

None of these criticisms are accurate. Yes, there are three-fifths majorities in Congress, but they are rare on matters of great contro-

Paul Simon, an Illinois Democrat who retired from the Senate this month, directs the Public Policy Institute at Southern Illinois University.

is put off until 2000 and 2001. Congress won't take responsibility any more than it did after adopting the Gramm-Rudman balanced budget proposal in 1985. Elected officials like to do popular things, and there is no popular way to balance the Federal budget.

The reality is that we are going to

straint and cover of a constitutional amendment.

How important is balancing the budget? In the 1996 fiscal year, we spent more than \$344 billion in interest to pay off the debt, more than 11 times the Federal education budget and twice our antipoverty spending. The General Accounting Office pro-

an article
don't tell

jected that if we could budget, within 20 years per capita income would be 10 percent. Every economist suggests that a balance would lift the economy, interest rates to drop and savings to narrow.

Unless we act now, however, in danger of heading for economic disaster, economists call "monetary" — continually increasing money supply — which is the problem but in the hyperinflation. This is what Smith described in "Vices" when he said to pile up debts and then finally attractive to debasement.

Unless we change course, we will devastate the Social Security fund and wipe out American individual savings. This will precipitate a global economic crisis, then, it would be too late for quick fixes. The sensible course is a balanced amendment now.

NYT A21 1-30-97

Safe Food? Not Yet

By Nicols Fox

PBASS HARBOR, Me. President Clinton wants to spend \$43 million of his 1998 budget on improving food safety. The good news is that \$11.5 million of this money would go to an early-warning system to identify causes of foodborne illness. But while this proposal could help us spot outbreaks more quickly, weaknesses in a new Agriculture Department meat inspection plan mean we aren't likely to see fewer such episodes any time soon.

In an age of widespread distribution of mass-produced foods, food poisonings are difficult to trace. Consumers have little idea where their food comes from or how it is processed. Producers cultivate trust with slick packaging, backed up by Government guarantees. Yet food makes millions of Americans sick each year.

Most cases are mild and require no medical treatment, but the Agriculture Department says that up to 9,000 people die from foodborne disease each year (as many as 500 of these deaths can be attributed to *E. coli* O157:H7, usually found in hamburger). Foodborne pathogens have also been linked to ulcers, Guillain-Barre syndrome, meningitis, reactive ar-

Nicols Fox, author of the forthcoming "Spoiled: The Dangerous Truth About a Food Chain Gone Haywire," writes for *The Economist*.

thritis and even miscarriages.

The best part of the President's proposal increases the number of food-safety surveillance centers nationwide from five to eight. These operations, which are run by the states under Federal guidelines, are vital. In 1994, for example, the Minnesota Department of Health's center traced widespread salmonella poisoning to a single tainted batch of ice cream, which was quickly recalled. (Trucks carrying the ice cream's premixture had previously hauled raw

New inspection rules fall short.

eggs.) More than 200,000 people around the nation became ill.

In general, when food poisoning occurs producers blame the consumer for failing to cook food thoroughly. Yet some foods have become unacceptably contaminated. An Agriculture Department study of chickens, quoted in the Federal Register, revealed that more than 99 percent of broiler carcasses had detectable *E. coli*, evidence of fecal contamination. Another Federal study found that 72 percent of chickens were contaminated with salmonella. Yet meat and poultry companies have agreed among themselves not to make safety a marketing strategy, so Americans do not have the

option, as consumers in Sweden do, of buying chickens labeled and guaranteed to be salmonella free.

The Agriculture Department's new "science-based" inspection system, called Hazard Analysis Critical Control Point, which went into effect this week, is neither a quick fix nor a long-term solution. The plan, which Mr. Clinton announced with great fanfare last summer, is a compromise between producers and the Government that will gradually transfer more oversight responsibility to the industry. Such a system has worked well for products like canned foods, which can be sealed and heated before shipping, but its effectiveness is unproved with raw products.

Unlike the old "prod and sniff" approach, the new plan requires that raw meat be sampled for microbes. But meat containing disease-causing microbes (with the exception of *E. coli* O157:H7) will not be considered adulterated, the legacy of a legal decision holding that microbes are "inherent" in raw meat. The Agriculture Department still will not have the authority to recall contaminated meat or to regulate farms, and chickens contaminated with salmonella will still be sold. Federal officials will eventually shift from inspecting the meat itself to inspecting records of such checks.

Quick fixes in the hands of an industry that has traditionally put profit before safety is not the answer. Mr. Clinton's initiative is a start, but tough regulations from farm to table, even if they result in slightly higher prices, would be preferable to contaminated food. □

Liberties

MAUREEN DOWD

Al Agonistes

Inside Mr. Gore's nervous brain.

WASHINGTON Is the Spot getting bigger? Tipper says it isn't, but I know it is. At this rate, by the year 2000 I'll look like Joe Biden, wandering around with okra plugs in my head. It's making me a little crazy. Actually, everything these days is making me a little crazy. I've been so loyal for four years, staying in the shadow of President Smarmy, and just waiting for

platform. His numbers are high enough as it is, and all he does is

the President's attempt to give me an aura of inevitability. Geez, I've had that aura since I was a boy. Can somebody please tell that guy to give it up? We are never going to elect Lizard Boy.

Deep breath. I'm O.K., you're O.K. Bill Bradley is actually the one giving me the jitters. And what about John Kerry and that millionaire

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Let's examine

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Briefly, the Clinton

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While the four-year

Washington Wire

A Special Weekly Report From
The Wall Street Journal's
Capital Bureau **A1**

CLINTON PLANS to seek a major budget boost to improve food safety.

He is expected to announce a \$50 million plan in his radio talk tomorrow. About \$42 million would go to the FDA for increased seafood inspection, expanding the system for tracking food-borne bacteria and an early warning system for new risks, such as mad-cow disease. About \$6 million would go to train Agriculture Department inspectors in high-tech procedures.

The plan still could face delay because of White House budget office concerns about such a large boost to the FDA's \$880 million annual budget. The increase also would likely face resistance from congressional Republicans, but it is expected to draw industry support.

The plan would add money for food-safety research at both the FDA and the Agriculture Department.

START ON TRUCKING: Clintonites push for truck-trade with Mexico.

With the election over, administration officials seek ways to open the U.S. border to Mexican-made trucks, as required by Nafta. Clinton wants the issue resolved before he goes to Mexico at the end of March; U.S. truck makers also want freer access to the Mexican market. But the Administration first must find a way to placate its political allies in U.S. labor.

The Teamsters conduct rallies in border states protesting "unsafe" trucks from Mexico. U.S. officials, who will need more concessions from labor in order to get a deal on "fast track" authority to negotiate future trade agreements, say they must walk a fine line. One option: get Mexico's promise to beef up its truck-safety regulations.

REPUBLICANS DIG for House votes to pass a balanced-budget amendment.

Backers need nine more votes to approve the measure, which GOP leaders said yesterday will be taken up Feb. 26. A 10-member "whip team" targets freshmen Democrats who narrowly won, such as North Carolina Rep. Etheridge. About 36 Democrats remain uncommitted; four Democrats, who opposed the amendment when it passed before, mull changing their votes.

But GOP sophomores led by Wisconsin Rep. Neumann also want a vote on not using Social Security reserves to help balance the budget. Otherwise, they fear Democratic charges that the GOP is undermining Social Security. White House aides put their chances of defeating the House amendment at 50%. Backers a p their in the Senate, where the measure barely lost.

THE WALL STREET JOURNAL

FRIDAY, JANUARY 24, 1997

DEMOCRATS FUME that they got little advance warning from the White House on the naming of Colorado Gov. Romer as Democratic Party chairman. Congressional Democrats also gripe that Republicans knew about Clinton's proposed Medicare cuts before they did, adding that Clinton will need Democratic support in coming budget fights.

QUICK FIX: Clinton's inaugural speech, which was widely panned, didn't much resemble a first draft that insiders say was much better. In-between, speechwriters presented the president with a 50-minute address last Friday that he reshaped until delivering his 22-minute version on Monday.

GINGRICH'S WOES open the doors of power to House chairmen and others.

Several are positioned to move up should the speaker falter after his reprimand. New York Rep. Paxon, who led the GOP campaign committee, will head leadership meetings. Ohio Rep. Boehner, the caucus chairman, shows new independence. The budget debate will ensure Budget Chairman Kasich a major role. Friction between House leaders Arney and DeLay adds to turmoil at the top.

Commerce Chairman Bliley plans to push FDA overhaul. Judiciary Chairman Hyde will move on Cato Institute-backed overhauls of civil-asset forfeiture laws. Gingrich wants chairmen to reach beyond conservative Democratic "Blue Dogs" to strike alliances with Democrats. In the spirit of cooperation, a narrower product-liability bill may be backed.

Chairmen welcome the new status, but one grouses that much of one day at a leadership retreat this week in Virginia was taken up by "touchy-feely" management training.

MINOR MEMOS: Comedy writer Bob Orben says Gingrich is writing a new book, "Ethics for Dummies." ... New Mexico Sen. Domenici tells recently engaged Fed chief Greenspan: "I understand you have recently invested in diamonds, and you will probably soon be investing in gold." ... Clinton punts on predicting whether The Green Bay Packers or New England Patriots will win Sunday's Super Bowl, saying, "I still have feelings for those places."

—RONALD G. SHAFER

Date: 01/24/97 Time: 17:58

FClinton wants \$43 million for food safety program

WASHINGTON (AP) President Clinton will ask Congress for \$43 million to beef up the nation's early warning system for food contamination and take other steps to fight millions of food poisonings that Americans suffer every year.

Clinton's proposal, which he will detail Saturday in his weekly radio address, comes in the wake of deadly outbreaks from hamburgers, apple juice and other foods. His request, part of the federal budget he will send Congress next month, attempts to reverse years of tighten budgets for food programs.

"We are at the very beginning of a food-safety revolution," predicted Caroline Smith DeWaal of the consumer advocacy Center for Science in the Public Interest. The Food and Drug Administration particularly is "critically underfunded for food safety and ... they need a big shot in the arm."

Dane Bernard of the National Food Processors Association welcomed the program as providing "better science and better data so we can make better decisions" on food safety.

Although the U.S. food supply is called the world's safest, some 9,000 Americans die every year from food poisoning, and 9 million to 33 million are sickened.

New and more virulent pathogens are threatening foods, such as a strain of E. coli bacteria that sickened more than 500 hamburger eaters in 1993, killing three children. Last fall, the bug sneaked into gourmet, unpasteurized apple juice, sickening dozens and killing a Colorado girl. And Britain raised fear last summer when it announced 10 people may have gotten a new strain of a brain killer by eating beef tainted with "mad cow disease." The U.S. government insists cows here are disease-free so far.

Critics say the FDA, the nation's chief consumer protection agency, spends less than a third of its budget \$225 million on food safety. And the Centers for Disease Control and Prevention has struggled since 1993 to establish an early-warning system for food threats, but this year has just \$1.6 million out of its total \$6.6 million food budget to do so.

Clinton envisions better collaboration between the FDA, CDC and the Agriculture Department to improve food safety.

The FDA would get the most new funding, \$23 million, mostly to implement a long-awaited seafood safety program that, beginning in December, forces companies to ensure seafood stays wholesome from the fishing boat to the dinner plate. Consumer advocates say the program could fight outbreaks like one last month that sickened at least 150 people who ate tainted Louisiana oysters.

About \$11.5 million would go to an early warning system for new food pathogens. The CDC would get the bulk of that money, \$10 million, to track and research illnesses and run "sentinel sites" in eight states that would detect early signs of new threats.

Minnesota already runs such a site, and smaller programs have started in California, Oregon, Connecticut and Georgia. The CDC funds would help expand those four small programs, and other states could apply for funds to start three more.

The Agriculture Department would get \$8.5 million of the new funding, partly to ensure mad cow disease doesn't threaten the U.S. meat supply. Also, on Monday USDA inspectors begin enforcing new regulations that require slaughterhouses to actually test meat and poultry for contamination like E. coli.

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

January 24, 1997

PRESS BRIEFING BY
MIKE MCCURRY

The Briefing Room

1:22 P.M. EST

MR. MCCURRY: Good afternoon, ladies and gentlemen.
This is the daily briefing. We can begin now.

Q What are the President's plans to improve food
safety?

MR. MCCURRY: They're significant, and he is taping a
radio address about them at this very moment.

Q What are the plans? Can you tell us any details?

MR. MCCURRY: How much of this do you want to put out right now, Mary Ellen? Come on, give them as much as you want to give them right now. You've got the paper on it.

MS. GLYNN: You've got the paper. (Laughter.)

Q Who's the boss here? (Laughter.)

MR. MCCURRY: Did you have to really ask, when it's Ms.

Glynn?

Ms. Glynn, it's all yours.

MS. GLYNN: There's not too much to say about it. (Laughter.) The President will be announcing a system which will help catch and respond to outbreaks of food-borne illness earlier, and to help give us the data we need to prevent future outbreaks.

Is that enough?

Q No.

MS. GLYNN: No? All right, all right --

Q I heard that there's a \$50-million plan.

MS. GLYNN: It is not. That's wrong. It's a \$43 million increase in the FY 1998 budget for food safety to fund the early warning system which is about \$11.5 million, and the \$10 million for the CDC, and about \$1 million for the FDA.

Q So that's \$54 million?

MS. GLYNN: No, that's \$43 million altogether.

Q How do you break it down?

MS. GLYNN: You have \$11.5 million for the early warning system; \$10 million for the CDC to track data and to try and track food-borne illness; and \$1 million for the FDA.

Q That's \$22.5 million.

MS. GLYNN: Plus \$23 million for the FDA for seafood safety inspections, research, risk assessment and education.

Q That comes to \$45.5 million.

Q Very good, Wolf. (Laughter.)

MR. MCCURRY: Look, we'll have a factsheet and other materials before the --

Q What's the genesis of this volunteer, and how --

Q What about the initiative to get your money back

from the --

Q Can we stay on the food -- is this in any way related to news stories about the unsafe handling of food that American consumers buy?

MR. MCCURRY: I'm not aware that this is -- this is being done because of the President's commitment to clean air, clean water, and safe food for the American people, and it's not related to any recent litigation involving food safety issues.

Helen, on the question about the genesis of the summit that the President is about to announce with President Bush shortly, for some time, President Clinton has been in discussion with Harris Wofford, who is over at the Corporation for National Service and has been so valuable in promoting this administration's efforts on national service, about how we can really reinvigorate the concept of volunteerism and community service. And for months -- I'd say going back at least since the middle of last year, Harris has thought about ways in which we could really get people working together and get people working together in a bipartisan way.

The President believes firmly that serving our community, giving something back to our country is not about being a Democrat or a Republican, it's really about being an American. It's about what we owe our country.

And President Bush, as many here know, was very keen on that same commitment during his term as President and began the Points of Light program, which he asked President Clinton to continue on Inauguration Day four years ago, I think. And the Points of Light Foundation has continued to exist. This administration has worked on other aspects of promoting national service, as you know, but this is a real opportunity, in President Clinton's view, to marry together a lot of the different efforts on volunteerism and bring this country together around the concept of giving something back to the community. And he'll have more to say about it shortly, so I think I'll leave it at that.

Q Mike, why does community service need invigorating?

MR. MCCURRY: Well, because one of the things the presidency can do, and in this case two Presidents, is really encourage Americans to get back involved in their community. There is anecdotal evidence that volunteerism is on the rise, especially, encouragingly, among the youngest people in America, the youngest adults. A number of philanthropic and volunteer organizations around the country report that there is more interest. But this is something that all Americans can do. And, remember, the President, as he told the nation in his inaugural address, says that government is not going to be the solution to every problem. And in many cases, we, the American people, working together are going to have to solve problems in our communities, especially in an era when the concept of big government programs is no longer available. So this is a way in which the President believes he can use the tools of the presidency to encourage the American people to come together, solve problems, and address community needs.

Q But it's not a response to a drop of some sort?

MR. MCCURRY: Not that I'm aware of. In fact, as I say,

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WHITE HOUSE POISED TO RELEASE DETAILS OF INTERAGENCY FOOD SAFETY PLAN

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

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

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

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

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

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

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

(See **FOOD SAFETY INITIATIVE**, Page 32)

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(FOOD SAFETY INITIATIVE, continued from Page 3)

Food Safety Initiative Details Have Been Kept Close to the Vest

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

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

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

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

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

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

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

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

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

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

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

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January 20, 1997

FOOD CHEMICAL NEWS

opportunities along the route for contamination and mishandling." But the U.S. food supply is among the safest in the world, the announcement said. The administration estimates that between 6.5 and 33 million cases of foodborne illness occur each year, with up to 9,000 deaths.

Congressional Critics Already Taking Aim at User Fee Provisions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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WHITE HOUSE POISED TO RELEASE DETAILS OF INTERAGENCY FOOD SAFETY PLAN

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

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

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

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

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

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CMad cow disease risk to humans called 'very, very small

WASHINGTON (AP) The risk of consumers contracting a deadly brain disease from food, drugs and cosmetics made from cow products is 'very, very small,' government scientists assured a congressional panel Wednesday.

'There is no definitive proof that a human being has become infected ... from any animal affected with those diseases,' said Clarence Gibbs, acting chief of central nervous system studies at the National Institutes of Health.

Last March, the British government announced a possible link between a deadly cattle disease, bovine spongiform encephalopathy, and a new version of the rare human brain illness called Creutzfeldt-Jakob disease.

The cattle illness, dubbed 'mad cow disease,' was first identified in Britain in 1986. It has yet to be detected in U.S. cattle.

In 1989, the U.S. Department of Agriculture banned imports of meat and other potentially hazardous products from countries where the illness exists.

Early this month, the Food and Drug Administration said it would act to ensure that no cows or sheep eat feed made with proteins from ground cows, sheep, goats, deer, elk or mink all known to be vulnerable to the disease.

But members of Congress said they wanted to hear for themselves steps the government is taking to protect the American public, the nation's blood supply and various products ranging from dietary supplements to cosmetics.

Under questioning, scientists from the FDA, NIH, the Agriculture Department and the Centers for Disease Control and Prevention said the risks to American consumers from all avenues was minimal.

Michael Friedman, deputy commissioner for operations at the FDA, said there were no recorded cases of humans contracting Creutzfeldt-Jakob disease from blood. It strikes about 250 people yearly in the United States.

Friedman said the agency was working to find and evaluate blood donors with the brain illness who don't know they have it, as well as individuals who have received blood from infected donors.

'Despite those best efforts, we know there are (diseased) individuals donating blood unbeknownst to themselves and unbeknownst to the blood bank and yet we're not seeing cases of (the disease) resulting from that,' he said. 'But we know that the risk must be very, very small.'

Lawrence Schonberger, the CDC's assistant director for public health, said some animal research suggests the disease may pass from animal to animal via blood, but that mode of transmission has yet to be documented in humans.

There's no test for the diseases, no treatment and no proven causes.

'The bottom line from our perspective is that it's a theoretical risk but it is not as yet really a real risk,' he said. 'There's nothing there to indicate a real risk.'

Rep. Chris Shays, R-Conn., chairman of the House subcommittee on human resources, said the British outbreak was 'tragic proof of the adage, 'You are what you eat.''

'We learned the hard way with hepatitis and AIDS that emerging infectious diseases can slip past our public health defenses. ... Better to protect against unproven risks than wait for proof that may only emerge in mortality statistics,' Shays said.

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April 30, 1997

NOTE TO: ANNE McGUIRE
ELIZABETH DRYE

FROM: KITTY HIGGINS *KH*

FYI.

*Armed me
Eliz D.
sgt
K.*

TALKING POINTS ON STRAWBERRY INVESTIGATION

- Through its investigation OIG learned that AMS received complaints in January alleging that some of the strawberries purchased for the school lunch program came from Mexico. Because it was a complaint about a contract violation and NOT a health risk, an audit was scheduled for April. If it would have been allegations involving a health risk, USDA in conjunction with FDA would have conducted an immediate investigation.
- Once the information about the complaint time lag was discovered through the OIG investigation, OIG and senior AMS officials in Washington informed the Secretary's office promptly. The Secretary DIRECTED OIG to initiate an immediate inquiry into the circumstances surrounding the complaint and AMS' handling of the matter.
- the AMS employee responsible for handling such complaints was promptly reassigned to other duties pending the outcome of the OIG investigation.
- The complaints about the purchase of Mexican strawberries came from within the California strawberry industry and did not single out a specific firm.
- Today OIG completed its review of AMS' handling of the complaint. Copies of the report have been sent to the U.S. Department of Justice for use in its ongoing strawberry investigation.
- As a result of the investigation, AMS has improved its procedures for dealing with complaints. From now on there will be written documentation and prompt verification of all complaints, including a field review. Those complaints that prove to be credible will receive immediate attention and the product will be placed on HOLD pending the outcome of the investigation. In addition, produce in the school lunch program found to have come from anyplace other than the U.S. (USDA mandates that all product purchased for the school lunch program must come from the United States) will be subject to recall.
- USDA is currently exploring its ability to increase administrative fines for companies who violate federal country of origin documents.
- In addition, after reviewing its internal procedures for ensuring country of origin documentation and surveillance, AMS has developed an 11 point plan to improve its certification process. That 11 point plan is already in place.
- The new procedures will require that all companies submit specific and documented information about the product, that documentation includes: a code so USDA can easily trace the origin of product. In addition, AMS will go from one person reviewing the written documentation to a 3 level process. AMS will also increase the number of unannounced on-site plant reviews to ensure full contract compliance.

- Before AMS begins purchasing commodities for the 97/98 school year, procurement officials from USDA will meet with vendors, explaining to them the serious consequences they face, including criminal penalties, if they do not comply with the certification process.
- To ensure full accountability at all levels, the Secretary is ordering his own internal review of AMS' handling of the complaint and he plans to take swift disciplinary action if necessary.