

FDA Was Aware of Dangers To Food

Outbreaks Were Not Preventable, Officials Say

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The [Food and Drug Administration](#) has known for years about contamination problems at a [Georgia](#) peanut butter plant and on [California](#) spinach farms that led to disease outbreaks that killed three people, sickened hundreds, and forced one of the biggest product recalls in [U.S.](#) history, documents and interviews show.

Overwhelmed by huge growth in the number of food processors and imports, however, the agency took only limited steps to address the problems and relied on producers to police themselves, according to agency documents.

Congressional critics and consumer advocates said both episodes show that the agency is incapable of adequately protecting the safety of the food supply.

FDA officials conceded that the agency's system needs to be overhauled to meet today's demands, but contended that the agency could not have done anything to prevent either contamination episode.

Last week, the FDA notified California state health officials that hogs on a farm in the state had likely eaten feed laced with melamine, an industrial chemical blamed for the deaths of dozens of pets in recent weeks. Officials are trying to determine whether the chemical's presence in the hogs represents a threat to humans.

Pork from animals raised on the farm has been recalled. The FDA has said its inspectors probably would not have found the contaminated food before problems arose. The tainted additive caused a recall of more than 100 different brands of pet food.

The outbreaks point to a need to change the way the agency does business, said Robert E. Brackett, director of the FDA's food-safety arm, which is responsible for safeguarding 80 percent of the nation's food supply.

"We have 60,000 to 80,000 facilities that we're responsible for in any given year," Brackett said. Explosive growth in the number of processors and the amount of imported foods means that manufacturers "have to build safety into their products rather than us chasing after them," Brackett said. "We have to get out of the 1950s paradigm."

Tomorrow, a House Energy and Commerce subcommittee will hold a hearing on the unprecedented spate of recalls.

"This administration does not like regulation, this administration does not like spending money, and it has a hostility toward government. The poisonous result is that a program

like the FDA is going to suffer at every turn of the road," said [Rep. John D. Dingell](#) (D-Mich.), chairman of the full House committee. Dingell is considering introducing legislation to boost the agency's accountability, regulatory authority and budget.

In the peanut butter case, an agency report shows that FDA inspectors checked into complaints about salmonella contamination in a [ConAgra Foods](#) factory in Georgia in 2005. But when company managers refused to provide documents the inspectors requested, the inspectors left and did not follow up.

A salmonella outbreak that began last August and was traced to the plant's [Peter Pan](#) and Great Value peanut butter brands sickened more than 400 people in 44 states. The likely cause, ConAgra said, was moisture from a roof leak and a malfunctioning sprinkler system that activated dormant salmonella. The plant has since been closed.

The 2005 report shows that FDA inspectors were looking into "an alleged episode of positive findings of salmonella in peanut butter in October of 2004 that was related to new equipment and that the firm didn't react to, . . . insects in some equipment, water leaking onto product, and inability to track some product."

During the inspection, the report says, ConAgra admitted it had destroyed some product in October 2004 but would not say why.

"They asked for some of our documentation and we made the request to them that they put it in writing due to concerns about proprietary information," ConAgra spokeswoman Stephanie Childs said last week. "We did not receive a written request, . . . they filed the report and that was that."

Until February of this year. That's when the [Centers for Disease Control and Prevention](#) notified the FDA of a spike in salmonella cases in states near the ConAgra plant. The agencies contacted the company, which initiated a recall and shut the plant for upgrades.

Brackett said that if the FDA inspector had seen anything truly dangerous the agency would have taken further action. But, he said, the agency cannot force a disclosure, a recall or a plant closure except in extreme circumstances, such as finding a hazardous batch of product.

The problem in 2005, he added, "doesn't necessarily connect to the salmonella outbreak right now. It's not unusual to have it in raw agricultural commodities."

The FDA has known even longer about illnesses among people who ate spinach and other greens from California's Salinas Valley, the source of outbreaks over the past six months that have killed three people and sickened more than 200 in 26 states. The subsequent recall was the largest ever for leafy vegetables.

In a letter sent to California growers in late 2005, Brackett wrote, "FDA is aware of 18 outbreaks of foodborne illness since 1995 caused by [E. coli bacteria] for which fresh or

fresh-cut lettuce was implicated. . . . In one additional case, fresh-cut spinach was implicated. These 19 outbreaks account for approximately 409 reported cases of illness and two deaths."

"We know that there are still problems out in those fields," Brackett said in an interview last week. "We knew there had been a problem, but we never and probably still could not pinpoint where the problem was. We could have that capability, but not at this point."

According to Caroline Smith DeWaal, who heads the Center for Science in the Public Interest, a consumer-advocacy group, "When budgets are tight . . . the food program at FDA gets hit the hardest."

In next year's budget, passed amid discovery of contamination problems in spinach, tomatoes and lettuce, Congress has voted the FDA a \$10 million increase to improve food safety, DeWaal said. The [Agriculture Department](#), which monitors meat, poultry and eggs and keeps inspectors in every processing plant, got an increase 10 times that amount to help pay for its inspection programs. The FDA visits problem food plants about once a year and the rest far less frequently, Brackett said.

William Hubbard, who retired as associate commissioner of the FDA in 2005 and founded the advocacy group Coalition for a Stronger FDA, said that when he joined the agency in the 1970s, its food safety arm claimed half its budget and personnel.

"Now it's about a quarter . . . at a time in which the problems have grown, the size of the industry has grown and imports of food have skyrocketed," Hubbard said.