated and, in some cases, hospitalized. But up to 1% do die—mostly children, the elderly and people with compromised immune systems. In all cases, antibiotics are not only useless but may actually make things worse, causing the bacteria to rupture and spill their toxin even more widely throughout the gut. Says Nancy Donley, a safe-food activist whose son died of *E. coli* infection: “We’re not talking about minor gastrointestinal distress. It is a brutally ugly death.”

When Dr. Kirk got Mayor Wooden on the phone, he told him that they had a serious public health threat on their hands. Wooden didn’t need to have his arm twisted. “If it’s a real problem,” he said, “let’s deal with it.”

For Kirk, dealing with the problem next meant reporting the outbreak to the county infectious-disease nurses, who in turn reported to Gayle Miller, Wyoming’s chief epidemiologist. Miller and her nurses knew immediately that even six cases meant an epidemic. They began canvassing the region to locate others who had been infected, and each time they found someone sick, they began interviewing that person, looking for a common source of infection. After a week they had 26 confirmed *E. coli* cases in four states, and the numbers seemed likely to grow.

A contagion this big was beyond the state’s capabilities, and at 3:30 p.m. on July 9, Miller sent e-mail to CDC headquar-



Scientists crunch data to test their hunches



# KILLER BACTERIA/E. COLI O157:H7

ters in Atlanta, asking that a group of scientists from the centers' Epidemic Intelligence Service—the SWAT team of infectious medicine—be sent to Wyoming. For epidemiologists, a billet in the EIS is a much coveted post. Researchers compete vigorously for the few available spots, and when a position is granted, the tenure lasts just two years. After that, EIS investigators are encouraged to seek work in the same field at the local level. Miller had been an EIS member, and when she called in the CDC, she knew she would get the best. "We speak the same language," she says.

Early the next morning, a three-member EIS team arrived in Alpine and set up shop in the town's city hall, an unlovely, one-room structure used for basketball games, karate classes, the occasional play and, when absolutely necessary, running the local government. The leader of the federal team was Thomas Breuer, a 37-year-old German physician in his second year as an EIS researcher. Working with him were Sonja Olsen and Malinda Kennedy.

Breuer, a veteran of four previous infectious-disease outbreaks, appreciated the enormity of the job ahead of him. Miller's nurses had turned up no food or other contaminant all the victims had



**DIED** McCall Akin, 2, contracted *E. coli* in the same Atlanta water park as Brody Weiss, below. She developed kidney complications and died last week

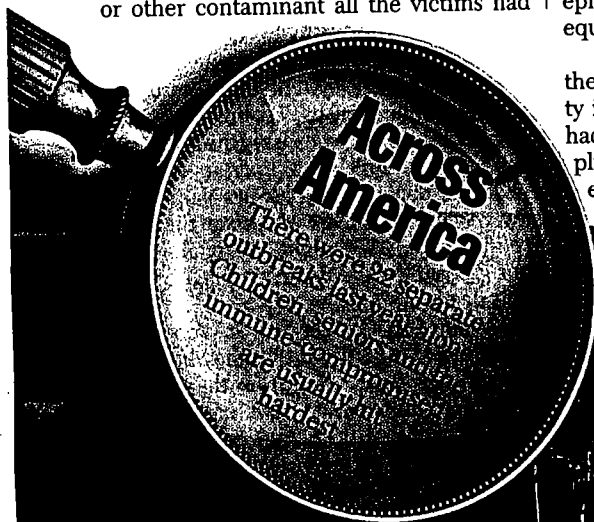
shared. This left only two possibilities: "Water and air," Breuer says, "two things epidemiologists hate." A contamination of this kind was a hit-and-run affair; the bacterial colonies could stream into a community, do their damage and flow out of the ecosystem in a matter of days, before the epidemiologists could even get their equipment unpacked.

Once Breuer, Olsen and Kennedy got themselves set up, they found a community in a state of high alert. Mayor Wooden had already switched the Alpine water supply from the natural springs to a chlorinated well system and instructed townspeople

to boil water before drinking it. Residents brought the CDC researchers ice that might be needed to keep stool samples cool during the eight-hour drive from Alpine to the state laboratory in Cheyenne. The phone company provided extra telephone lines for the duration of the crisis.

Breuer, Olsen and Kennedy quickly made use of those lines, spending the next several days phoning people who had already got sick, who might be getting sick or who had remained uninfected, looking for anything they did—or didn't—have in common. The calls turned up some promising leads. One woman worked in an Alpine day-care center and routinely drank eight glasses of tap water a day and even gave some to her infant daughter. Yet both of them were healthy. That seemed to exonerate the water supply, until the woman added one final detail. When she is home on the weekends, she told Kennedy, she drinks only from her own well. It was during the last weekend in June that many victims said they began feeling sick. By avoiding town water on those days, the woman and her daughter might have dodged an infectious bullet. If the water supply was in fact contaminated, this one clue might help pinpoint just when the bug was present.

Expanding the scope of their calls, the EIS team turned up the motorcyclist who had passed through town long enough for his two-glass dose of local water on Friday, June 26. In the days since, he had developed a confirmed O157 infection. Because *E. coli* can be passed by touch from one



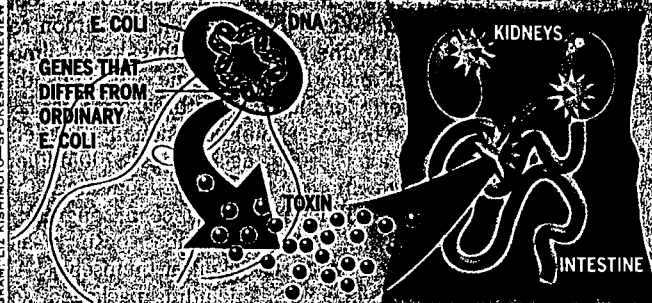
**GEORGIA** In June kids playing in a pool at this Atlanta water park contracted *E. coli*, perhaps from a child with a leaky diaper. Brody Weiss, right, three-year-old son of Atlanta Brave Walt Weiss, was infected but recovered in time to watch his dad play in the All-Star game

**NUMBER INFECTED**

**THE SOURCE**



## WHAT MAKES THIS E. COLI SO BAD



1. Unlike ordinary *E. coli*, the strain O157:H7 has extra genes that allow it to stick to the walls of the intestine and produce the virulent Shiga toxin.
2. The toxin injures cells in the intestinal wall as well as blood vessels in the intestine, leading to bleeding.
3. Once in the bloodstream, the toxin damages other blood vessels, particularly those in the kidneys, leading to renal failure.

TIME Diagram by Joe Lertora

## OTHER BUGS TO WATCH FOR THIS SUMMER

| Bug                           | Source                                              | Symptoms                                                       |
|-------------------------------|-----------------------------------------------------|----------------------------------------------------------------|
| <i>Campylobacter jejuni</i>   | Poultry, milk, untreated water                      | Chiefly diarrhea, sometimes paralysis                          |
| <i>Salmonella</i>             | Eggs, poultry, meat, fresh produce                  | Severe dysentery; Long-term chronic arthritis                  |
| <i>Listeria monocytogenes</i> | Cheese, deli cuisine, pâté, etc.                    | Fever, headache, vomiting, meningitis, stillbirths             |
| <i>Cryptosporidium parvum</i> | Recently contaminated water and food                | Diarrhea; In AIDS patients may be chronic or lethal            |
| <i>Vibrio</i>                 | Shellfish from warm water areas                     | Varies from flulike symptoms to shock and death                |
| <i>Trichinella</i> (a worm)   | Undercooked or raw pork (also walrus and bear meat) | Flulike symptoms that can lead to heart and breathing problems |

Source: CDC, FDA

person to another before it's unknowingly ingested, it was possible that he had picked up the bug from one of his friends in Alpine. But the water-bacteria link was too promising to ignore. Breuer also contacted LaFonda Scott, the woman who had organized the family reunion in Alpine. Scott reported that she and several of her relatives had tested positive for O157. Over the next few days, Breuer interviewed 41 of the 43 Scotts who had visited Alpine and came up with some sobering numbers. None of those who had avoided the local water were ill. Of those who had drunk even a few sips, half had become infected.

By now the Alpine outbreak had spread to 13 states—or at least it seemed to have. Thirteen states could also mean 13 separate outbreaks. Earlier this year, the CDC took a step to eliminate such uncertainty, employing an innovative network of biotech machines called PulseNet. The hardware allows scientists to scan a bacterium and come up with a sort of genetic fingerprint unique to that cell line. Studying samples of the Wyoming *E. coli* as well as bugs from the surrounding states, the EIS researchers discovered that their profiles matched perfectly. The Alpine infection, it appeared, was indeed widespread.

The EIS team had been in Wyoming for a week, and the database they had compiled was enormous. On the evening of Thursday, July 16, they gathered in the city hall to enter all the findings into their laptop computers and see what conclusions they could draw. Their early observations and calculations all pointed to Alpine's water, but they had not yet run any final statistical analyses, and they knew not to draw conclusions before all the tallies were in. Says Breuer: "I'm always worried before we look at the numbers."

The three investigators worked those numbers late into the night, bending over

### INDIANA

The trail in this fast-food outbreak led to a cabbage patch in Texas

NUMBER INFECTED 27

THE SOURCE



### WISCONSIN

A single dairy plant shipped bad cheese to three counties

NUMBER INFECTED 63

THE SOURCE



### WASHINGTON

Sick children became carriers, bringing *E. coli* into their homes

NUMBER INFECTED 9

THE SOURCE



# KILLER BACTERIA/E. COLI O157:H7

overhead and their forgotten dinner—a pineapple-and-bacon pizza—grew rubbery and congealed. Over the course of hours, graphs and tables flashed on the screen and streamed from the printer in a growing pile. Finally, Breuer was ready to ask the computer his final questions.

From the data that had been compiled, he inquired, was there any statistical link between eating hamburgers and the current O157 infection? No, the computer answered. What about venison? No. Beef jerky? No. Any relationship between contact with cattle and the appearance of the disease? Again, no. At last, Kennedy tapped the commands asking the computer about a link between Alpine tap water and *E. coli*. The researchers leaned in as the question was processed and the numbers were tallied. After a long moment, the screen began to fill with numbers.

"Wow," someone said. "What a relief," someone else echoed.

A person who drank Alpine tap water, the computer reported, was eight times as likely to become infected with *E. coli* O157 as someone who didn't. Someone who was in town during that weekend in June was 14 times as likely. Testing the reliability of the numbers, the computer concluded that if the same study were conducted 10,000 times, those results would appear by chance only nine times. "Which is nice," Breuer said. "Which is very nice."

How the bug got into the Alpine water supply was anybody's guess, but the EIS team had an idea. The winter storms around the town had been fierce enough in the early part of the year to topple fences erected to keep animals away from the springs. If even a single animal did wander in, any feces it left behind could have been washed into the water supply by spring rains. Bacteria in the feces would have moved through the Alpine pipes in a single foul rush and then drained away. "Once the *E. coli* hit town it was at once everywhere," Breuer says. And then, just as quickly, it was gone.

In the end, 61 people tested positive for the Al-

and an additional 159 were suspected of being infected, making it the largest water-borne outbreak of O157 in the U.S. So far none of the Alpine victims have died; given the bacteria's low but consistent mortality rate, however, that is as much a stroke of luck as anything else.

**H**OPING FOR SIMILAR GOOD FORTUNE in the future is not the best way to fight the microbe. Until a drug treatment is available, the best answer is prevention, and several groups are taking action. Alfalfa seeds, which have been implicated in past *E. coli* outbreaks, are now being irradiated to kill bacteria, and last year the Food and Drug Administration gave the cattle industry the green light to treat meat the same way. The procedure is generally effective, but critics are uneasy, questioning whether it's ever a good idea to irradiate something consumers are intended to ingest.

More effective than cleaning food after it's been contaminated is preventing it from getting dirty in the first place. Already

stricter standards in slaughterhouses and tighter inspection procedures to keep *E. coli*-contaminated meat out of the food chain. While this has been a common refrain in the past after outbreaks of salmonella and other food-borne pathogens, the severity of the O157 outbreaks may at last prod the government into action. President Clinton is proposing a modest \$100 million in new funding to improve food safety, but he is still meeting resistance in Congress.

Until Washington does bestir itself, consumers must look after themselves. All fresh vegetables—including packaged, so-called triple-washed vegetables—should be thoroughly cleaned. Steaks can be safely eaten relatively rare, since *E. coli* is typically found only on the surface of food, and cooking will generally kill it. Hamburger is another matter. Grinding beef distributes bacteria throughout the patty, so the only safe burger is a well-done burger.

For human-to-human infection, common sense is the rule. Hand washing after bathroom trips was a good idea when the fiercest *E. coli* was ordinary *E. coli*; with O157 at large, it's even more important.

Parents should take similar precautions when changing diapers, and diaper-age babies should not go into swimming pools. Even in wading pools, toddlers should wear a water-proof bathing-suit liner.

Apart from these measures, there's not much even the most germ-wary person can do. Eating, drinking and human contact are not optional, and as long as O157 is out there, some people are going to get sick. As long as some people get sick, at least a handful are going to die.

A few weeks after the Alpine outbreak subsided, LaFonda Scott and one of her daughters attended a church luncheon. Still shaky after their battles with the bug, mother and daughter made their way to a nearby table, where seven-year-old Janessa spotted a pitcher of water. Eying it warily, she asked, "Mom, is that safe water?"

Her mother could only reply, "I don't know." —**Reported by Dick Thompson/Alpine**

## HOW YOU CAN AVOID E. COLI

### WHEN YOU'RE SHOPPING

Avoid unpasteurized milk and milk products. Don't buy unpasteurized fruit juice. Keep raw meat separate from ready-to-eat foods.

### WHEN YOU'RE PREPARING FOOD

Wash your hands and all food you are going to eat raw. After handling meat, wash hands, cutting boards and any plates, bowls or utensils with which the meat came into contact. Cook all meat and poultry thoroughly.

### WHEN YOU'RE DINING OUT

Don't order meat—especially hamburgers and other ground meat—rare. In fact, all food, including vegetables, should be well cooked. Avoid unchlorinated water.

### WHEN YOU'RE SWIMMING

Toddlers in diapers shouldn't go in swimming pools. Don't let kids swim if they've had diarrhea. Avoid swallowing lake water while swimming.

GEORGE MATEL—ENVISION; STEVEN NEEDHAM—ENVISION (3)



Sign-in

Food  
7/29/98  
Suker

| <u>Name</u>        | <u>Agency</u> | <u>Phone / fax</u>         |
|--------------------|---------------|----------------------------|
| Dalton Payne       | OPHS/HHS      | 202 205-5829 / 205-9478    |
| Janice Olson       | FOIA/HHS      | 202-205 4307 / 205-5125    |
| Albra Jackson      | CDC/HHS       | 202-690-8598 / 202-690-85  |
| Dana Flower Lake   | OMB/NRD       | 202-395-6826 / 202 395-494 |
| Bruce Sidwell      | EPA/OPP       | 703-305-7761 / 305-5884    |
| Tom Freedman       | WHE           | 202 456-5587 / 456-743     |
| John Mondshine     | USDA/FSIS     | 202 722-4150 / 202-050     |
| Caum Wilcox        | USDA/FS       | 202 720 0350 / 690 0820    |
| Wendy Taylor       | OMB           | 202 395-4815 / 395-6974    |
| Michael Fernandez  | EPA/OPPTS     | 202-260-1843 / 260-1847    |
| Margaret Malanosti | OMB           | 202-395-3122 / 395-7285    |
| KAREN HULBAK       | FDA           | 301 827 0586 / 443 6906    |
| Jean Long          | NPR           | 202 694 0043 / 632 0390    |

PHOTOCOPY  
PRESERVATION

**CSPI** CENTER  
FOR SCIENCE  
IN THE  
PUBLIC INTEREST

---

*Food  
Safety -  
EW*



Publisher of *Nutrition Action Healthletter*

**Caroline Smith DeWaal**

Director, Program on Food Safety

1875 Connecticut Avenue, N.W.

Suite 300

Washington, D.C. 20009-5728

Web Site: [www.cspinet.org](http://www.cspinet.org)

(202) 332-9110, Ext 366

Fax: (202) 265-4954

E-mail: [cdewaal@cspinet.org](mailto:cdewaal@cspinet.org)

## **1998 Budget**

The agreement provides \$420,000 for a study by the National Academy of Sciences on the scientific and organizational needs for an effective food safety system, including functions overseen by the Food Safety and Inspection Service, the Food and Drug Administration, and other Federal, state and local agencies with responsibilities for food safety. The study will be conducted in two phases. The first phase will examine the current mechanisms in place for assuring a safe food supply and the extent to which they are effective in addressing food safety issues from the farm to the table. It will also analyze the extent to which current functions (i.e., inspection, surveillance, monitoring, research, risk assessment, and education) should be assigned or reassigned to existing or independent food safety agency and identify whether any functions would be

compromised by such an action. If an independent food safety agency is recommended, the second phase will develop further guidance to ensure that the food safety system protects the public's health and is cost-effective. A report on the first phase should be transmitted to the appropriate Committee of Congress no later than August 15, 1998.

**United States Senate**  
**Washington, DC 20510-1504**

***Statement of U.S. Senator Richard J. Durbin***

***November 8, 1997***

***Introduction of the Safe Food Act***

Mr. President, today I am introducing legislation that would replace the current fragmented federal food safety system with a consolidated, independent agency with responsibility for all federal food safety activities — the Safe Food Act (S. 1465). I am pleased to be joined by Senator Torricelli in this important effort.

Make no mistake, our country has been blessed with the safest and most abundant food supply in the world. However, we can do better. The General Accounting Office estimates that as many as 33 million people will suffer food poisoning this year and more than 9,000 will die. The Department of Health and Human Services predicts that foodborne illnesses and deaths are likely to increase 10 to 15 percent over the next decade. The annual cost of foodborne illnesses in this country may rise to as high as \$22 billion per year.

According to a Princeton Research survey conducted last summer, 44 percent of Americans believe that the food supply in this country is less safe than it was 10 years ago, while another 30 percent feel it is only "about as safe." The survey also found that 48 percent of Americans are "very concerned" about the safety of the food that they eat.

Currently, 12 different federal agencies and 35 different laws govern food safety and inspection functions. Of these 12 agencies, six have major roles in carrying out food safety and quality activities. With so many bureaucrats in the kitchen, breakdowns can more easily occur. With overlapping jurisdictions, federal agencies many times lack accountability on food safety-related issues. A single, independent agency would help focus our policy and improve the enforcement of food safety and inspection laws.

At a time of government downsizing and reorganization, the U.S. simply can't afford to continue operating multiple systems. In order to achieve a successful, effective food safety and inspection system, a single agency with uniform standards is needed.

The Safe Food Act would empower a single, independent agency to enforce food safety regulations from farm to table. It would provide an easier framework for implementing U.S. standards in an international context. Research could be better coordinated within a single agency rather than among multiple programs. And, new technologies to improve food safety could be approved more rapidly with one food safety agency.

With incidents of food recalls and foodborne illnesses on the rise, it is important to move beyond short-term solutions to major food safety problems. A single, independent food safety and inspection agency could more easily work toward long-term solutions to the frustrating and potentially life-threatening issue of food safety.

The Administration has stepped forward on the issue of food safety — from working with Congress to enact HACCP to increased funding to improve surveillance and monitoring to last week's announcement on the "Fight Bac — Keep Food Safe From Bacteria Campaign" initiative. I commend President Clinton and Secretaries Glickman and Shalala for their commitment to improving our nation's food safety and inspection systems. A single, independent food safety agency is the logical next step.

Mr. President, together, we can bring the various agencies together to eliminate the overlap and confusion that have, unfortunately, at times characterized our food safety efforts. I encourage my colleagues to join me in this effort to consolidate the food safety and inspection functions of numerous agencies and offices into a single, independent food safety agency.

105TH CONGRESS  
1ST SESSION

S. 1465

---

IN THE SENATE OF THE UNITED STATES

Mr. DURBIN introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

---

**A BILL**

To consolidate in a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies.

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.**

4       This Act may be cited as the "Safe Food Act of  
5       1997".

6       **SEC. 2. PURPOSES.**

7       It is the purpose of this Act—

8               (1) to establish a single agency, the Food Safe-  
9       ty Administration, to regulate food safety and label-

1 ing and to conduct food safety inspections to ensure,  
2 with reasonable certainty, that no harm will result  
3 from the consumption of food by preventing food-  
4 borne illnesses due to microbial, natural, or chemical  
5 hazards in food: and

6 (2) to transfer to the Food Safety Administra-  
7 tion the food safety, labeling, and inspection func-  
8 tions currently performed by other Federal agencies.

9 **SEC. 3. DEFINITIONS.**

10 For purposes of this Act:

11 (1) ADMINISTRATION.—The term “Administra-  
12 tion” means the Food Safety Administration estab-  
13 lished under section 4.

14 (2) FOOD SAFETY LAWS.—The term “food safe-  
15 ty laws” means—

16 (A) the Federal Meat Inspection Act (21  
17 U.S.C. 601 et seq.);

18 (B) the Poultry Products Inspection Act  
19 (21 U.S.C. 451 et seq.);

20 (C) the Egg Products Inspection Act (21  
21 U.S.C. 1031 et seq.);

22 (D) the Federal Food, Drug, and Cosmetic  
23 Act (21 U.S.C. 301 et seq.), with regard to  
24 food safety, labeling, and inspection under that  
25 Act;

1 (E) the food safety responsibilities under  
2 the Federal Insecticide, Fungicide, and  
3 Rodenticide Act (7 U.S.C. 136 et seq.); and

4 (F) such other laws and portions of laws  
5 regarding food safety, labeling, and inspection  
6 that the President considers appropriate to con-  
7 solidate under the administration of the Admin-  
8 istration.

9 **SEC. 4. ESTABLISHMENT OF INDEPENDENT FOOD SAFETY**  
10 **ADMINISTRATION.**

11 (a) **ESTABLISHMENT OF ADMINISTRATION.**—There is  
12 established in the executive branch an agency to be known  
13 as the “Food Safety Administration”. The Administration  
14 shall be an independent establishment, as defined in sec-  
15 tion 104 of title 5, United States Code.

16 (b) **RESPONSIBILITIES OF ADMINISTRATION.**—The  
17 Administration shall be responsible for the administration  
18 and enforcement of the food safety laws.

19 **SEC. 5. CONSOLIDATION OF SEPARATE FOOD SAFETY AND**  
20 **INSPECTION SERVICES AND AGENCIES.**

21 (a) **TERMINATION.**—As soon as possible after the ef-  
22 fective date of this Act, the President shall terminate the  
23 Federal agencies specified in subsection (b) to the extent  
24 that the activities of such agencies relate to the adminis-  
25 tration or enforcement of the food safety laws.

1       (b) COVERED AGENCIES.—The Federal agencies re-  
2       ferred to in subsection (a) are the following:

3               (1) The Food Safety and Inspection Service of  
4       the Department of Agriculture.

5               (2) The Center for Food Safety and Applied  
6       Nutrition of the Food and Drug Administration.

7               (3) The Center for Veterinary Medicine of the  
8       Food and Drug Administration.

9               (4) The National Marine Fisheries Service of  
10      the National Oceanic and Atmospheric Administra-  
11      tion of the Department of Commerce.

12              (5) The Office of Pesticide Programs under the  
13      Assistant Administrator of the Environmental Pro-  
14      tection Agency for Prevention, Pesticides, and Toxic  
15      Substances.

16              (6) Such other offices, services, or agencies as  
17      the President may designate to further the purposes  
18      of this Act.

19       (c) TRANSFER OF ASSETS AND FUNDS.—Consistent  
20      with section 1531 of title 31, United States Code, the per-  
21      sonnel, assets, liabilities, contracts, property, records, and  
22      unexpended balances of appropriations, authorizations, al-  
23      locations, and other funds of a Federal agency terminated  
24      in whole or in part under subsection (a) that are used in  
25      connection with the administration or enforcement of the

1 food safety laws shall be transferred to the Administration  
2 upon the termination of the Federal agency. Unexpended  
3 funds transferred pursuant to this subsection shall be used  
4 by the Administration only for the purposes for which the  
5 funds were originally authorized and appropriated.

6 (d) REFERENCES.—After the termination of a Fed-  
7 eral agency under subsection (a), any reference in any  
8 other Federal law, Executive order, rule, regulation, docu-  
9 ment, or other material to that Federal agency or the head  
10 of that agency in connection with the administration or  
11 enforcement of the food safety laws shall be deemed to  
12 be a reference to the Administration.

13 (e) SAVINGS PROVISIONS.—The termination of a  
14 Federal agency under subsection (a) shall not affect—

15 (1) an order, determination, rule, regulation,  
16 permit, agreement, grant, contract, certificate, li-  
17 cense, registration, privilege, or other administrative  
18 action issued, made, granted, or otherwise in effect  
19 with respect to that agency before the termination  
20 date regarding functions transferred to the Adminis-  
21 tration under this Act; and

22 (2) any suit commenced before the termination  
23 of that agency, any other proceeding (including a  
24 notice of proposed rulemaking), or any application  
25 for any license, permit, certificate, or financial as-

1       sistance pending before that agency with respect to  
2       functions transferred to the Administration under  
3       this Act.

4   **SEC. 6. LIMITATION ON AUTHORIZATION OF APPROPRIA-**  
5                   **TIONS.**

6       For the first fiscal year beginning after the date of  
7   enactment of this Act, the amount authorized to be appro-  
8   priated to carry out this Act shall not exceed the amount  
9   appropriated for fiscal year 1998 for the Federal agencies  
10   to be terminated under section 5(a) to administer the food  
11   safety laws.

12   **SEC. 7. EFFECTIVE DATE.**

13       This Act shall take effect on the earlier of—

14               (1) the date that is 180 days after the date of  
15       enactment of this Act; and

16               (2) such date during that 180-day period as the  
17       President may direct in an Executive order.

# Battles Over Jurisdiction Likely To Block Merger of Agencies

Policing the food supply involves maneuvering a complex web of federal agencies with overlapping jurisdiction. Consider how regulators safeguard the nation's egg supply.

Eggs in shells fall under the purview of the Food and Drug Administration (FDA), but once the eggs are cracked and processed, they come under the jurisdiction of the U.S. Department of Agriculture (USDA).

The USDA is responsible for regulating meat and poultry, while the FDA handles most other food products, including seafood and produce.

These two agencies share responsibility for enforcing the bulk of food safety laws, but other parts of the government also play a prominent role. The Environmental Protection Agency oversees pesticides applied to crops, for example, and the Centers for Disease Control and Prevention tracks food-related illnesses.

Consumer groups and many Democrats say the system is outdated and that the best solution would be to create a single food safety agency that could target inspections, streamline safety programs and use resources more efficiently.

Lawmakers are awaiting the results of a congressionally commissioned study by the National Academy of Sciences. Democrats have introduced legislation (HR 2801, S 1465) that would create such an agency.

But the idea has generated little enthusiasm among lawmakers and industry. Congress itself is perhaps the biggest obstacle, where a battle over turf would doom the idea. House Commerce has oversight of the FDA, while the Agriculture Committee keeps an eye on USDA.

"The whole question of food safety is split, and Agriculture is not about to give up jurisdiction," said House Agriculture Committee Chairman Bob Smith, R-Ore.

The concept is vigorously opposed

by growers and manufacturers, who fear a single agency would impose onerous new regulations and could be used by empire-building bureaucrats looking to expand their budget and regulatory authority.

John R. Cady, president of the National Food Processors Association, said the industry fears that a new "food czar" would be armed with the authority to recall products and in-

spectors located at about 6,200 plants. Inspectors are required to examine every carcass that passes through the slaughterhouse.

The FDA has about 430 inspectors to keep tabs on more than 53,000 establishments that produce, process or store food other than meat and poultry. The agency carries out about 5,000 inspections per year. In contrast to meat and poultry inspection, the average company is subject to FDA inspection every 10 years.

Questions about how to deploy personnel are likely to grow more pressing as the Clinton administration implements new rules (known officially as Hazard Analysis and Critical Control Point, or HACCP) for meat and poultry inspection.

The rules, which went into effect for large companies in January and will be phased in for other companies over the next two years, require slaughterhouses to implement safe-handling procedures at points in the production process where contamination could occur, rather than relying on meat inspectors to eyeball carcasses.

The system is potentially less labor-intensive, but under the current process, USDA inspectors could not easily be reassigned to other agencies such as FDA. Advocates of a single agency say it would solve this problem.

"We cannot let the inside-the-Beltway politics prevent the move to a better system for better food," said Caroline Smith DeWaal, director of the program on food safety at the Center for Science in the Public Interest, a consumer group.

For DeWaal and other advocates, however, creating a new agency remains a distant possibility. They are resigned to a system they say is rife with inefficiencies such as the frequently cited pizza example: Cheese pizzas are FDA's responsibility, but if they have pepperoni on top, Agriculture inspectors step in.

— Allan Freedman



**Caroline Smith DeWaal, shown discussing food safety in November, advocates a single food agency.**

pose huge fines on their makers.

"The czar could easily use that unbridled authority to raise money for his agency, especially during tight budget times, destroying a brand product and putting a company and its workers out of business altogether for the slightest reason," said Cady.

But consumer groups and other critics point out that the current system is a patchwork of 12 agencies and 35 statutes.

The system was built up as Congress layered one law atop another, these critics say, with little regard to how it should work as a whole.

The Agriculture Department now employs about 7,500 full-time in-

# The Living Section

The New York Times

WEDNESDAY, APRIL 9, 1997

NE C1

## EATING WELL

# The Debate Over Merging Government Food Agencies

By MARIAN BURROS

**F**OLLOWING an outbreak of the hepatitis A virus from contaminated strawberries, an increasing number of food safety experts are questioning whether it is time to retire the Federal Government's fragmented system of regulation and start all over again.

The stakes are considerable. Food-borne illnesses make millions of Americans sick each year and kill at least 9,100. So far, about 170 children have been diagnosed with hepatitis A from the frozen strawberries, served in the Federal school lunch program.

Thousands more may be at risk. Food contamination problems are more widespread than most consumers think. In January, it was oysters contaminated with the hard-to-detect Norwalk virus, a gastrointestinal affliction that is often caused by eating uncooked shellfish.

Last year, apple cider, eggs, raspberries and lettuce all made people ill from salmonella, cryptosporidia, cyclospora and, the most deadly of all, E. coli

O157:H7. (Like the strawberries, the raspberries were imported.)

This rundown of food-borne ailments covers only food regulated by the Food and Drug Administration; it does not include any caused by tainted meat or poultry, which are regulated by the Agriculture Department.

Even before the strawberry contamination, food safety officials and health professionals had been preparing to do the customary but confusing Washington dance, debating different solutions, weighing the practical and political consequences and trying to settle on a compromise that would make a difference in everyday life. President Clinton entered the debate in January, when he announced a \$43 million food safety initiative as part of his 1998 budget.

But some food safety experts say the President did not go far enough. Instead of piecemeal reforms, they favor combining the food safety functions of several agencies, principally the

Continued on Page C8



Associated Press

Sorting berries in Irapuato, Mexico. Imported strawberries contaminated with the hepatitis A virus have added to the debate on food safety.

# Eating Well

Marian Burros

Continued From Page C1

Food Safety and Inspection Service of the Agriculture Department and the Center for Food Safety and Nutrition of the F.D.A. This single independent food safety entity would be financed with money now divided among 21 Federal agencies.

"There's no question that organizational fragmentation and inconsistency in statutory requirements are major obstacles to having the best possible food safety system," said Michael Taylor, who until last November was the Acting Under Secretary for the Food Safety and Inspection Service. "Particularly when it comes to making the best use of Federal food safety dollars."

For example, there is a Federal inspector in each meat and poultry slaughter plant under Agriculture Department jurisdiction every day, but processing plants under F.D.A. jurisdiction are hardly ever inspected, maybe once every 10 years, says a Government report issued in February on food safety budget allocations.

"Responsibility is widely diffused in the system, making it much more difficult to manage," Mr. Taylor said. "We don't necessarily need more resources; we need to make better use of the resources we have."

Caroline Smith DeWaal, the director of food safety at the Center for Science in the Public Interest, a Washington-based consumer advocacy group, agreed that one central agency would be the least expensive and most effective way to safeguard the nation's food supply.

"Either we need \$200 million to remake the F.D.A. or we take all the money currently earmarked for food safety in the different agencies — about \$1 billion — and make a new agency," she said.

But, she continued, the one-agency idea would not gain ground without support from the food industry, with which she has had some preliminary conversations.

The Institute of Food Technologists, a group of scientists in the food industry and Government, also believes that it is time for a change. It supports the President's national food safety initiative.

"The possible outcome of this initiative may be the creation of one agency to oversee surveillance, rapid response to outbreaks, research and education," said Robert E. Smith, the president of the institute.

Ms. DeWaal and Mr. Taylor were not the first to suggest a single agency.

In 1993, the Vice Presidential commission that looked into streamlining the Government called for the cre-

## The debate over merging Government food agencies.

ation of an independent agency.

"We unanimously and strongly recommended a single food safety agency," said Dr. Edward Menning, a member of the commission's task force on food safety, who recently retired as director of the National Association of Federal Veterinarians. But when the panel's findings were announced, the one on food safety had been modified to a recommendation for the consolidation of all Government food safety activities within the F.D.A.

Criticism of the way food safety is regulated in this country is hardly new. In 1981, the General Accounting Office, the investigative arm of Congress, charged the Agriculture Department with unacceptable inspection practices.

It has continued to criticize both the Agriculture Department and the F.D.A. and has proposed a single

Federal food safety agency.

But there is general agreement among experts that the healthfulness of what Americans eat is jeopardized by many problems that did not exist 20 years ago. Nor are today's problems the sort that rocked the nation in the early 1900's, when Upton Sinclair dramatically depicted the need for regulation with "The Jungle," his graphic account of turn-of-the-century slaughterhouses in Chicago.

Today's hazards are mostly invisible, and they stem from shifts in agriculture, trade patterns, technology and dietary habits.

At the same time, surveillance of the food supply has been cut sharply and inspection methods are just beginning to catch up with the new hazards. The following factors have affected food safety over the last two decades:

- Greater reliance on food imported from countries that have less stringent sanitary and pesticide regulations means a greater likelihood of epidemics like the one resulting from the strawberries contaminated with hepatitis A.

- There has been an increase in new disease-causing microbes. Just in the last year, new forms of salmonella and E. coli have appeared. E. coli O157:H7 was not discovered until 1982. Originally thought to be only in animal products, it has been found in apple juice and lettuce.

- Farms have been transformed into factories, leading to the crowding of livestock and an increased use of chemicals: pesticides, fertilizers, antibiotics and hormones.

- Americans' eating habits have been revolutionized, with more fresh, rather than processed, food and more fruits, vegetables, fish and poultry.

- Americans are also eating more food prepared outside the home, much of it minimally processed and refrigerated rather than frozen, providing opportunities for contamination. The preparation of such foods in central locations for shipment to

stores and restaurants also provides opportunities for far-flung outbreaks.

- There has been a significant contraction in Federal monitoring of the food supply, particularly at the F.D.A. Recalls of food for life-threatening microbial contamination have increased almost fivefold since 1988.

"Government agencies are currently reacting to food safety problems, rather than acting to prevent them," Ms. DeWaal said.

The number of inspectors at the Agriculture Department's Food Safety and Inspection Service dropped from 12,000 in 1978 to 7,500 today, but it is still much better staffed than the F.D.A. That agency has fewer than 700 inspectors for 53,000 United States plants and for imported food.

In 1981, it carried out 21,000 inspections a year; today, it conducts about 5,000. In the mid-1970's, it inspected about 20 percent of the imported food under its jurisdiction. Today, the agency is sampling only 1 to 2 out of every 100 shipments.

The Centers for Disease Control and Prevention estimate that 9,100 people die each year from food-borne illnesses, but that figure may be the tip of the iceberg because of underreporting. Similarly, the number of Americans who become ill each year from food-borne illnesses is put at anywhere from 6.5 million to 81 million.

No one is certain how the recent contamination of strawberries occurred. And that's just the problem. It could have happened anywhere along the way, from the Mexican fields where the strawberries were grown to the plant in California where they were packed.

"In an ideal world, there should be a single agency monitoring foreign countries to make certain they are enforcing tougher standards," Ms. DeWaal said. "And an independent agency can better identify emerging hazards."

NE **A27**

# One Agency for Food Safety

By Caroline Smith DeWaal

WASHINGTON  
**I**t seems that almost monthly, there is news of yet another outbreak of food poisoning. Last week, Hudson Foods recalled 25 million pounds of potentially contaminated ground beef after 17 people in Colorado contracted poisoning from E. coli O157:H7, a particularly dangerous strain of bacteria.

In March, strawberries contaminated by Hepatitis A were served in public school lunches, causing hundreds of illnesses. In May and June, imported raspberries containing the cyclospora parasite caused more than a thousand people to get sick.

While the Clinton Administration has been tough in addressing these individual emergencies, there is a fundamental flaw in its approach. It has dealt with each crisis as it has come up instead of creating a single process to prevent and deal with all future outbreaks. Now that food is increasingly mass produced and shipped all over the world, this piecemeal approach to addressing safety problems is a hazard to the public health.

Food poisoning is responsible for millions of illnesses and as many as 9,000 deaths every year in the United States. The economic cost of contaminated food is high — it may be as much as \$22 billion per year. This estimate fails to take into account the pain and suffering experienced not only by the victims, but also by their families and extended communities.

And these costs will only increase. According to the Department of Health and Human Services, the incidence of food-borne illnesses and

deaths is likely to grow 10 percent to 15 percent over the next decade, as new, more dangerous contaminants are spreading. Also, familiar bacteria like E. coli are appearing in unexpected foods. For example, last year there were several E. coli outbreaks from contaminated lettuce and unpasteurized juice. Moreover, while imported foods have increased by nearly 50 percent since 1992, Government inspection of imports has declined.

That's why President Clinton's food safety initiative, which was recently passed in the balanced budget legisla-

taminated to begin with.

We need a new approach that combines all the Federal Government's food-related functions into a single agency. There are many benefits to consolidating these duties. For example, safety inspections could be done on a frequent and consistent basis. Currently, food plants regulated by the Department of Agriculture receive daily visits from Government inspectors, while those regulated by the F.D.A., including some that deal with high-risk products like seafood and eggs, are inspected an average of once every 10 years.

A single food safety agency would also have the power and the flexibility to enforce food-safety regulations from farm to table. That would increase the chance that contamination would be caught at an earlier stage, before dozens of people became sick. In addition, the agency would be most effective if it had tough enforcement tools like the authority to recall tainted food and to enforce penalties on companies that don't meet standards.

At a time of Government downsizing and reorganization, we cannot afford to continue to have multiple systems. The only way to achieve a successful system of safety regulation is to create a single agency with uniform standards. □

---

**We must stop  
lurching from  
crisis to crisis.**

---

tion, isn't comprehensive enough. The initiative proposes tinkering with the current system by establishing new systems of industry-designed hazard controls for processing plants.

But multiple agencies will still share responsibility for inspecting food. The Department of Agriculture oversees meat, poultry and egg products; the Food and Drug Administration inspects and oversees the safety of all other products, and the Environmental Protection Agency sets limits for certain chemicals in food.

The jurisdictions for these agencies sometimes overlap, so there is little accountability, and the agencies also have other duties, like promoting American agricultural products or approving drugs, that interfere with their safety responsibilities. Moreover, the current system is inefficient and focuses too much on recalling food after it has already been contaminated rather than on keeping food from becoming con-

*Caroline Smith DeWaal is the director of food safety at the Center for Science in the Public Interest.*