THE SECRETARY OF AGRICULTURE
WASHINGTON, D.C.
20250-0100

Food Safety

5/11/99

Dear Bruce -

Enclosed is a speech I gave at Purdue Univ. last week. I thought you might be interested.

Dan

TOM

REMARKS BY
U.S. SECRETARY OF AGRICULTURE DAN GLICKMAN
PURDUE UNIVERSITY
WEST LAFAYETTE, IN -- APRIL 29, 1999

Thank you very much, Vic, for that kind introduction. And thank you for the expertise that you're lending to USDA, as Chairman of our Advisory Board on Research, Extension, Education and Economics.

It's a great honor to be at one of the most prestigious land-grant universities. Touring your new Food Science Center and getting a glimpse of some of your rich research just confirmed what I already knew -- that this is a school with a rich tradition of accomplishment and innovation in the field of agriculture. That's one of the reasons I'm here. I hope you won't hold it against me, but I'm a graduate of another Big Ten school, the University of Michigan. But I'm glad to be here at the home of 1999 NCAA Women's Basketball Champions.

I'm proud that USDA and Purdue have built such strong partnerships on everything from soil erosion to plant genetics to food safety. And it's good to know that we share personnel too. In fact, if you browse through the faculty directory here, it almost seems like the Department of Agriculture is some kind of farm team for Purdue University. Purdue is home to one of my predecessors, former Secretary and now professor emeritus Earl Butz...as well as Don Paarlberg, who served as a senior adviser to the Secretary of Agriculture before I was old enough to shave.

I also want to single out Jill Long Thompson, who is with me today. Jill was a strong leader for Indiana in the House of Representatives, and now she's doing an outstanding job as USDA's Under Secretary for Rural Development.

I work closely with both of your Senators, Evan Bayh and Dick Lugar. Senator Lugar is a good friend, and he has served this state and championed this university so effectively for so many years. And as Chairman of the Senate Agriculture Committee, he is a friend to farmers -- and an advocate for their interests -- nationwide.

Those of you emerging from Purdue's agriculture program will be tomorrow's leaders in farm production, agribusiness and science. You will be the ones to steer the ship at a time of staggering change in the structure and composition of the farm economy, but also the national economy and the global economy. So this seemed an ideal place to have a forward-looking discussion about the place agriculture may occupy in American life in the 21st century. All of us involved in agriculture - students, faculty, researchers, farmers, community leaders, and those of us in government - must work together to deal with the monumental changes taking place in agriculture... and we must make our decisions and set our priorities accordingly.

It can be a little difficult to have this kind of objective, intellectual dialogue when we're in the middle of serious farm problems. Falling prices and natural disasters demand stopgaps, quick fixes and emergency responses. It's hard to talk about the long-term when there are many producers staring every day at the prospect that they may not have a long-term at all...at least not in farming.

Nevertheless, we can't let our focus become all trees and no forest. Eventually, farm prices and income will rebound and exports will improve. Without minimizing or neglecting the very real hardship being experienced in farm country, we have to look toward the future. We have to ask – and begin to answer -- the questions: What might American agriculture look like in the 21st century? And perhaps more importantly: What do we want it to look like? Because we can't just sit idly by and let change happen to us.

Role of Government

The role of government in the farm economy is changing dramatically, particularly as it relates to the operation of farm programs. We will spend $15 billion this year in direct payments to farmers, the highest of any fiscal year on record. But notwithstanding that, with the passage of the 1996 Farm Bill, we are in the process of minimizing the government role, of stripping USDA of many of its authorities to intervene in the market on farmers' behalf and deal with issues of supply and demand. So we have to rely on different tools.

The '96 Farm Bill, however, didn't provide a clear roadmap for federal farm policy in the future. It offered no hard guidelines. In fact, the part of the bill covering farm programs is called "The Agricultural Market Transition Act." So there's got to be a transition...but to what we don't really know.

On some level, there will always be farm programs. But we have to start thinking proactively about USDA in a new role. We can be catalysts, helping farmers and ranchers compete, without artificially guaranteeing them a certain level of income. Government can no longer assume complete production and marketing risks, but we can point producers toward the tools that will help them manage those risks. We can and should find sensible ways to strengthen the farm safety net, with a strong crop insurance program and other risk management tools. But policymakers, particularly in Washington, have to get away from this focus on micro-program changes, and instead explore ways to empower farmers to thrive in a modern world.

For example, the National Commission on Small Farms, which I appointed two years ago, has come back to me with a number of recommendations. It suggested a Beginning Farmer Development Program, which would establish training and assistance centers for beginning farmers; a small farm research initiative; and an entrepreneurial development initiative for small farmers.

Producing For The Market

We also have to help farmers learn to thrive in a consumer-driven environment. What we have had in the past -- although I think it's changing now -- is a kind of "if we grow it, they will come" mentality. The Big Three automakers found out what happens when you defy the consumer. They used to forcefeed cars to a closed-mouth public, and they got left in the dust by Japanese and German competitors. But they learned their lesson, and now they tailor their production to the needs and demands of their consumers.

Many farmers are doing this. But to be successful, agriculture must always stay ahead of the consumer curve. And it just so happens that, when it comes to food, we're living in a time when consumer tastes and preferences are becoming more and more sharply defined. Who would have thought forty years ago that grocery shoppers would be asking for turkey bacon, veggie burgers or tofu ice cream? Americans and people around the world are more knowledgeable about food and nutrition and more discriminating about what they put in their mouths. In addition to the traditional foods that most consumers buy, many people are now looking for leaner beef, organic foods, free-range chicken or foods that are "natural".

There is a heightened consciousness about food labeling. People want to know where their food comes from and what goes into it. They're worried about their cholesterol levels and their recommended daily allowance of folic acid. These are the kinds of consumer dynamics that farmers must learn to read and respond to...or else ignore them at their own peril. And there are even more consumer dynamics to consider when it comes to our overseas customers, who represent the greatest potential growth market for American agriculture.

Farmers and ranchers must develop market antennae. As Barry Flinchbaugh of Kansas State University and the chair of the Commission on 21st Century Production Agriculture put it: producers must learn to manage markets in the same way that they used to manage farm programs. The days of farmers simply growing crops and raising livestock without meeting specific market needs are over.

All of us have to be partners and facilitators in this process. We in government have to help farmers make the transition, instead of simply reauthorizing and refunding the same old programs year after year. And the land-grant colleges have a pivotal role as well. Just as government can't be a captive of the past, neither can you. Agriculture can't be taught the way it was in the past. You in this room and at land-grants around the country have to adapt your extension and outreach programs for this modern, market-driven farm economy. And your research priorities must reflect these new realities as well.

Concentration

It so happens that watershed changes in farm policy are happening at a time of increased concern about structural and technological changes in agriculture. So farmers, without the kind of support they've traditionally enjoyed from their government, are preparing to compete in a world of transition and a climate of uncertainty. This is especially true of small and medium-sized operators.

One of the things that we see in agriculture – and, really, in every other sector of the economy – is a trend toward fewer and larger operations. This has been a long time in the making. In 1900, there were 5.7 million farms averaging 147 acres apiece. By 1950, it was about 5.4 million farms with an average acreage of 216. The trend has dramatically accelerated in the second half of the century. By 1998, the number of farms had been cut by more than half to 2.19 million, while the average acreage doubled to 435.

Consolidation can sometimes lead to some increased efficiency in an economic system. But now what we're seeing goes beyond just farm consolidation. Now, at every link along the food production chain, there are concentrated markets, clusters and alliances, relationships both formal and informal, that may present serious challenges to the small and medium-sized producer trying to move goods to market.

This is especially true when it comes to livestock processing. In the beef industry, four meat-packing plants now control 80% of the steer and heifer slaughter market. We're also seeing a profound restructuring of the hog industry. I know people in Indiana are well aware of that. Since 1967 the number of hog operations has fallen by 90%. Large operators of more than 2,000 hogs represent just under 6% of producers, but account for almost two-thirds of inventory. As more farmers raise more hogs under contract with fewer processors, the very nature of the industry relationships are changing.

And while contracting is often a good deal for the small farmer or rancher, concentration can force producers into accepting lopsided contractual terms, simply because there's no ability to shop around for the best deal. Most poultry production now operates under contract, and the farmers are now almost extensions of the processors – in some ways employees of those firms.

That is not the role we want farmers to play. I don't think we want to live under a system of agricultural Darwinism, with survival of the fittest becoming survival of the biggest. We don't want to get to the point where farmers lose control of their economic destiny and are reduced to serfs in a kind of feudal agricultural system.

So how do we cope with these forces?

One thing we're doing at USDA and the Justice Department is keeping a watchful eye on some of these major mergers and, within the framework of our authorities, vigilantly monitoring for anti-competitive behavior. Just a few weeks ago, USDA filed a complaint against Excel Corporation, alleging that the company violated the Packers and Stockyards Act by engaging in unfair pricing practices affecting about 1200 producers. That case is now in litigation, and it is my belief that more cases will be filed under the Packers and Stockyards Act in the months to come.

On the grass roots level, there are things family farmers can do – things USDA can help them do – to stay competitive in a top-heavy farm economy.

If the larger agricultural interests can form clusters and alliances, so too can smaller producers – in the form of cooperatives. A single small producer, up against some of the mightiest players in the economy, may stand little chance of exercising meaningful bargaining clout. But by forming cooperatives, by banding together, they give themselves more leverage in the marketplace. In addition to using co-ops to bargain for better prices, many have used them as entrepreneurial tools, to help them build their own processing and manufacturing facilities and position themselves as strong competitors in their industry.

To help co-ops, USDA offers a variety of tools, worth more than $200 million a year, including everything from an initial feasibility study to the implementation of a business plan.

Let me give you just one example. Last year, we helped the Hermitage Tomato Cooperative Association in Arkansas with a $3 million guaranteed loan, which gave them some working capital and allowed them to purchase land and equipment. Before the loan, the members were barely staying afloat, marketing their tomatoes at auctions and through two other firms. But with some help from USDA, last year the co-op generated nearly $4 million in sales supplying tomatoes to the fast-food industry. They've gone from 75 to 116 employees, and they are making plans for a second processing facility that would add another 100 jobs.

I would like to see even more opportunities for cooperatives in the future. In some countries, like Ireland for example, co-ops can become publicly traded entities; by issuing stock, they can increase their capital base and enhance their ability to compete. Our laws, however, don't make it easy to do this in the United States. And our tax laws do not encourage genuine innovation in farm cooperatives.

There are also ways for producers to enhance their income in this era of rapid consolidation. Let me talk for a minute about direct marketing and farmers markets. We have been very aggressive at USDA in promoting farmers markets. They used to be just a quaint thing you'd stumble across on a country drive. Now they're everywhere. When we began collecting data on farmers markets in 1994, there were only about 1,700 of them in the country. Today, we estimate that there are nearly 3,000.

Farmers markets are a win-win. Farmers increase their income through direct access to their consumers. And consumers get access to locally-grown, farm-fresh produce. There is the added benefit that it strengthens the relationship between grower and consumer. Too often, there is a measure of cultural estrangement in this country between the people who produce our food and the people who eat it. Farmers markets bring the two together. Farmers gain a better understanding of what their consumers like. And consumers gain an enhanced appreciation for the labor that puts food on their tables. And social benefits aside, farmers markets and other direct marketing schemes have proven to be very profitable as well.

There are also niche markets to explore, for example the rapidly growing demand for organic products, a real opportunity for farmers of all sizes but particularly the mid-sized producer. Right now, we're in the process of coming up with uniform national standards on what, exactly, constitutes an organic product. We believe the standards will improve consumer confidence in organic products and open new opportunities, both domestic and international, for our producers. This is not some goofy fringe market. It is becoming very much a part of the agricultural mainstream, and it holds out the potential for enormous profit, as it grows to an estimated $6.6 billion market in the next year.

So there are a lot of ways we can help producers become a part of the new agricultural era. But we can't just do the same things we've done in the past. We have to constantly come up with innovative, creative solutions.

Science/Biotechnology

We can't talk about agricultural challenges for the 21st century without some discussion of science, and specifically biotechnology.

Science and technical progress are certainly to be celebrated. For hundreds of years, the physical and life sciences have helped make agriculture safer, more efficient and more productive. It has increased yields and reduced production costs. Science is everywhere in our shopping carts -- from frozen dinners to low-fat cheeses to seedless grapes. Our new science-based food inspection system at USDA, to give just one example, is improving our ability to protect consumers from deadly pathogens.

And now, nearly a half century after Watson and Crick discovered the double helix and unearthed the mystery of the structure of the DNA molecule, we are able not only to read the genetic code...we can manipulate it and reprogram it as well.

Biotechnology can be an indispensable tool as we try to serve global agricultural demand in a sustainable manner. The world is growing, and it's growing in developing nations, which have experienced the greatest food insecurity. We have more and more people to feed...more and more fiber to produce...and a limited amount of arable land to put into production...at a time when water is becoming a more and more precious and scarce commodity. Biotechnology can help us generate higher yields, while lessening the strain on our natural resources. It can also help farmers produce a new generation of specialty products, which the market may demand in the future.

I remember visiting the wheat research center in Mexico where some of the research was done on the wheat gene Norin 10, which helped developing countries like India and Pakistan increase their wheat harvests by 60 percent. At the center, there is an inscription on the wall that reads: "A single gene has saved 100 million lives."

That's a powerful notion. Nevertheless, those of us in government, the private sector, the academic community and the farm community can't be afraid to ask the difficult questions. We cannot be science's blind servant. We have to understand its ethical, safety and environmental implications. Our testing has to be rigorous. We have to be as vigilant as ever. And we have to make sure that those involved in determining the safety of genetically-engineered products are staying at arm's length from the people who stand to profit from them. At USDA, for example, we took our food safety division out from under the umbrella of our marketing programs, an important step that has avoided even the appearance of impropriety in this area.

We also can't force these new genetically engineered food products down consumers' throats. While people around the world have embraced biotechnology's twin, information technology, the fact is that they're still quite cautious about biotech. My belief is that farmers and consumers will eventually come to see the economic and health benefits of these products. But dismissing the skepticism that's out there is not only arrogant, it's also a bad business strategy. My confidence in biotech -- or industry's confidence in biotech -- is ultimately irrelevant. Only when consumers have confidence -- and when they express that confidence at the grocery-store checkout line -- will we be able to see the return on the enormous public and private investments we've made in biotechnology.

This is an important challenge for those of you in the research community. Innovations may be born in the laboratory, but they find success in the marketplace. So it's not enough to celebrate science for science's sake. Technological progress must always be accompanied by public information and consumer education efforts that address concerns and allay fears. Scientists should always remember that there's another kind of research -- market research -- without which all the patents and all the ingenuity in the world add up to very little. When it's all said and done, the public opinion poll is just as powerful a research tool as the test tube.

Just yesterday, two of the largest grocery chains in the United Kingdom said that they will work to eliminate GMO ingredients, just another sign that the biotech issue remains a highly explosive one. I think these grocery chains need a little bit of educating, but I don't think we can just sit here and berate them. We've got to work with them, so they understand -- and consumers understand -- what the benefits are.

Also, we have to be careful about ratcheting up the expectations on some of these technologies. There is no one silver bullet that will allow us to meet all of tomorrow's agricultural and food security challenges. We have a way in this country of latching on to solutions, pursuing them to the exclusion of others, and then watching them sometimes backfire.

We did it in the late 70s when we embraced nuclear power as the primary solution to our energy needs. Then, Three Mile Island happened. Now, nuclear power is till a part of our energy grid, but it's not the only part. Just in the past few years, we looked at the growth of emerging markets and decided that trade was the panacea. Before we knew it, Asian financial markets collapsed, setting off a chain reaction that has led to recession in just about half of the world.

So, yes, let's be enthusiastic about these technologies and pursue them. But let's not put all of our eggs in the biotech basket. Just as the securities industry tells us to diversify our investment portfolios, so must our agricultural science portfolio be rich and diverse.

Vibrant Rural Communities

Before I close, I want to talk for a second about the importance of rural America and its changing fabric and infrastructure.

To preserve the family farming tradition in the 21st century, the truth is that, for many, there will have to be additional avenues of economic opportunity in rural America. It's unfortunate, for some producers, that they have to pursue off-farm income. But ironically enough, that may be the only way to keep many of them on the land. If people can supplement their livelihood doing something else, then farming will at least remain viable as a part-time vocation, even for those who can't make it producing crops or livestock alone. So we need a diversified rural economy that has all the tools, the infrastructure and the technology to give people various ways to make a living.

That's why USDA has a whole agency, led by Jill Long Thompson, devoted exclusively to rural development. We extend loans and grants that invest in rural businesses, rural utilities and rural housing. Over 50 rural areas have been targeted for tax incentives and other economic development support as part of President Clinton's Empowerment Zone/Enterprise Community initiative.

Rural areas have a lot to offer, and we're beginning to see people move to the country in search of a different kind of lifestyle. Rural counties have actually grown by about 3 million in the 1990s. I was just reading an article the other day about a woman who was raised in the suburbs, had tried the city life, but now was settling in a community of 900 people in New Hampshire. She likes the more affordable real estate, the recreational opportunities, as well as the informality and familiarity of rural life. And information technology now makes it possible for people like her to live in the country and still connect with professional and social networks that they might be leaving behind.

With apologies to the creators of *Cheers*, rural America really is the place where "everybody knows your name." Rural America may be a place of rugged individualism, but it's also a place of social cohesion. We don't see many barn-raisings anymore, but it is that spirit of volunteerism – of pitching in on behalf of the entire community -- that still prevails in small towns around the country. People who live in rural areas are vested in their community. They know their neighbors; they watch each other's children; they treat each other as extended family. And by living these kinds of values, rural towns send a message to – and set an example for – communities around the country.

Just watching the news over the last week, I can't help but think -- and I don't want to overgeneralize here -- that it's that sense of intimacy and cohesion that was missing at Columbine High School in Littleton, Colorado. When you have a high school of some 1800 students, it's easy to see how kids who are maladjusted or socially outcast, who are having trouble coping with adolescent pressures, simply get lost and fall through the cracks of the system. But in the close-knit environment of a rural community or small town, where everybody knows everybody else, it's easier to identify social problems before they erupt into violence.

If we're going to preserve and cultivate rural America's unique qualities, we have to keep it economically viable. First and foremost, that means keeping production agriculture as economically viable as possible. But beyond that, if we're going to attract new residents and new business investment to rural areas, the infrastructure and the economic base have to be there. No one is going to locate in a town where the sewer facilities are inadequate or the water isn't safe to drink. But still a quarter of a million rural households live without clean, safe drinking water. Another 2 million live in substandard housing.

In addition to clean water and decent housing, rural communities have to have a trained workforce, good schools, first-rate medical care, child care options, adequate telephone and electricity service and Internet connectivity -- everything that would make someone want to bring their family or business to a community. And even as we develop and diversify rural America, we also have to preserve the open spaces and natural resources that make rural life unique and draw people there in the first place.

Conclusion

Shakespeare wrote: "What's past is prologue." There is certainly some truth in that statement, but I would offer this caveat. When it comes to agriculture, our approach to the future should certainly be shaped by the experience of the past. But we cannot and should not approach the future by trying to recapture the past.

We have to start with a recognition that America is no longer a predominately agrarian society. It's naive and just plain unconstructive to wax nostalgic about some kind of pre-industrial Jeffersonian model.

In 1900, farmers represented 38% of the labor force. By 1950, the number of farms had decreased only by a few hundred thousand, but farmers dropped to only 12% of the labor force. By 1990, there were barely 2 million farms, and farmers made up 2.6 % of the workforce. Sixty years of aggressive farm programs have not been able to reverse this trend.

But as we approach the new millennium, the family farm still remains a central building block of American society. And while it has changed in definition, size and structure, there are still enormous opportunities for family farm agriculture and farm prosperity in the year 2000 and beyond.

But seizing those opportunities is going to require a different approach from all of us.

Farmers will have to become more entrepreneurial, more market-oriented. They will have to recognize that this isn't their father's farm economy. They will have to be better educated and more technologically sophisticated than ever before.

We in government have to adjust our programs. We can't wring our hands about the authorities we once had; we must work tirelessly to forge a new farm policy paradigm, one that puts government in the role of partner.

And universities like Purdue have a critical role as well. You understand that you can't teach agriculture the way you did in 1950. The research you conduct, the courses you offer, and the skills you impart must conform to the needs of a farm economy in transition...and an American and global economy in transition.

The challenges are enormous...but so are the opportunities. I'll close with a story about a former president of a major American corporation, who went to a high school to give a commencement speech. At the end of the speech, the chief executive looked at these kids and said: "I have one piece of advice for you. And that advice is, you've got to jump when opportunity knocks."

And a kid in the front row said: "That's great for you. You're president of one of the biggest companies in the world. That's easy for you to say. But, tell me, how do you know when opportunity knocks?"

And the man said: "You don't. And that's why you have to keep jumping all the time."

If we work together -- if we all keep jumping -- we can seize those opportunities and preserve for our farmers and ranchers and our rural communities their share of the American Dream in the 21st century. Thank you very much.

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CSPI Center for Science in the Public Interest
Publisher of *Nutrition Action Healthletter*

File - ?
Food Safe

September 24, 1999

The Honorable George V. Voinovich
Subcommittee on Oversight of Government Management,
Restructuring and the District of Columbia
601 Hart Senate Office Building
Washington, DC 20510

Dear Senator Voinovich:

Thank you for holding the hearing on food safety on August 4 in the Senate Governmental Affairs Committee, Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia. I am happy to answer additional questions from the Committee.

Question 1. You mentioned in your testimony that in poll after poll, food safety ranks high on the list of things that consumers would like to see improved. Could you provide this public opinion data for the record? Does recent polling data indicate changes in consumer confidence in the safety of the US food supply or a change in consumer confidence in the US government agencies responsible for food safety? What actions would you recommend that Congress or the Federal agencies take to maintain or improve confidence in the safety of the food supply?

Every year, the Center for Science in the Public Interest (CSPI) polls a representative sample of our members/donors on which food and nutrition issues they believe are most important to address during the coming year. Improving food safety has been our members' top priority since 1988. This year's mail-in survey was conducted in January and garnered 18,000 responses. (See attachment A.)

While responses from our members clearly indicate the views of consumers that are most concerned about food and nutrition issues, other opinion polls have generally reflected similar concern among consumers. For example, a 1999 nationwide survey of consumers by CMF&Z Food Practices Consulting Group found that food safety was ranked as "very important" by 83% of the respondents. Drinking water safety, crime prevention, and health and nutrition were statistically even: "very important" garnered 86%, 83% and 81% percent of respondents, respectively. Protecting the environment was rated as "very important" by 69%. This nationwide poll was completed in July and included 400 consumers. (See attachment B.)

In 1998, a poll by the same organization showed that consumers' concerns about food safety (89% ranked it as "very important") surpassed their concerns about drinking water safety (85%) and crime prevention (82%). The areas of greatest concern were *E.coli*, Hepatitis,

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pesticide residues, and *Salmonella*. The survey found that nearly two thirds of the public said food safety regulations were not tough enough, while one third thought they were just right. The telephone survey of 300 people was conducted in June 1988. (See attachment C.)

A 1998 survey by *Restaurants and Institutions* magazine on consumer attitutes toward restaurant food safety found that 43% of consumers thought the likelihood of contracting foodborne illness from food prepared in a restaurant or a food service establishment has increased over the past five years. Consumers identified the following initiatives to increase food safety: improved methods to detect harmful foodborne bacteria (55%); more frequent inspection of restaurants (52%); more frequent inspection of food processing plants (48%); programs to educate workers in the food service industry (45%); more inspection of foods that are imported into the U.S. (39%). This mail-in survey was completed by 738 households during May and June, 1998. (See attachment D.)

Another survey, conducted in 1997, found that consumers viewed food safety as needing "a lot of regulation to protect consumers' interests," which surpassed all other issues. In this survey of over 600 consumers, food safety garnered a 64% response, higher than airline safety (61%), environmental hazards (57%), health plans and health insurance (46%), and automobile safety (44%). This telephone survey was conducted in December 1997. (See attachment E.)

Finally, in a 1999 survey conducted annually by the Food Marketing Institute, product safety was ranked among the most important attributes in choosing food by 70% of supermarket shoppers. In surveys going back to 1990, product safety is always among the top three attributes listed. Between 1990 and 1999, it was chosen consistently by between 69% and 75% of those surveyed. The 1999 telephone survey included over 2000 households, and was conducted in January. (See attachment F.)

These surveys repeatedly show that food safety is a significant concern for consumers, one that must be addressed by governmental action. In one survey, when consumers were asked who was doing the best job of assuring food safety, government agencies ranked among the lowest (named by only 39% of respondents), behind farmers (60%), supermarkets (56%), consumers (53%), food processors (45%), and restaurants (44%). Meat packers scored the lowest, identified by only 38% of consumers. (See attachment B)

It is time for Congress to step in to ease consumers' concerns about food safety. It is time to merge the existing federal food safety agencies into a single agency with a farm-to-table mission to reduce the numbers of foodborne illnesses and deaths.

Question 2. In your written testimony, you mentioned that in the 1980s, the Centers for Disease Control and Prevention (CDC) discontinued their annual listing of food-borne illness outbreaks. What is the value of having such information made available on a timely basis?

The "Jack in the Box" outbreak in the early 1990s, in which over 700 people became ill and four children died from *E. coli* O157:H7 in hamburgers, illustrates the importance of thorough and coordinated outbreak investigations. In that outbreak, the first death was recorded in late December 1992, but California health officials failed to identify the source and alert the public. For the next three weeks, consumers in four western states continued to eat hamburgers contaminated with the deadly *E. coli* O157:H7. Ultimately, three more children died. Finally, on January 22, 1993, health officials in Seattle, Washington, announced that the Jack in the Box restaurant chain had been identified as the source of the contaminated hamburgers and the outbreak was stopped.[1] While CDC and the states have been working to improve communication on outbreak surveillance since 1993, the system has not improved sufficiently to ensure that long delays in identifying the cause of an outbreak and alerting the public will not occur again.

Just as a prompt alert to the public can help stop an outbreak, prompt information on outbreak trends is also critical to preventing illnesses. Outbreak information provides an early warning of new hazards in the food supply and allows federal and state health officials to look for related outbreaks both nationally and in their communities.[2]

With headline after headline reporting food-poisoning outbreaks[3], the public certainly expects that some government agency maintains a comprehensive inventory of foodborne-illness outbreaks in the U.S. Such an inventory would allow policy makers, the food industry, and the public to monitor trends, issue public health alerts, change production practices, and, ultimately, reduce the number of illnesses and deaths caused by contaminated foods. Publishing outbreak information can also help alert the public to the emergence of a new pathogen, or to the

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[1] U.S. Department of Agriculture, "USDA Fights Foodborne Illness in Washington State," *USDA News*, Release No. 074.93, January 22, 1993; State of Washington, Department of Health, "Illnesses in Western Washington Linked to Jack in the Box," No. 93-04, January 18, 1993; "State Officials Announce Levels of Coliform Contamination in Beef," No. 93-05, January 22, 1993.

[2] CSPI's outbreak lists show three examples of outbreak clusters: Lettuce, summer and fall 1995; apple cider, fall 1996; alfalfa sprouts, summer 1997 through summer 1998. In these instances, harmful bacteria appeared on products that health officials would be less likely to suspect.

[3] "Outbreaks" are when two or more consumers become ill from a specific contaminated food item. "Cases" represents the number of individual illnesses that occur, either individually or as part of an outbreak.

appearance of a familiar pathogen on a new food source. Surprisingly, though, no federal agency maintains a comprehensive list of food-related outbreaks.

The Centers for Disease Control and Prevention (CDC) is the nation's primary disease monitor, a job that includes reporting on foodborne hazards. One might expect CDC to maintain a list of outbreaks caused by contaminated food in order to identify new hazards in the food supply. However, despite the relative simplicity of creating and maintaining a list of foodborne-illness outbreaks, CDC has determined that doing so is not a priority. While CDC is getting new funding to enhance its surveillance of foodborne illness, most of that funding is being spent on the agency's sentinel surveillance project, which studies foodborne illness intensively in a few "sentinel" sites. The basic functions of collecting and publishing information on outbreaks from around the country remain unfulfilled.

To help fill this key gap in CDC's current system, CSPI has been maintaining its own partial inventory of foodborne-illness outbreaks that occurred since 1990, which is available in our report *Outbreak Alert*. CSPI's inventory is the only one of its kind available today, but even it includes only a small fraction of the outbreaks being reported to the CDC and other federal agencies; in turn, those outbreaks represent only a small fraction of all foodborne-illness outbreaks that occur.[4] CSPI's information on outbreaks has been collected from numerous medical journals, government reports, and other sources.

In the early 1980s, CDC published annual summaries of foodborne diseases that included a "Line Listing of Foodborne Disease Outbreaks." That listing is comparable to the inventory CSPI has developed. Unfortunately, CDC's listing was discontinued during the 1980s due to budget constraints.[5] Today, the CDC compiles foodborne-illness data in many formats, but doesn't maintain a comprehensive list of outbreaks available to policy makers or the public. For example, the *Summary of Notifiable Diseases* and the *Surveillance Summaries on Foodborne-Disease Outbreaks* both list the total number of cases of illness linked to reported outbreaks from various pathogens and foods, but they are published months or sometimes years after the outbreaks.[6] Also, those summaries don't give information linking the food with the pathogen for

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[4] *Surveillance for Foodborne-Disease Outbreaks, pp.13-15.*

[5] Telephone conversation with Dr. Patricia Griffin, Chief of Foodborne Diseases, Foodborne and Diarrheal Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA, January 14, 1999; E.g., Centers for Disease Control, "Line Listing of Foodborne Disease Outbreaks, 1982," *Foodborne Disease Surveillance, Annual Summary 1982*, (Atlanta, GA: Centers for Disease Control, September 1985), pp. 19-24.

[6] *Surveillance for Foodborne-Disease Outbreaks*; *Summary of Notifiable Diseases.*

each outbreak. The *Surveillance for Foodborne-Disease Outbreaks -- United States, 1988-1992* includes only brief descriptions of a few highlighted outbreaks by year, and the *Summary of Notifiable Diseases, United States, 1997* briefly describes only one foodborne-illness outbreak.[7]

Some reports of individual outbreak investigations conducted by CDC are published in its *Morbidity and Mortality Weekly Report* or in peer-reviewed journals.[8] However, without an outbreak inventory to put these reports in context, it is difficult to know whether the outbreaks that are described in those journals are truly illustrative of the most important trends.

Rather than leaving the job of compiling food poisoning outbreak information in the hands of a private organization like CSPI, CDC should serve as a clearinghouse for information on foodborne-illness outbreaks. CDC currently receives more outbreak information from state and local health departments than any other federal agency, so it is best situated to collect and release all available information. CDC should put a high priority on encouraging states to report all foodborne-illness outbreaks and, once this data is obtained, on compiling the numbers and promptly reporting on the trends observed. CDC should make information acquired during foodborne-illness outbreaks fully available to other government agencies, to the public, and to the food industry so that prompt action could be taken to prevent future outbreaks.[9]

To remedy this problem, CSPI has developed the following recommendations:

- **CDC should maintain a comprehensive inventory of foodborne-illness outbreaks and issue timely reports on those outbreaks.**

CDC should regularly collect reports from the states and publish (in written reports and over the Internet) quarterly lists of outbreaks and annual reports on outbreak trends. Funding should be provided in the National Food Safety Initiative to ensure that CDC has adequate staffing to handle those responsibilities.

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[7] *Surveillance for Foodborne-Disease Outbreaks*, pp. 4-9; *Summary of Notifiable Diseases, 1997*, p. xii.

[8] CDC "Trip Reports" also are informative. These reports are written by the lead CDC Epidemic Intelligence Service (EIS) Officer on a foodborne-illness outbreak investigation. While Trip Reports are not publicized or indexed, they are available from CDC if requested for a specific outbreak.

[9] For example, following several outbreaks associated with fresh juices, the Food and Drug Administration required unpasteurized juices to bear a warning label to alert consumers to the hazards associated with these products. 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.

- **States should report all foodborne-illness outbreaks to CDC.**

States should send reports to CDC of all investigations of outbreaks conducted by state and local health departments. An electronic reporting system should be developed to minimize the burden on health departments and on CDC. CDC should also actively monitor media reports and request information from health departments, as it does for the FoodNet surveillance programs.[10]

- **Congress should fully fund the National Food Safety Initiative, a program coordinated by the White House to develop and fund projects to reduce the incidence of foodborne illness.**

The Clinton administration has requested $105 million in new food-safety funding in its fiscal year 2000 budget request, including $40 million for the Department of Health and Human Services, the parent agency of CDC. CDC needs additional funding to improve its surveillance systems and to develop a clearinghouse on foodborne-illness outbreaks. In addition, the funding sought for FDA to enhance inspection of both domestic and imported food is vitally important to reduce the number of outbreaks linked to FDA-regulated foods.

Respectfully submitted,

Caroline Smith DeWaal

Caroline Smith DeWaal
Director, Food Safety
Center for Science in the Public Interest

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[10] U.S. Department of Health and Human Services, "FoodNet: CDC's Emerging Infections Program," updated April 1998, available at <http://www.cdc.gov/ncidod/dbmd/foodnet/foodnt498.htm>.

Attachment A

Issues Survey of CSPI Members/Donors

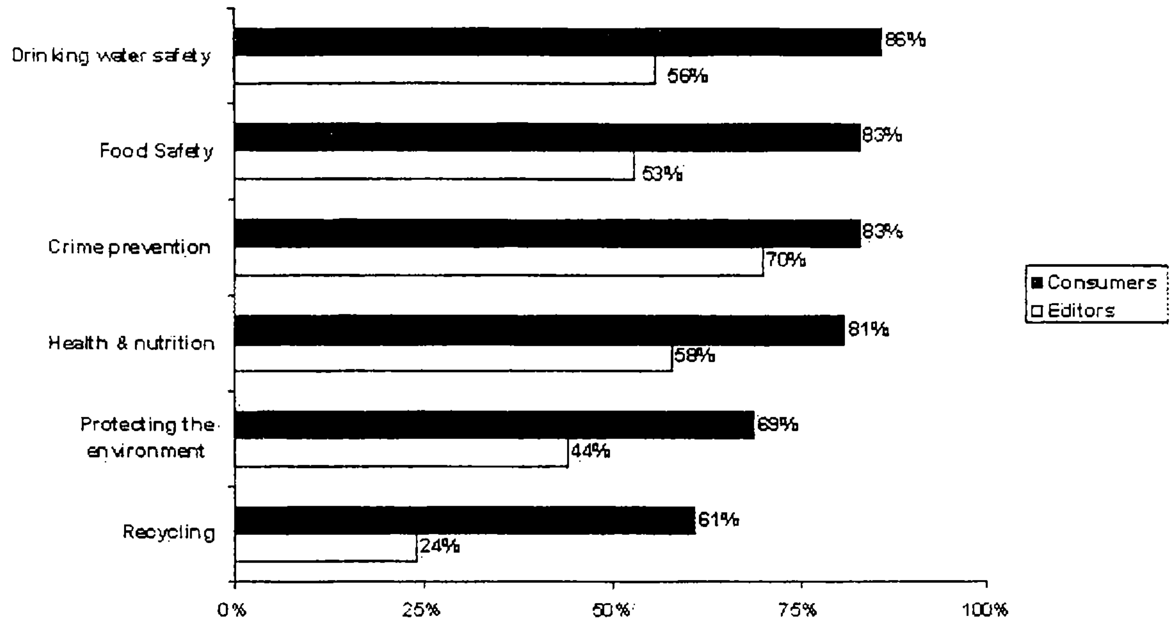
September 24, 1999

Issue	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	U.S. 1999
Safe Food	1	1	1	1	1	1	1	1	1	1	1	1
Food Additives	**								2*	2	2	2
Food Labels	2	3	2	3	2	2	2	2*	2*	3	3	3
Food Ads	3	4*	3		3	3		2*	2*			
Children Nut.		4*	4	4	4	4*						
ConsumrNutEd	4		5			4*		3	4	5		5
Alcohol	5			5								
Saturated Fats		2										
Food Testing				2		4*						
Fast Food					5							
Supplements					6	6						
Restr. Food						7	4	3	5			
Restr. Fd Safty										4		
Internat. Threat												4

* virtual tie.

** *We survey on a limited number of issues each year, so there is no data for many of these categories for certain years.*

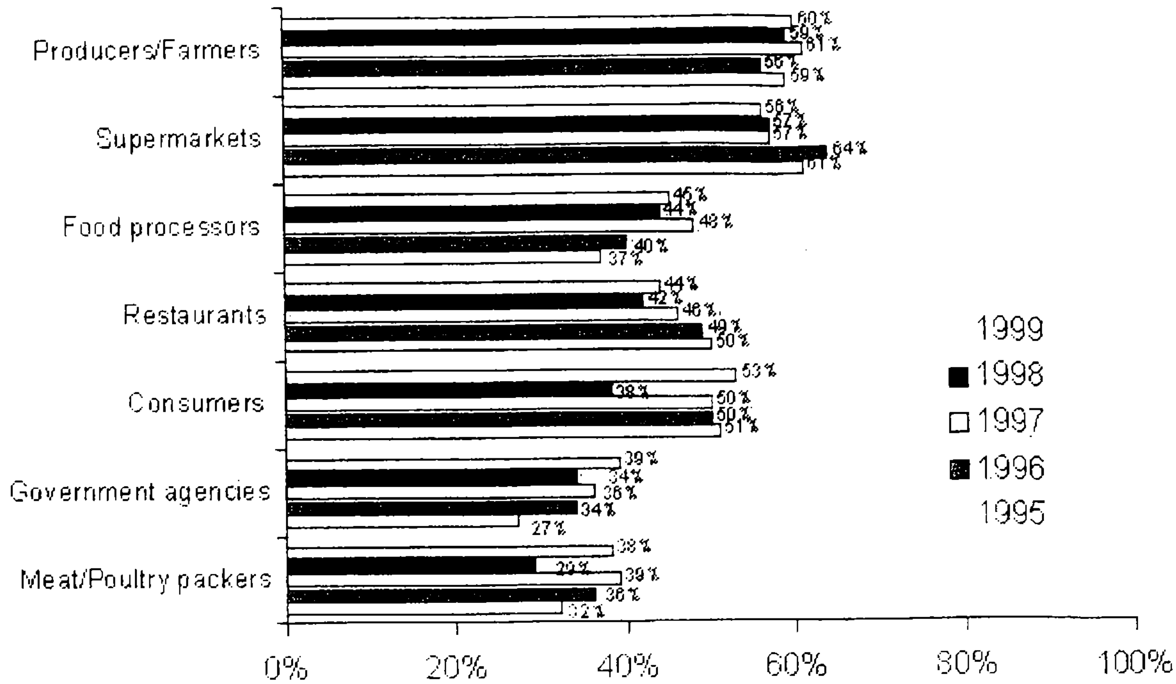
Food Safety Ranks Among Top Public Issues
(Rating of "Very Important")



Back to the Results Table of Contents

Back to Food Safety

Who's Doing the Best Job of Assuring Food Safety?



Back to the Results Table of Contents

Back to Food Safety

1999 Food Safety Survey Abstract:

The anticipated commercialization of food irradiation requires processors to proactively manage the responses that will impact their businesses. The Food Issues Survey provides perspectives on consumer attitudes toward irradiation and processor accountability and effectiveness in impacting food safety.

1999 Food Safety Survey Objectives:

- Identify food issues and trends of greatest concern and importance to the public and the media.
- Explore attitudes toward the role and credibility of interest group industry participants.
- Assess public perceptions of media credibility and influence on consumer food purchases.

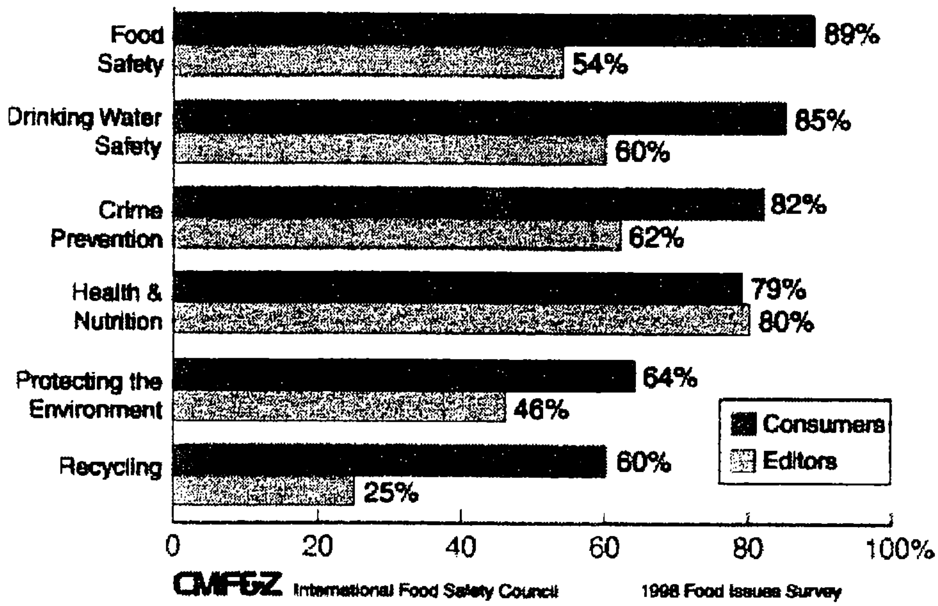
1999 Food Safety Survey Methodology:

- CMF&Z's Market Research Group has conducted the annual survey since 1993.
- It is based on a nationwide, random sample of 400 consumers and 150 editors, and is conducted by telephone each spring.
- Trend analysis is performed annually.
- Margin of error on consumer surveys is + 4.9%.
- Margin on error on editor surveys is + 8%.

Back to Food Safety

Consumers & Editors Rank Public Issues

For the first time, consumers ranked food safety higher than other issues addressed by this survey. Previously, crime prevention, safe drinking water and general health and nutrition were considered more important than food safety. The importance consumers placed on food safety surpassed the expectations of food editors, who continued to place more emphasis on other public issues.



Back to the Results Table of Contents

Back to Food Safety

1998 Food Issues Survey Objectives & Methodology

1998 Food Issues News Releases

1998 Food Issues Survey Objectives:

- Identify trends in the perceived importance of food safety to the American public and print media.
- Explore editors' beliefs on how informed the American public is about food safety and food-related issues.
- Identify food-safety-related issues of greatest concern and potential action.
- Identify the public's perceptions of media credibility on food safety issues.
- Explore consumer and editor attitudes toward the role and credibility of interest groups.
- Determine how well various groups do in communicating with media.

1998 Food Issues Survey Methodology:

- 300 telephone interviews are conducted for the survey -- 150 with a random sample of newspaper editors or food safety writers, and 150 with a random sample of the general public.
- The interviews for the 1998 Food Safety Survey were conducted in June of 1998.
- The survey has a margin of error of + 8 percentage points.

Back to Food Safety

1998 Food Issues Survey News Releases

1998 Food Issues Survey Results

Des Moines Register Sept 22, 1998 P10S

Food safety consumers' top concern

■ E-coli, hepatitis, pesticides and Salmonella rank highest in a new survey.

BY ANNE FITZGERALD
REGISTER AGRIBUSINESS WRITER

U.S. consumers are more concerned about food safety than crime prevention or water quality, according to a new survey being released this week.

When asked to rate the importance of food safety as a public issue, 89 percent of the consumers surveyed rated it as very important, while 86 percent said the same about drinking water safety, and 82 percent about crime prevention. The study listed consumers' top concerns as E-coli viruses, hepatitis, pesticide residues and Salmonella.

More than half the consumers surveyed said farmers (59 percent) and supermarkets (57 percent) do an excellent job of ensuring a safe food supply. Only a third (34 percent) gave the same credit to government agencies. Meat and poultry processors ranked the lowest, with 29 percent saying they do an excellent job on food safety.

Conducted in June by CMF&Z, a marketing and public relations firm with offices in Des Moines and Cedar Rapids, the telephone survey of 150 U.S. consumers was co-sponsored by the International Food Safety Council, a coalition representing the restaurant and food service industries. It is the fourth annual survey of consumers' attitudes on food safety conducted by CMF&Z since 1995.

In earlier surveys, food safety ranked high, but this marks the first time it has ranked No. 1, said CMF&Z spokesman Bill Brewer.

A companion survey of 150 food editors across the country was conducted at the same time to gauge newspaper editors' perceptions of public attitudes toward food safety issues. Both surveys had an 8 percent margin of error.

In the new public survey, nearly two-thirds said food safety regulations were not tough enough, while one-third rated regulations "just right."

Three-fourths (77 percent) of consumers said media reports of food-borne illness affected their consumption.

In several cases, the responses of consumers differed markedly from those of editors.

For example, 54 percent of the editors said food safety was very important as a public issue, compared with 89 percent of consumers. Also, when both groups were asked to rate their levels of concern on 15 different food-safety issues, consumer concern ranked higher in all cases except one: fat content.

Two-thirds (67 percent) of the editors listed fat content as an issue of high concern, while just half (51 percent) of consumers did.

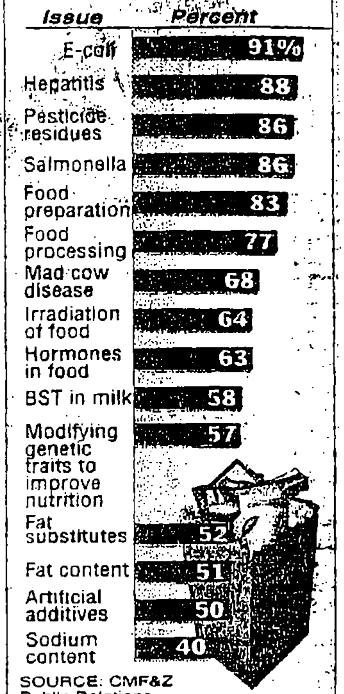
On most of the other issues, though, the levels of concern among consumers ran 15 to 25 percentage points higher than among the editors.

Both groups, however, agreed on which issue is of the most concern: E-coli contamination. They also agreed on which issue is of least concern: sodium content.

Sharon Pilmer, manager of consumer research at CMF&Z in Des Moines, said she thought the editors' responses differed from consumers in part because of their proximity to news and access to more information about the issues explored in the survey.

Consumer concerns

■ Each of the 150 people interviewed for the survey was asked to rank issues on a scale of one to five, where one represented "not concerned" and five was "very concerned." Listed below are the percent that listed their level of concern as either a four or a five. The margin of error for the survey is plus or minus 8 percent.



SOURCE: CMF&Z Public Relations

MARK MARTURELLO/THE REGISTER

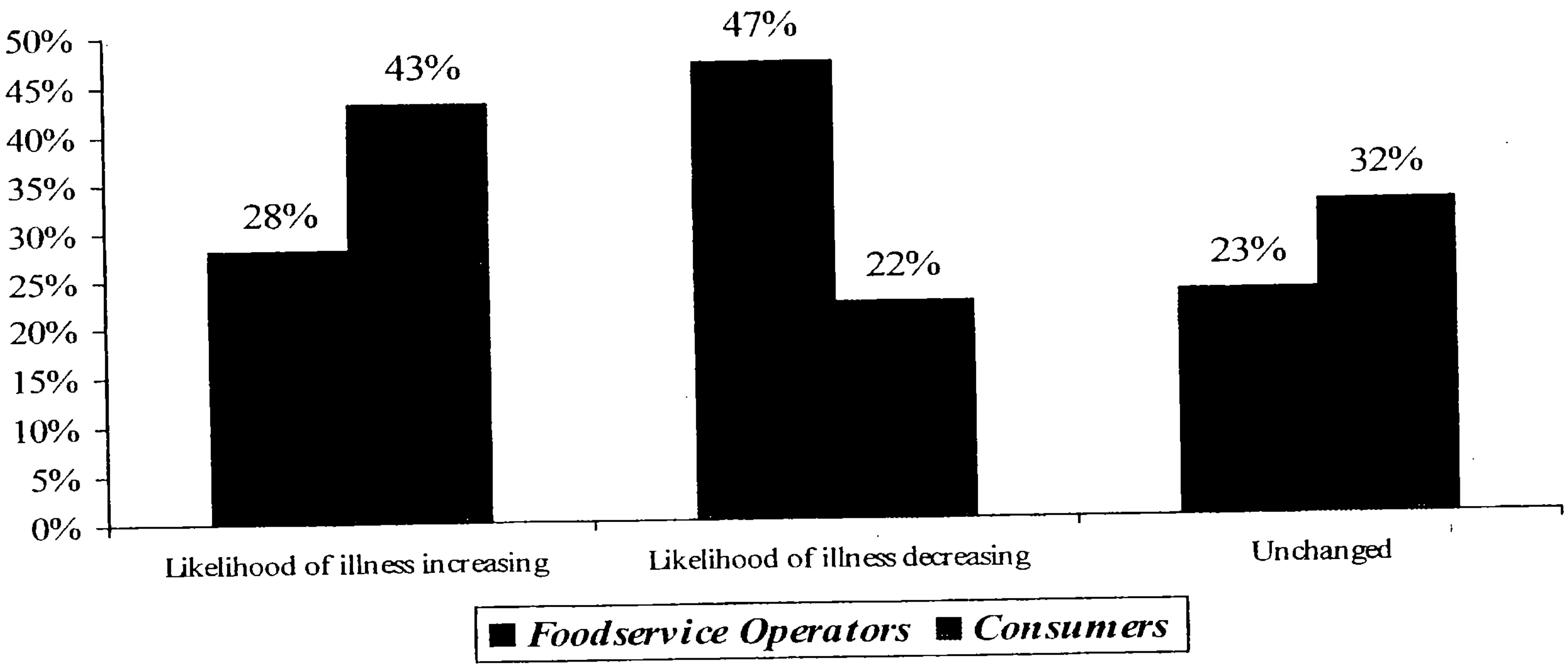
Agribusiness writer Anne Fitzgerald can be reached at (515) 284-8122 or fitzgeralda@news.dmreg.com

Under the Microscope: Food Safety Perceptions and Practices

Barbara Allelujka
Research Director
Food & Lodging Group
Cahners Business Information

RESTAURANTS AND INSTITUTIONS

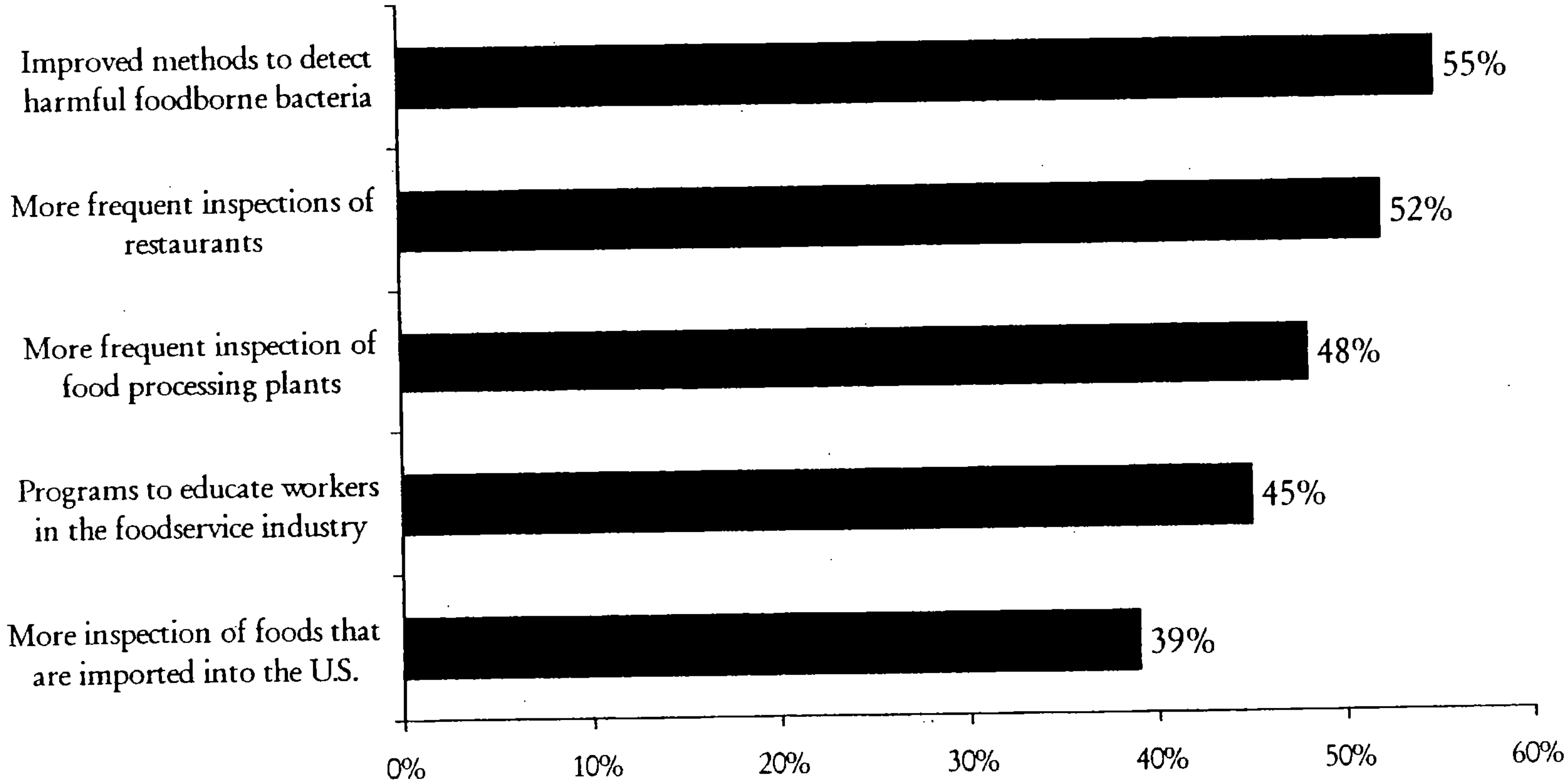
Perceived Likelihood of Contracting a Foodborne Illness from Food Prepared at a Restaurant/Foodservice Establishment*



*Compared to 5 years ago.

RESTAURANTS AND INSTITUTIONS

Consumer Opinions: Top 5 Initiatives That Definitely Will Increase Food Safety



Base: 738 consumers

RESTAURANTS AND INSTITUTIONS

Health Care

PUBLIC AGENDA ONLINE
The Journalist's Inside Source for Public Opinion and Policy Analysis

Survey Organization: Princeton Survey Research Associates
Sponsored by Kaiser Family Foundation, Harvard University

Question: To begin, please tell me how much government regulation you think is needed to protect consumers' interests in some different areas. In general, how much government regulation is needed to protect consumers' interests in the area of [INSERT ITEM]? Would you say a lot, some, very little, or none?

	A lot	[illegible]	Very little	[illegible]	Don't know
Food safety	64%	[illegible]	4%	[illegible]	2%
Airline safety	61%	[illegible]	5%	[illegible]	3%
Environmental hazards	57%	[illegible]	6%	[illegible]	3%
Health plans and health insurance	46%	[illegible]	9%	[illegible]	3%
Automobile safety	44%	[illegible]	9%	[illegible]	2%

Sample: 1,204 Adults
Methodology: Telephone Interview Conducted December 12-30, 1997
Asked of half sample
Margin or error for half sample +/- 4

Understanding the Issue:
Overview | Notable & Newsworthy | Fact File | Framing the Debate | Sources & Resources | Story Angles |

Public Opinion:
People's Chief Concerns | Major Proposals | Who Should Decide? | A Nation Divided? | Red Flags | Selection Criteria

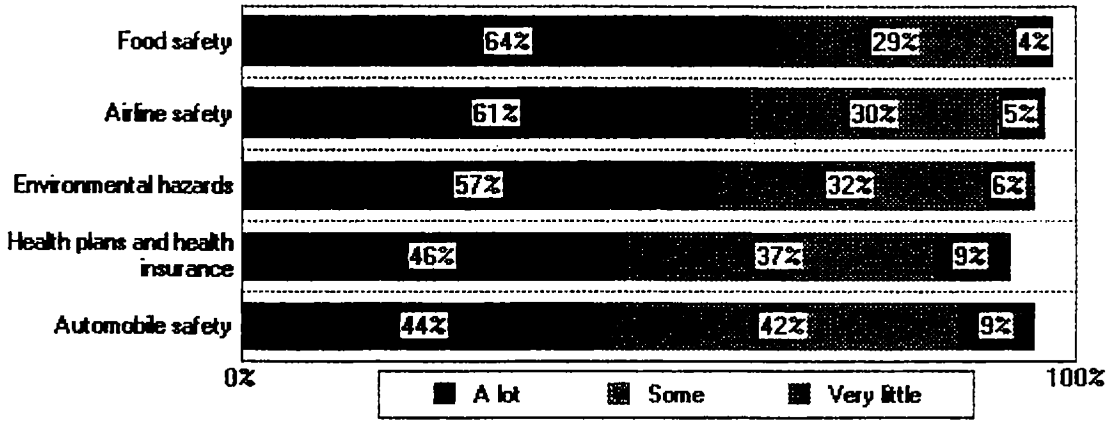
Health Care

PUBLIC AGENDA ONLINE
The Journalist's Inside Source for Public Opinion and Policy Analysis

Health Care: Red Flags

People are less likely to support extensive government regulation of health care than of some other major industries

Please tell me how much government regulation you think is needed to protect consumers' interests in some different areas.



Source: Princeton Survey/Kaiser/ Harvard 12/97

For more details

Contact Us

Trends in the United States

Consumer Attitudes & the Supermarket, 1999

Conducted for the Food Marketing Institute

By Research International USA

Price $35 Members
$90 Nonmembers
Multiple-copy discounts available

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Food Marketing Institute
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Washington, DC 20006

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TABLE 46

IMPORTANCE OF VARIOUS FACTORS IN FOOD SELECTION, 1990-1999

I'd like to start by reading a list of food related factors that may or may not be important when a person shops for food. For each factor please tell me whether it is very important, somewhat important, not too important or not at all important to you when you shop for food.

Base: 1,002 shoppers

	Very Important									Jan. 1999				
	Jan. 1990 %	Jan. 1991 %	Jan. 1992 %	Jan. 1993 %	Jan. 1994 %	Jan. 1995 %	Jan. 1996 %	Jan. 1997 %	Jan. 1998 %	Very Important %	Somewhat Important %	Not Too Important %	Not At All Important %	Not Sure %
Taste	88	90	89	91	90	90	88	87	89	92	7	1	1	*
Nutrition	75	75	77	75	76	74	78	77	76	70	25	4	1	*
Product safety	71	72	71	72	69	69	75	73	75	70	20	6	2	3
Price	66	71	75	74	70	69	66	66	64	63	30	5	1	*
Storability	43	43	46	45	41	41	43	44	45	42	35	15	5	3
Ease of preparation	33	34	36	37	34	35	36	37	37	35	45	14	6	1
Food preparation time	36	38	41	36	36	35	38	39	36	35	43	16	5	1
Product packaging that can be recycled	x	48	45	41	38	34	34	31	31	29	37	22	12	*

x Not asked.
* Less than 0.5 percent.
May not add to 100 percent due to rounding.

452-7431

Need cost 5 fruits/veggies

DRAFT

Costs of labeling imported meat

S. 617 would amend the Federal Meat Inspection Act (FMIA) to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin. Meat from animals imported less than 10 days prior to slaughter would also have to be labeled to identify the country of origin. Meat food products prepared in the United States using any carcass, part thereof, or meat imported into the United States would have to be labeled to identify the country of origin.

The current situation

In 1995, the United States imported 2.4 billion pounds of meat and poultry from 34 countries. FSIS reviews meat and poultry inspection systems in countries that export to the United States. FSIS also reinspects meat and poultry at port-of-entry before they are allowed into U.S. commerce. Because health certificates indicating the wholesomeness of the product and other documents accompany the meat, at the point of reinspection, all meat is identified by its country of origin. However, the country of origin identity is not preserved as the meat moves through the U.S. processing and distribution system.

Meat imports into the United States in 1996 totaled 2.764 billion pounds carcass weight or 1.985 billion pounds retail weight (table 1). Domestic consumption of meat in 1996 was 119.1 pounds per capita or about 31.616 billion pounds, retail basis. Assuming all imported meat is consumed within the United States, imported meats account for about 6.3 percent of domestic meat consumption.

Meat production from imported animals slaughtered with 10 days of arrival is estimated at 1.229 billion pounds, retail weight (table 2). Adding this quantity to amounts imported as meat gives total imported meat of 3.214 billion pounds, retail weight. Thus, using the concept of imported meat from the proposed amendment to the FMIA, imported meat accounted for 10.2 percent of domestic meat consumption in 1996. This assumes that no imported meat or meat from imported animals is exported.

Table 1--Meat imports, 1996

Meat	Carcass weight 1,000 pounds	Retail weight 1,000 pounds	Conversion factor
Beef and veal	2,072,173	1,440,160	.695
Lamb and mutton	72,452	64,483	.890
Pork	618,884	480,254	.776
Total	2,763,509	1,984,897	

Table 2--Live cattle and hog imports, 1996

Animal	Head	Retail weight 1,000 pounds	Conversion factor

Total cattle	1,965,448		
Feeder stock	74,293		
For slaughter	1,891,155	944,790	2.402
Total hogs	2,779,175		
Feeder stock	766,974		
For slaughter	2,012,201	284,075	1.70
Total	4,744,623	1,228,865	

Note: Feed stock number for cattle is only for imports from Canada. Because feeder stock cattle from other origins, primarily Mexico, have not been not accounted for, the number of cattle for slaughter is likely overstated. Imported cattle for slaughter are assumed to average 1,200 pounds live weight. Imported hogs for slaughter are assumed to average 240 pounds live weight. Conversion factors apply to live weight.

Analysis of costs

It is assumed that the intent of the proposed amendment to the FMIA is to require labeling of retail packages of raw and processed meat products, but not to require labeling on imported meat that is served for consumption in hotels, restaurants, and institutions. An unknown amount of imported meat is used in this later way. However, for purpose of analysis, and to present the likely range of costs, it is assumed that all imported meat is sold at retail establishments that would be required to label the packages with the country of origin of the meat.

Costs of the labeling requirement include

- Costs of preserving the country of origin identification of imported meat from the point of entry into the United States to the retail counter. Distributors and retailers would incur costs of marking shipments and segregating imported meat from domestic meat. Retailers or meat packaging firms would incur the costs of affixing the correct label on imported meats.

- Costs of preserving the country of origin of live imported animals and the meat derived from them through to the retail counter. Slaughter plants would incur costs to segregate imported animals in holding pens and to mark carcasses and parts of carcasses shipped to processors and retailers.

- FSIS enforcement costs to ensure compliance. FSIS has little presence in retail establishments. There were 24,557 supermarkets (annual sales of at least $3.469 million) in 1994. There were even more grocery stores and specialized food stores such as meat markets.

Costs of preserving Country of Origin of Imported Meat
Consider first the costs of affixing labels. USDA's analysis of the costs of applying safe food handling labels to meat and poultry provides a basis for estimating this cost (*Federal Register* November 4, 1993, pp. 58992-58934). It was estimated that the label cost for large retailers who

have efficient equipment that prints and affixes labels would be $0.00375 per package and that other retailers would have costs for labels averaging $0.01 per package. Large retailers were believed to account for 80 percent of the retail packages sold. The safe food handling analysis has an implied average retail package size for meat of about 3 pounds. Thus, the 3.214 billion pounds of imported meat and meat from imported animals equates to about 1.07 billion packages. The cost for labels is about $5,356,000 = ((1.07 bil.*.8*$.00375) + (1.07 bil.*.2*$0.01)). These label costs may be understated because the safe food handling label analysis dealt with the addition of a generic statement while country of origin labeling will require labels for each of the 34 countries exporting to the United States.

Large retailers are assumed to have equipment that simultaneously prints and affixes labels so they have no new recurring costs for applying labels. Other retailers will have recurring labor costs. The safe handling analysis estimated the recurring labor cost associated with the 20 percent of packages labeled by other retailers to be $3.2 million. Adjusting this figure for a smaller number of packages of imported meat (214.3 million) and increases in the employment cost index (1996/1993 of 1.083) gives a recurring labor cost of $371,368. This is just the labor cost involved in affixing labels.

There are other labor, material, and management costs for preserving the identify of imported meat prior to retail packaging. There is little empirical information from which to estimate these costs, but they could be large. Distributors and retailers might have to add separate cold storage rooms or use different trucks to carry domestic and imported product. Costs would depend on the number of shipments of meat and animals, the number businesses dealing in imported meat or animals, the penalties for noncompliance, the level of enforcement, and other factors.

Businesses handling imported meat and animals have little incentive to preserve the identity of imported meat unless it commands a market price premium over domestic meat or the penalties for noncompliance are larger than the potential savings from not labeling. If there is a premium for imported meat, e.g., Danish pork or New Zealand lamb, the industry will voluntarily label retail packages with the country of origin and will have an incentive to misbrand domestic meat as imported.

Costs of Preserving the Country of Origin of Imported Live Animals

Importers of live animals intended for slaughter would likely have costs for maintaining segregating holding pens to ensure that the country of origin is preserved. Batch processing of imported and domestic animals would avoid the need for separate pens but would involve added management costs. Slaughter plants would face costs to mark, tag, or otherwise identify carcasses or carcass parts to preserve the identity. Estimates of the costs of preserving the identity of imported animals cannot be estimated because we do not know what steps importers will take. Ear tags are a low cost system but once slaughter is initiated these tags are separated from the meat. Annual costs can be expected to run into the millions of dollars, because approximately 4 million animals are imported for slaughter every year.

Feeder stock animals--younger, lighter weight animals--are generally fed to higher weights and then slaughtered, but they can be slaughtered at any age. Depending on the enforcement policies adopted, importers might need to maintain the identity of imported feeder stock, for at least 10 days to establish that imported animals are not being slaughtered and their meat marketed without a country of origin label. Thus, importers of feeder stock would bear the costs of temporarily maintaining the identity of imports and postponing the commingling of anonymous animals.

FSIS Enforcement Costs

Enforcement costs could be very high. Costs will depend on the potential penalty for violations, incentives for noncompliance, and how strictly USDA pursues enforcement. USDA does not now have a routine presence in retail establishments. If USDA visited each retail establishment just 3 times a year, that would involve about 750,000 site visits. If the cost of a visit--labor time, travel costs, records, etc--is conservatively estimated at $100 a visit, the annual costs to taxpayers would be $75 million. This is a low estimate because USDA would also need to visit wholesalers, meat processors, and slaughter plants. Credible monitoring and enforcement could require hiring and training 1,000 additional staff years. Taxpayers at large would bear the costs of enforcement.

Other Costs

The analysis has assumed that meat from domestically produced and slaughtered animals would not be labeled. If it were necessary to label domestic meat, the costs for labels would increase by $87 million and the annual recurring costs for affixing the labels would increase by $6 million. It might be necessary to require labeling domestic meat if labeling foreign meat only were found to violate trade agreements.

Summary

The costs for labeling only imported meat include the following quantifiable costs: label costs, $5.4 million, recurring labor costs to affix labels, $0.4 million, enforcement costs, $75 million. Total quantified costs are $80.8 million per year. Other costs, which could be quite large, include the costs of maintaining the country of origin identity of imported meat and animals from the point of entry through to the retail sales case.

Food Safety

What will USDA's role be in supporting the new FDA guidelines (Good Manufacturing Practices and Good Agricultural Practice) for fresh fruit and vegetables?

USDA's role will be threefold:

1. USDA will accelerate the research outlined in the FY98 President's Food Safety Initiative, to develop intervention technologies to eliminate and/or reduce levels of pathogens.

2. USDA and FDA will develop and deliver research-based educational programs to food producers, processors, handlers, and consumers and assist in providing guidance and procedures to reduce or eliminate contaminants.

3. USDA, FDA, and CDC will develop new assessment procedures for imported foods and provide technical assistance to existing countries to improve the safety of their products.

What will USDA's role be in outreach and education for farmers?

USDA's network of agencies and programs that operate on a grassroots level, provides an effective, efficient and farmer-friendly interface for the development, delivery, and ultimate evaluation of appropriate Best Agricultural Practices for specific commodities on a regional or localized basis. Appropriate USDA-supported agencies with extensive farmer outreach capabilities include, but are not limited to, Cooperative Extensions, the network of Agricultural Service Centers, county and regional Farm Service Agency offices and local conservation districts.

How could USDA assist in monitoring and testing domestic and imported fruit?

USDA could expand the scope of its nationwide, statistically valid pesticide residue monitoring program for domestic and imported fresh fruits and vegetables, the Pesticide Data Program (PDP) , to develop a scientifically-sound microbiological surveillance program for foodborne pathogens and spoilage microflora on domestic and imported produce. (NOTE: This requires new funding and has not been approved.)

What additional actions will USDA take to build upon this Presidential Directive?

Today's directive builds on previous actions the Administration has taken to increase the safety of the nation's food supply. In addition, USDA will focus on a farm-to-table strategy to assess the risks of food contamination and to aid in the prevention of foodborne outbreaks for both domestically-produced and imported products.

Additional actions will build on the progress made in the 1998 Administration initiative. For example, our FY99 budget will continue our commitment to further expand the FoodNet sentinel site program, expand our educational and outreach efforts to improve awareness of food safety at the farm, retail or restaurant level, and enhance research and risk assessment.

How will USDA monitor potential food safety problems in exporting countries? (Assessing agricultural production, transportation, and processing practices in these countries)

USDA will work with FDA, CDC, and the exporting countries to develop profiles of exporting countries and evaluate the food production, transportation, and handling practices. These profiles will provide information that will target our inspection and testing resources to ensure that food being shipped to the United States is safe.

How will USDA assist exporting countries to develop good agricultural practices?

USDA will encourage the adoption of good practices abroad through technical assistance, training, and cooperative research efforts.

Food Safety!

Counterattack planned as germs spread in food

Americans get sick despite safest fare

By Lauran Neergaard A1
ASSOCIATED PRESS

Alfalfa sprouts contaminated by E. coli. Hepatitis-tainted strawberries in school lunches. Children sick from unpasteurized apple juice, and 140 persons struck by bacteria-laden raw oysters.

The recall of 25 million pounds of hamburger is merely the latest scare about dangerous germs contaminating Americans' food. Keeping hamburger safe mostly takes common sense: Cook meat thoroughly. But consumer advocates say a larger threat may come from germs lurking in unexpected places, such as raspberries or fresh basil, that slip through the government's patchwork of safety rules.

"Almost monthly we are seeing new causes for concern based on food problems," said Caroline Smith DeWaal of the Center for Science in the Public Interest. "We don't have a government system to fix those problems."

But the government and food makers are preparing to fight back. The Food and Drug Administration is considering putting warning labels on unpasteurized apple juices and ciders, perhaps this week, after dozens of children were sickened by E. coli that got into one trendy brand. Pasteurization kills potentially deadly E. coli bacteria.

Scientists are investigating whether irradiating beef could kill

see **FOOD,** *page A8*

FOOD

From page A1

E. coli and other disease-causing microorganisms and whether irradiating fresh berries would kill cyclospora, a parasite that sickened about 1,400 Americans who ate Guatemalan raspberries this spring.

Manufacturers are beginning to advertise to consumers that they have adopted a safety program called HAACP — an ungainly acronym that means companies check for contamination repeatedly as ingredients move from harvest to grocery store.

"How many hurdles can we put in the way of bugs so we reduce the risk? We're not going to be able to go to zero," said Dane Bernard of the National Food Processors Association.

The latest scare comes after 16 Colorado residents were infected with E. coli linked to hamburgers processed by Hudson Foods Inc. The Agriculture Department says an outside slaughterhouse likely was the source, but Hudson recalled 25 million pounds of hamburger after investigators discovered the company used leftover raw meat from one day in the next day's production, potentially causing a chain of contamination.

Although the U.S. food supply is considered the world's safest, about 9,000 Americans die every year from food poisoning. A new Centers for Disease Control and Prevention study says 6 million to 80 million Americans are sickened each year; a good count isn't possible because many mild cases go unreported.

The easiest protection is good hygiene, said FDA food-safety chief Janice Oliver. She's amazed by people who say they had no idea fruits and vegetables should be washed before eating.

The new CDC study says the biggest food poisoner — a bug called campylobacterium that lurks in unpasteurized milk and raw poultry — particularly strikes young men with "poor food preparation skills." In other words, they don't wash their hands between putting raw poultry on the grill and setting the table.

The biggest food poisoner particularly strikes young men with "poor food preparation skills."

Then there are raw oysters, which every year sicken hundreds of Americans. Cooking oysters kills the bacteria, but aficionados say that just isn't the same. On Friday, the FDA warned that 140 persons in Canada, California and Washington had been sickened, and shipments of live oysters from northern Pacific waters were stopped.

But thorough cooking and cleaning only help so much. The Clinton administration has asked Congress for $43 million to begin, in October, hiring more food inspectors and researching better poisoning prevention.

The best protection, the CDC's Dr. Mitchell Cohen says, is to rapidly identify an outbreak's cause and set up steps to keep that contamination from happening again. That happened in the Hudson recall, when Colorado — one of a handful of states capable of using DNA to "fingerprint" food poisonings — discovered 15 patients with the same E. coli strain. The bacteria matched those in a sample of Hudson beef from one patient's freezer.

Produce growers are searching for more hygienic ways to grow everything from lettuce to alfalfa sprouts, both of which have sickened Americans with E. coli. To prevent another outbreak, officials need to know if something as simple as using manure as fertilizer — common among organic growers — was to blame.

But some foods may simply be too hazardous to allow in this country, consumer advocate DeWaal says. She points to frozen strawberries that gave about 150 Michigan schoolchildren hepatitis A in the spring.

The Washington Times
TUESDAY, AUGUST 26, 1997

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Jimmy Wyatt?

Food Safety

Q&A on the Safety of Imported Food
September 25, 1997

Q: I have young children and I am worried about the safety of the food I buy for them. I am especially concerned about the stories I have read about the outbreaks of foodborne disease linked to imported food. Is food produced in the United States safer than imported food?

A: Both U.S. and foreign produced food are extremely safe. In fact, our nation's food supply today is probably the safest it has ever been, and we are working to make it even safer. During the last four and half years the Clinton Administration has taken a number of steps to further improve the safety of the food we eat. With the help of the Vice-President's National Performance Review, we have fundamentally enhanced the way we ensure the safety of meat, poultry, and seafood. We put in place important new protections against the risks of pesticides in our food, especially for our children. And Congress has recently agreed to provide most of the $43 million the President requested to improve food safety and beginning next month we will be using that money to further reduce the incidence of foodborne illness.

In rare cases, however, food produced either here or abroad has caused an outbreak of foodborne illness. We are committed to taking additional steps to further ensure that all of our food is safe whether domestic or imported.

Q: It seems like we are hearing about more outbreaks of foodborne illness. Are we experiencing an increase in the number of outbreaks of foodborne disease?

A: Even though our food supply is among the safest in the world, each year there are still millions of Americans who get sick from the food they eat. The overwhelming majority of these cases are what is known as sporadic illnesses. These illnesses are individual cases not related to one another and are not caused by a single, specific contaminated food. An "outbreak" of foodborne disease is when many people become sick from being exposed to the same source of contaminated food.

As a result of new steps we have taken over the last four years, we are doing a more thorough job looking for outbreaks than we have ever done before. Experts we have consulted say that our improved surveillance is one of the primary reasons we are hearing about more food-related illnesses. We our catching and quickly responding to outbreaks of foodborne illness that we often missed in the past.

with exporting countries to improve the safety of imported fruits and vegetables.

5. **Expanded Federal Resources for Testing and Inspecting Fruits and Vegetables.** The Administration supports federal legislation to expand FDA's ability to test and inspect fruits and vegetables, both domestically and overseas. The Administration also supports an appropriation to expand USDA's testing program to include microbial pathogens like E. Coli.

6. **Accelerated Food Safety Research**. The President emphasized the need to expand and accelerate research efforts in order to develop faster and better tests to identify pathogens on food products and to develop effective tools to prevent contamination from occurring.

Food Safety

only 30 percent. That period also saw a contraction of 85 percent in farms producing eggs. 40 percent in cattle feeding operations and 35 percent in broiler operations. It also details the shifts in hog production into the Southeast, milk production to the West and cattle feeding from the Corn Belt to the Great Plains despite relative feed cost disadvantages.

Perhaps most significant are the conclusions that "economic incentives for continued structural change in livestock production appear to be significant" and that "forces outside of agriculture are likely to have an increasingly important role in determining the direction of change." The big one, of course, is what author William D. McBride calls the concern about how higher concentration of animal waste affects the environment -- emphasized this month by North Carolina's legislative moratorium on new hog confinement operations and a warning by Maryland's governor in the wake of massive fish kills in Chesapeake Bay rivers that poultry farmers can expect tighter regulation.

"Industrialization" of the pork industry may mean lower prices and higher quality pork because of lower production costs, more efficient processing and greater control over hog quality, says another report analyzing pork industry changes. *Vertical Coordination and Consumer Welfare* suggests future consolidation and vertical coordination may be altered not only by environmental worries but also by concerns about market power. Author Steve W. Martinez and his colleagues describe in detail how supply and quality needs create pressure for contracting and integration and how legislative decisions could influence the trend.

Rounding out this reading list is last June's report suggesting the food chain "may be increasingly dominated by firms exercising control over several stages of food production." *From Farmers to Consumers* says greater contract production and vertical integration across agriculture is due to more discriminating buyers and new technology. Demographic change and demand for convenience also contribute. ERS suggests the rend will see more defined raw commodities, such as chicken of specific weight and size or corn with specific protein content. Although farmers relinquish some control over decision-making in many contract arrangements, they are compensated through quality premiums and reduced uncertainty.

The three reports, available from ERS-NASS Publications at (800) 999-6779, are:
Vertical Coordination and Consumer Welfare: The Case of the Pork Industry, AER-753, August 1997
Change in U.S. Livestock Production, 1969-92, AER-754, August 1997.
From Farmers to Consumers: Vertical Coordination in the Food Industry, AIB-720, June 1996

Fissure in Farm Front: Food, Agriculture Not United on Fast Track

Even as a coalition of 11 producer groups and 28 agribusiness firms and associations gathered here to support a White House bid to renew fast-track trade negotiating authority, cracks appeared in what is normally a united front of mainstream agriculture. Support was most enthusiastic from Farmland Industries, the National Pork Producers Council, National Cattlemen's Beef Association, American Soybean Association and National Corn Growers Association. But distinguished by their absence from a table where they usually have a prominent place were the American Farm Bureau Federation, National Council of Farmer Cooperatives, American Sugar Alliance and the National Association of Wheat Growers.

Perhaps even more significant, from a political standpoint, is lack of support by most farm groups in California -- many of whom are traditional backers of and beneficiaries from expanded trade -- and Florida fruit and vegetable producers. The stance of the two states' agricultural sectors could be pivotal to the congressional decision; the two elect nearly one of

Hearing Scheduled on USDA Bid for Meat Recall Authority

The Senate Agriculture Committee will hear testimony Oct. 7 on USDA's request for authority to order recalls of tainted meat. Chairman Richard Lugar, R-Ind., expressed initial skepticism but is believed to have an open mind. USDA submitted a draft bill to require meat recalls and give it authority to impose fines up to $100,000 per day per violation.

every six members of the House -- California 52 and Florida 23 of 435. Florida's opposition is outright -- derived from competition by vegetables from Mexico and fear of increased imports of orange juice concentrate from Brazil -- the California position and that of the American Farm Bureau are regarded as tactical. Part appears designed to apply pressure to keep labor and environmental standards out of trade talks, part to seek redress of existing trade complaints.

A new California Agriculture Industry Coalition, consisting of 27 farm groups and cooperatives, said it would withheld support of new trade agreements until existing disputes were resolved. Farm Bureau seeks specific commitments for tariff equalization, increased market access, resolving sanitary and phytosanitary disputes on the basis of sound science and improving dispute resolution procedures. Other major trade developments this month:

Dairy Complaint Against Canada: A united U.S. dairy industry filed a petition challenging Canada's dairy export pricing. National Milk Producers Federation, International Dairy Foods Association and U.S. Dairy Export Council asked the U.S. Trade Representative to take the complaint to the World Trade Organization. USTR has 45 days to respond to the petition but it's likely to agree. WTO procedures would force a decision by mid-1998. The three organizations say Canada is using its export price pooling scheme to exceed export subsidy limits it had agreed to accept. The lower export price is like a plan advanced unsuccessfully by U.S. dairy co-ops in the past and NMPF's Ed Coughlin said the idea would come up again in Washington if the WTO challenge should fail to make the Canadian plan illegal.

Mexican Sugar, Apple Tariffs Face Challenges: USTR has requested WTO consultations about Mexico's anti-dumping investigation of U.S. high fructose corn syrup (HFCS) because they "appear inconsistent with its obligations under the WTO agreement." Mexico's sugar industry filed a petition against imports of U.S. corn sweetener in January and the government imposed provision tariffs in June. Chairman Bob Smith, R-Ore., of the House Agriculture Committee is protesting Mexico's 101.1% import duty on U.S. apples. With $40 million in sales last year, Mexico is the leading market for U.S. apples.

A Challenge to EU Rule: The administration appears deadly serious in its opposition to a European Union rule that would ban imports of beef tallow and its derivatives beginning in January 1998 in an attempt to prevent the spread of bovine spongiform encephalopathy (BSE). The United States insists it be exempt from the ban because BSE has never been found in U.S. cattle. U.S. exports of tallow amount to more than $100 million a year but products made from tallow -- cosmetics, soap and pharmaceuticals -- run into the billions of dollars. U.S. officials argue that the ban would be struck down under WTO rules because it has no scientific basis.

Food Safety

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: Edits on Directive, 1 pager + new USDA Q+A. I'll be in a mtg from 1-3. If you need me, you can call 720-7813. You should call Cathie Woteki - 720-0350 or Joan Mondshein, 720-4150, if you need assistance.

Thanks.

Also sending to FDA

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

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

During my Administration, we have taken significant steps to strengthen our entire food safety system, including expanded research, education, and surveillance activities. We also have put into place enhanced safety standards relating particularly to meat, poultry, and seafood products. These measures ~~are~~ will greatly improv~~ing~~e the safety of the nation's food supply.

no data to support must change

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, particularly with respect to produce imported from foreign countries. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that these fruits and vegetables are ~~produced under safety systems equivalent to~~ as safe as those ~~existing~~ produced in the United States, ~~at the same time that~~ especially as we upgrade our own domestic standards.

changes are necessary to address national treatment issue as it relates to voluntary guidance

As you know, I am introducing legislation in Congress that will help accomplish this task. This legislation will authorize 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 authority~~, which is equivalent to~~ authority the USDA now has to halt the importation of ~~meat and poultry~~ food products, will enable the FDA to prevent the importation of potentially unsafe foreign ~~produce~~. In addition, I will provide the necessary funds in my Fiscal Year 1999 budget to enable the FDA to expand dramatically its international inspection force. With this greatly increased ability to inspect food safety conditions abroad and at our ports of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries. need both

At the same time, I direct you to take administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce. You should accelerate whatever food safety research is necessary to support these actions.

First, I direct the Secretary of Health and Human Services~~, in partnership with the~~ and the Secretary of Agriculture to report back to me within 90 days with a plan on how to improve the use of existing and projected resources to monitor agricultural and manufacturing practices abroad, assist foreign countries to improve those practices, and 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 resources toward those areas where problems are most likely to occur.

Second, 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

must delete
will help domestically

within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should ~~address such matters as sanitation, worker health, and water use, should~~ take into account differences in both crops and regions, and should address potential food safety problems throughout the food distribution and marketing 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~~, foreign and domestic,~~ 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.

These steps, taken together and in coordination with the legislation I will send to Congress, will ~~ensure to the fullest extent possible~~ improve the safety of fruits and vegetables for all Americans. I will also direct the Administrator of the Environmental Protection Agency and the Secretary of Labor to provide you with assistance in achieving this goal.

Delete

Raises national treatment issue

Initiative to Safeguard Imported Foods
Summary of Initiative

The Clinton Administration proposes to increase assurances that all foods, from farm to table, and including imported foods, meet high standards of safety. As we recognize the increasing complexity of food systems, from domestic to international, from production to retail and food service, and the gaps in our knowledge about foodborne illness outbreaks, their causes and sources, we need to take the appropriate steps to maintain the safety of our food supply. Therefore, the Administration is proposing the following steps.

be based on scientifically known risks of contamination throughout the food production and distribution system such as

Guidance for Fresh Fruits and Vegetables

FDA will develop "Guidance to Minimize Microbial Food Safety Risks for Fruits and Vegetables" in collaboration with USDA and with the food industry. This guidance will include ~~such issues as~~ sanitation in ~~harvesting and production facilities, transportation~~ and, water quality, ~~and worker health and safety~~. FDA and USDA will convene a public meetings to discuss guidance concepts by mid-November 1997. Information from the public meetings will be used to publish this guidance for all fresh fruits and vegetables by January 1, 1998. Working with USDA and the food industry, FDA will publish good agricultural practices (GAPs) and good manufacturing practices (GMPs) guidance by the end of 1998 that will build on the broader guidance ~~and be further tailored to apply specifically to each of four to eight produce categories (representing a significant proportion of the fresh produce consumed annually in the United States)~~.

beginning in

series of

NO

Enhanced FDA Oversight Authority for Imported Foods

where necessary,

The Administration will propose legislation to enable FDA to ensure that no food may be imported into the United States unless it is produced under a system that provides the same level of public-health protection provided by the U.S. food-safety system. (USDA already has such authority for ensuring the safety of imported meat and poultry.) ~~In addition, legislation will be proposed that will allow FDA to refuse importation of a food that comes from a facility that refused to permit FDA inspection.~~ USDA ~~and FDA~~ will develop country profiles assessing the food production, transportation, and handling practices in place in foreign countries. USDA and FDA will also encourage the adoption of good practices overseas through technical assistance, training, and cooperative research efforts. The agencies will target these activities and assistance to suppliers of products being shipped to the United States.

Raises serious domestic issue re: national treatment

new ~~paper~~ In coordination with international agencies (AID e.g.) and organizations, FDA, CDC, and USDA

New Resources to Oversee Imported Foods

The Administration will ask Congress to appropriate new funding, beginning in FY'99, to implement these initiatives. These funds will allow the federal agencies responsible for food safety to carry out such activities as hiring of new FDA inspectors to inspect foreign food producers and to inspect food imported into this country, ~~and~~ to carry out research to develop methods to detect and prevent disease-causing pathogens in food, and to improve our knowledge of pathogens on fruits and vegetables through statistically-designed sampling of domestic and imported products.

Report to the President

FDA and USDA will report back to the President by October 1, 1998, with a status report on progress toward the establishment of guidance to minimize microbial food-safety risks for fruits and vegetables, the legislation to enhance FDA's authority to keep unsafe foods out of the United States, and the testing, research, education, outreach and any other actions needed to implement this initiative. For example, this report will detail needs for better understanding of how food becomes contaminated--at every point in its production and distribution--and our needs for better scientific methods to more rapidly identify and eliminate pathogens from our food supply.

?

How does this track w/ 90 report in directive?

What will USDA's role be in developing and supporting the new FDA guidelines (Good Manufacturing Practices and Good Agricultural Practice) for fresh fruit and vegetables?

USDA will work in partnership with FDA and the agricultural community in developing the guidelines. USDA has a wide range of scientific and agricultural expertise in agencies like the extension service, the natural resource conservation service, and the agricultural research service, that will help to make the guidance as effective as possible.

In addition,

1. USDA will accelerate the research outlined in the FY98 President's Food Safety Initiative, to develop new technologies to more rapidly identify and eliminate or reduce levels of pathogens.

2. USDA and FDA will develop and deliver research-based educational programs to food producers, processors, handlers, and consumers and assist in providing guidance and procedures to reduce or eliminate contaminants.

3. USDA, FDA, and CDC will develop new assessment procedures for imported foods and provide technical assistance to existing countries where necessary to improve the safety of their products.

What will USDA's role be in outreach and education for farmers?

USDA's network of agencies and programs that operate on a grassroots level, provides an effective, efficient and farmer-friendly interface for the development, delivery, and ultimate evaluation of appropriate Best Agricultural Practices for specific commodities on a regional or localized basis. Appropriate USDA-supported agencies with extensive farmer outreach capabilities include, but are not limited to, Cooperative Extension, the network of Agricultural Service Centers, county and regional Farm Service Agency offices and local conservation districts.

How could USDA assist in monitoring and testing domestic and imported fruit?

USDA could expand the scope of its nationwide, statistically valid pesticide residue monitoring program for domestic and imported fresh fruits and vegetables, the Pesticide Data Program (PDP) , to develop a scientifically-sound microbiological surveillance program for foodborne pathogens and spoilage microflora on domestic and imported produce. (NOTE: This requires new funding and has not been approved.)

What additional actions will USDA take to build upon this Presidential Directive?

Today's directive builds on previous actions the Administration has taken to increase the safety of the nation's food supply. In addition, USDA will focus on a farm-to-table strategy to assess the risks of food contamination and to aid in the prevention of foodborne outbreaks for both domestically-produced and imported products.

Additional actions will build on the progress made in the 1998 Administration initiative. For example, our FY99 budget will continue our commitment to further expand the FoodNet sentinel site program, expand our educational and outreach efforts to improve awareness of food safety at the farm, retail or restaurant level, and enhance research and risk assessment.

How will USDA monitor potential food safety problems in exporting countries? (Assessing agricultural production, transportation, and processing practices in these countries)

USDA will work with FDA, CDC, and the exporting countries to develop profiles of exporting countries and evaluate the food production, transportation, and handling practices. These profiles will provide information that will target our inspection and testing resources to ensure that food being shipped to the United States is safe.

How will USDA assist exporting countries to develop good agricultural practices?

USDA will encourage the adoption of good practices abroad through technical assistance, training, and cooperative research efforts.

Foodsafty

ENSURING THE SAFETY OF IMPORTED FOODS

Are Imported Foods Safe to Eat?

- At a time when the Congress is considering legislation that would renew presidential authority to negotiate trade agreements that would increase U.S. access to foreign agricultural markets, concerns about the safety of imported foods are being expressed.

- The food safety standards that apply to domestically produced foods also apply to imported foods. For example, the U.S. standards, or "tolerances," for permissible levels of pesticide residues in foods also apply to imported foods.

- The Centers for Disease Control and Prevention (CDC) reports that, while foodborne illnesses associated with imported foods may be different than those associated with domestic products, the overall risks to consumers appear, in general, to be similar for both imported and domestic foods.

- The President's Food Safety Initiative announced earlier this year includes many activities to strengthen the programs already in place to help ensure the safety of both domestic and imported foods.

What Are The Benefits to the United States of Agricultural Trade?

- The U.S. economy benefits greatly from agricultural trade. Agriculture has consistently shown a trade surplus, every year since 1960. U.S. agricultural exports support almost 1 million jobs.

- Fruits and vegetables are an essential component of a healthy diet, and agricultural trade helps make available to Americans a variety of fresh fruits and vegetables throughout the year.

What Action is the U.S. Government Taking To Improve Food Safety?

- As announced last summer by President Clinton, surveillance and sentinel site activities designed to detect food-borne illness before it spreads are being enhanced as part of the Administration's Food Safety Initiative.

- The initiative includes the development of a new early warning system by Federal, State, and local governments to help detect outbreaks of food-borne illness earlier and allow the regulatory network to respond more quickly. Actions would include stopping shipments at the border and increasing the frequency of testing of imported meat and poultry products.

- The Food Safety Initiative includes risk assessment and research on better detection methods for foodborne pathogens and toxins.

- U.S. food safety agencies continually gather and evaluate information from around the world on potential sources of food-borne illness to prevent entry of suspect foods into the United States.

- When this intelligence indicates a possible problem with an imported food from a given country, the Federal Government increases the monitoring of that food at border checkpoints and takes other action to prevent distribution of the food within the United States. When necessary, the Federal Government will work with the exporting country to address the underlying problems.

- The Federal Government maintains strong research and surveillance activities intended to identify emerging food-borne hazards.

What Are The Federal Government's Food Safety Programs with Regard To Imports?

- With regard to meat and poultry products specifically, the Federal inspection laws require countries that export meat or poultry to the United States to impose inspection requirements equivalent to U.S. requirements.

- Countries exporting meat or poultry to the United States undergo a rigorous review of their infrastructure and programs to gain eligibility to export meat or poultry to the United States.

- The United States evaluates a foreign country's controls on livestock and poultry slaughter and processing establishments in specific areas of risk: animal diseases, residues, contamination, food processing, economic fraud, and labeling.

- In July 1996, a final rule on pathogen reduction and Hazard Analysis and Critical Control Point (HACCP) systems for meat and poultry plants was published.

- In January 1997, the first two components of a new food safety system for meat and poultry became mandatory:

--All domestic meat and poultry plants and foreign meat and poultry plants exporting to the United States are required to adopt and follow written standard operating procedures (SOP) for sanitation to reduce the likelihood of harmful contamination or adulteration of products.

--All domestic and foreign meat and poultry slaughter plants that produce carcasses used in products exported to the United States will be required to conduct microbial testing for generic *E. coli*, to verify that controls on processing are working.

SAFETY OF IMPORTED FOODS

- All domestic meat and poultry plants and those foreign meat and poultry plants exporting to the United States are required to implement HACCP by January 2000.

- In December 1995, the United States government published a final rule requiring HACCP programs at seafood processing plants. That requirement will go into effect on December 18, 1997. HACCP programs will be required at all domestic and foreign seafood processing plants shipping products into the United States.

- The United States regulatory agencies are working with their foreign counterparts to increase the number of international cooperative agreements. Under these agreements, regulatory agencies in each country ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.

- U.S. laws require food agencies to go through a public notice and comment process before finding another country's system equivalent.

How Does The North America Free Trade Agreement Assure The Safety Of Our Food Supply?

- U.S. food safety officials hold leadership positions on committees of the North American Free Trade Agreement (NAFTA).

- NAFTA did not change the requirement that imported foods comply with the same food safety standards as domestically produced food. Indeed the ability of countries to preserve safety requirements is explicitly protected.

- In fact, NAFTA provides a framework for increasing the likelihood that food produced in other countries meet U.S. standards.

- For example, under NAFTA, technical working groups have been established to address specific food safety issues, such as microbial contaminants, pesticides and chemical contaminants, for specific food groups such as fruits, vegetables, dairy products, and seafood.

- Through the technical working groups, the three countries share information about their pesticide regulatory systems and are working to coordinate the systems more closely.

- U. S., Canadian, and Mexican officials work together along the borders to monitor food shipments and, if necessary, to stop suspect shipments. This cooperation has resulted in a decrease in the number of detentions of food shipments from Canada and Mexico.

- The United States, Canada, and Mexico have established a technical cooperative initiative to promote staff exchanges and the sharing of information among the three countries.

- In the case of Mexico, the United States is providing information and technical assistance to the Mexican Government and groups of Mexican growers to help that country meet U.S. safety standards for foods intended for export to the United States.

How Will New Trade Agreements Assure The Safety Of Imported Foods?

- U.S. representatives have leadership positions in the international organizations charged with ensuring the safety of food produced around the world.

- U.S. food safety officials frequently meet with their counterparts in foreign governments to evaluate and discuss emerging food safety issues. The bilateral meetings take place routinely--independent of any specific trade agreements or discussions--to develop programs to control microbiological and chemical contaminants in foods.

- The United States participates in the Sanitary and Phytosanitary Committee of the World Trade Organization (WTO) on food safety issues. The U.S. participation ensures that U.S. food safety standards are emphasized and not compromised in the interest of facilitating trade.

- The United States participates in all committees of the Codex Alimentarius Commission, an international food standard-setting forum created in 1962 under the sponsorship of the WHO and the Food and Agriculture Organization of the United Nations.

- U.S. participation in Codex ensures that the views of the United States on critical food safety issues will be addressed in the development of all international food standards.

- In summary, the U.S. government's international activities help to raise the global standards for food safety.

Food Safty

DRAFT

What Will Be The Followup To This Directive?

USDA and FDA will report back to the President. Also, additional actions will be developed to build on this initiative. For example, in addition to farmers and food processors, we may need to develop action plans to address food safety concerns regarding transportation and handling of fruits and vegetables. We will also expand the FoodNet sentinel site program, and educational and outreach efforts to improve awareness of food safety at supermarkets, restaurants, and in homes.

Will Additional Legislation Be Needed?

Currently USDA and FDA are evaluating the need for additional legislation. Imports already must meet U.S. safety standards. What is needed most urgently are the resources to tackle this problem.

OPTIONAL FORM 99 (7-90)

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DRAFT

What exactly are Good Agricultural and Manufacturing Practices?

Good Agricultural and Manufacturing Practices are those which minimize the occurrence of foodborne disease by identifying points in the food production, delivery, and preparation process where harmful pathogens may be introduced. Many food producer and manufacturer groups have taken a leadership role in developing processes and procedures aimed at reducing these harmful pathogens in America's food supply. USDA and FDA will continue to support these industry efforts while working cooperatively with farmers and food manufacturers to develop better, quicker, and more accurate methods of preventing and ridding fresh fruits and vegetables of these adulterants.

Are Fruits and Vegetables Safe?

Fruits and vegetables certainly are safe and a key part of a healthful diet. Yet, recent occurrences of foodborne illness traceable to fruits and vegetables demand a redoubled effort to make America's food supply even safer. The difficulty is that food safety experts do not know exactly where or how the contamination occurs. It could be at any number of places between the growing and the consuming of food, including harvesting, transportation, packaging, distribution, retail display, and commercial or at-home preparation.

Are Imports Less Safe Than Domestic Product?

According to available data, we just don't know. However, this initiative is about making both domestic and imported product even safer. In cooperation with exporting countries, USDA and FDA will develop profiles of food production, transportation, and handling practices there. These profiles will give us information that we can use to target our inspection and testing resources to ensure that we are not importing unsafe food from those countries. It also will allow us to help exporting countries develop their own best practices for food safety.

Will This Initiative Require More Federal Resources?

USDA will ask for additional resources to expand the nationwide sampling program for pesticide residue on domestic and imported fruits and vegetables. It will be increased to include microbial pathogens such as E.coli. FDA will seek additional resources to test and inspect fruits and vegetables, including at country of origin.

Where Does Research Fit In?

We need more knowledge and tools to improve food safety. We don't know exactly how certain harmful pathogens show up in meat or on different fruits and vegetables. We need better, more rapid tests to identify these pathogens before they enter the retail food chain. And, we need to develop the methods and equipment to prevent this contamination from occurring.

A fundamental part of the Administration's 1998 initiative involved research. We need to accelerate food safety research in FY 98 and build on that effort in our FY 99 budget.

Food Safety

Total Pages: ____

LRM ID: ACP163

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

Thursday, August 28, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Ronald K. Peterson (for) Assistant Director for Legislative Reference
OMB CONTACT: Alison C. Perkins
PHONE: (202)395-3857 FAX: (202)395-5691

SUBJECT: **AGRICULTURE Draft Bill on Meat and Poultry Enforcement Enhancement Act of 1997**

DEADLINE: **10 am Tuesday, September 2, 1997**

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: **The attached USDA legislative proposal, which has been cleared by OMB for transmittal to Congress, is essentially the same as earlier cleared legislation. We anticipate that USDA will transmit the proposal to Congress by no later than the middle of next week. Please be aware that we will also circulate for comment, probably tomorrow morning, an HHS draft bill that would provide similar authorities, as appropriate, for the FDA.**

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LRM ID: ACP163 **SUBJECT:** AGRICULTURE Draft Bill on Meat and Poultry Enforcement Enhancement Act of 1997

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Alison C. Perkins Phone: 395-3857 Fax: 395-5691
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-6194

FROM: ______________ (Date)
______________ (Name)
______________ (Agency)
______________ (Telephone)

The following is the reponse of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: ______________

_____ FAX RETURN of _____ pages, attached to this reponse sheet

Honorable Albert Gore
President of the Senate
Washington, D. C. 20510

Dear Mr. President:

In order to protect the public from foodborne illness or death from meat products contaminated with *E. coli* O157:H7, the Department of Agriculture (USDA) has recently initiated the largest food recall in American history. This recall incident highlighted critical gaps in USDA's food safety enforcement authorities. Congressional action is required to provide the additional authorities the Secretary needs to ensure food safety.

Today, I am transmitting to Congress a draft bill to improve public health and food safety by providing USDA with enhanced enforcement powers. This draft bill is an important part of the Clinton Administration's initiative to improve food safety for American consumers. The Administration recommends that the draft bill be promptly enacted.

The draft bill would give the Secretary of Agriculture a more complete range of enforcement tools with which to protect the public health. The bill would amend the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by adding three new enforcement sections providing for mandatory recall of meat and poultry products, more explicit authority to refuse or withdraw inspection, and the power to assess civil monetary penalties.

Specifically, the bill authorizes the Secretary of Agriculture:

- to stop the distribution and order the recall of adulterated or misbranded meat and poultry in situations that pose a reasonable probability of a threat to public health;
- to refuse or withdraw inspection based on any willful or repeated violation of the FMIA or the PPIA; and
- to impose civil monetary penalties for violations of the FMIA and the PPIA.

Although the recent recall was done at the Department's request, compliance with that request was voluntary. Until the Department has mandatory authority to require the recall of products at any point in the production and distribution chain, establishments and others can refuse to comply. Such mandatory recall authority would enable the Secretary to move more quickly to stop the distribution of adulterated products and to protect the public from food products contaminated with dangerous bacteria like *E. coli* O157:H7.

In addition, this legislation would provide the Secretary the authority to refuse or withdraw inspection when a company has either willfully or repeatedly violated USDA laws or regulations.

Finally, the legislation would give the Secretary the authority to impose civil penalties for violations of the FMIA or the PPIA. Currently, USDA is limited to seeking criminal penalties in the Federal courts. Civil penalty authority will better protect public health and improve food safety by providing a more timely and effective remedy against those who violate USDA meat and poultry laws.

The January 1993 outbreak of *E. coli O157:H7* in Washington State affected more than 700 people and resulted in four deaths. That outbreak was a tragic reminder of the potential consequences of illness due to foodborne pathogens. Since then, the Clinton Administration has taken aggressive steps to improve food safety, by implementing science-based inspection systems for meat, poultry, and seafood and by expanding foodborne illness surveillance. Additionally, the Administration's Food Safety Initiative contained in the 1998 budget proposes a comprehensive strategy for enhancing food safety. The Administration's efforts over the past four years to improve food safety contributed significantly to the successful containment of the recent outbreak.

The Clinton Administration has made great progress in improving food safety, but more work remains to be done. We look forward to working with Congress to achieve this critical goal.

The Office of Management and Budget advises that there is no objection to the presentation of this proposed legislation from the standpoint of the Administration's program.

A similar letter is being sent to the Speaker of the House.

Sincerely,

DAN GLICKMAN
Secretary

Draft 8/28/97 9am

A BILL

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

Be it enacted by the Senate and the House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "The Food Safety Enforcement Enhancement Act of 1997."

SEC. 2. The Federal Meat Inspection Act (21 U.S.C. 601, et seq.) is amended:

(1) by redesignating section 411 as section 414, and

(2) by inserting after section 410 the following new sections:

NOTIFICATION AND RECALL

"SEC. 411 (a) Any person, firm, or corporation which has a reasonable basis for believing that any carcasses, parts thereof, meat, or meat food products are adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such articles.

"(b) (1) If the Secretary finds, upon such notification or otherwise, that (A) any carcasses, parts thereof, meat, or meat food products are adulterated or misbranded and (B) there is a reasonable probability that human consumption of such articles presents a threat to public health, as determined by the Secretary, the Secretary shall provide the person, firm, or corporation with an opportunity to: *(i)* cease distribution of such articles, *(ii)* notify all persons, firms, and corporations transporting, storing, or distributing such articles, or to which such articles have been transported or sold, to immediately cease distribution of such articles, *(iii)* recall such articles, and *(iv)* provide, in consultation with the Secretary, notice to consumers to whom such articles were, or may have been, distributed. (2) If such person, firm, or corporation refuses to or does not voluntarily cease distribution, make notification, recall such articles, and provide notice to consumers, within the time and in the manner prescribed by the Secretary, the Secretary shall, by order, require, as the Secretary deems necessary, such person, firm, or corporation, to: *(i)* immediately cease distribution of such articles, and *(ii)* immediately notify all persons, firms, and corporations transporting, storing, or distributing such articles, or to which such articles have been transported or sold, to immediately cease distribution of such articles. (3) The Secretary shall, as the Secretary deems necessary, provide notice to consumers to whom such articles were, or may have been, distributed.

"(c) The Secretary shall provide any person, firm, or corporation subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible but not later than 48 hours after the issuance of the order, on the actions required by the order and on why the articles that are the subject of the order should not be recalled.

"(d) (1) If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that there is a reasonable probability that human consumption of the articles that are the subject of an order under subsection (b) presents a threat to public health, the Secretary, as the Secretary deems necessary, may: *(i)* amend the order to require recall of such articles or other appropriate action, and *(ii)* specify a timetable in which the recall will occur, require periodic reports to the Secretary describing the progress of the recall, and provide notice to consumers to whom such articles were, or may have been, distributed. (2) If, after such a hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

(c) The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

REFUSAL OR WITHDRAWAL OF INSPECTION

"SEC. 412 (a) The Secretary may, for such period, or indefinitely, as the Secretary deems necessary to effectuate the purposes of this Act, refuse to provide or withdraw inspection under title I of this Act with respect to any establishment if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such inspection, that the applicant or recipient, or any person responsibly connected with the applicant or recipient (as defined in section 401), has committed any willful violation of this Act or the regulations promulgated thereunder or repeated violations of this Act or the regulations promulgated thereunder.

"(b) The Secretary may deny or suspend inspection under title I of this Act, pending opportunity for an expedited hearing, with respect to an action under subsection (a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or suspension in the public interest to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under this Act.

"(c) The determination and order of the Secretary with respect to the refusal or withdrawal of inspection under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection files application for judicial review within thirty days after the effective date of such order and simultaneously sends a copy of such filing by certified mail to the Secretary. Inspection shall be refused or withdrawn as of the effective date of such order pending any judicial review of such order unless the Secretary directs otherwise. Judicial review of any such order shall be in the United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit, and shall be on the record upon which the determination and order are based.

"(d) The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

CIVIL PENALTIES

"SEC. 413 (a) Any person, firm, or corporation that violates any provision of this Act or any regulation or order issued under this Act may be assessed a civil penalty by the Secretary of not more than $100,000 for each such violation. Each violation and each day during which a violation continues shall be a separate offense. No penalty shall be assessed by the Secretary under this section unless such person, firm, or corporation is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code. The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses; and may be reviewed only as provided in subsection (b).

"(b) An order assessing a civil penalty under subsection (a) shall be final and conclusive unless the person, firm, or corporation files, within thirty days from the effective date of the order, an application for judicial review in the Court of Appeals of the United States for the circuit in which such person, firm, or corporation resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in such Court and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such Court a certified copy of the record upon which such violation was found and such penalty assessed. The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

"(c) If any person, firm, or corporation fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed in an appropriate district court of the United States. In such collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

"(d) All penalties collected under authority of this section shall be paid into the Treasury of the United States.

"(e) If any person, firm, or corporation fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of

Appeals has entered final judgment in favor of the Secretary, the Secretary may refuse to provide inspection to, or suspend inspection from, any such person, firm, or corporation until the assessed civil penalty is paid or until otherwise ordered by the Secretary.

"(f) Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, violations of this Act whenever the Secretary believes that the public interest will be adequately served by assessment of civil penalties.

"(g) The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.".

SEC. 3. The Poultry Products Inspection Act (21 U.S.C. 451 <u>et seq.</u>) is amended:

(1) in section 5 © by deleting "and 12-22 of this Act" and inserting in lieu thereof "12-22, and 31-33 of this Act", and

(2) by inserting after section 30 the following new sections:

NOTIFICATION AND RECALL

"SEC. 31 (a) Any person which has a reasonable basis for believing that any poultry or poultry products are adulterated or misbranded shall immediately notify the Secretary, in such manner and by such means as the Secretary may by regulation prescribe, of the identity and location of such poultry and poultry products.

"(b) (1) If the Secretary finds, upon such notification or otherwise, that (A) any poultry or poultry products are adulterated or misbranded and (B) there is a reasonable probability that human consumption of such poultry or poultry products presents a threat to public health, as determined by the Secretary, the Secretary shall provide the person with an opportunity to: *(i)* cease distribution of such poultry or poultry products, *(ii)* notify all persons transporting, storing, or distributing such poultry or poultry products, or to which such poultry or poultry products have been transported or sold, to immediately cease distribution of such poultry or poultry products, *(iii)* recall such poultry or poultry products, and *(iv)* provide, in consultation with the Secretary, notice to consumers to whom such poultry and poultry products were, or may have been, distributed. (2) If such person refuses to or does not voluntarily cease distribution, make notification, recall such poultry or poultry products, and provide notice to consumers, within the time and in the manner prescribed by the Secretary, the Secretary shall, by order, require, as the Secretary deems necessary, such person to: *(i)* immediately cease distribution of such poultry or poultry products, and *(ii)* immediately notify all persons transporting, storing, or distributing such poultry or poultry products, or to which such poultry or poultry products have been transported or sold, to immediately cease distribution of such poultry or poultry products. (3) The Secretary shall, as the Secretary deems necessary, provide notice to consumers to whom such poultry or poultry products were, or may have been, distributed.

"(c) The Secretary shall provide any person subject to an order under subsection (b) with an opportunity for an informal hearing, to be held as soon as possible but not later than 48 hours after the issuance of the order, on the actions required by the order and on why the poultry or poultry products that are the subject of the order should not be recalled.

"(d) (1) If, after providing opportunity for an informal hearing under subsection (c), the Secretary determines that there is a reasonable probability that human consumption of the poultry or poultry products that are the subject of an order under subsection (b) present a threat to public health, the Secretary, as the Secretary deems necessary, may: *(i)* amend the order to require recall of such poultry or poultry products or other appropriate action, and *(ii)* specify a timetable in which the recall will occur, require periodic reports to the Secretary describing the progress of the recall, and provide notice to consumers to whom such poultry or poultry products were, or may have been, distributed. (2) If, after such a hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

(e) The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

REFUSAL OR WITHDRAWAL OF INSPECTION

"SEC. 32 (a) The Secretary may, for such period, or indefinitely, as the Secretary deems necessary to effectuate the purposes of this Act, refuse to provide or withdraw inspection under this Act if the Secretary determines, after opportunity for a hearing is accorded to the applicant for, or recipient of, such inspection, that the applicant or recipient, or any person responsibly connected with the applicant or recipient (as defined in section 18(a)), has committed any willful violation of this Act or the regulations promulgated thereunder or repeated violations of this Act or the regulations promulgated thereunder.

"(b) The Secretary may deny or suspend inspection under this Act, pending opportunity for an expedited hearing, with respect to an action under subsection (a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or suspension in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under this Act.

"(c) The determination and order of the Secretary with respect to the refusal or withdrawal of inspection under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection files application for judicial review within thirty days after the effective date of such order and simultaneously sends a copy of such filing by certified mail to the Secretary. Inspection shall be refused or withdrawn as of the effective date of such order pending any judicial review of such order unless the Secretary directs otherwise. Judicial review of any such order shall be in the United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit, and shall be on the record upon which the determination and order are based.

"(d) The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.

CIVIL PENALTIES

"SEC. 33 (a) Any person that violates any provision of this Act or any regulation or order issued under this Act may be assessed a civil penalty by the Secretary of not more than $100,000 for each such violation. Each violation and each day during which a violation continues shall be a separate offense. No penalty shall be assessed by the

Secretary under this section unless such person is given notice and opportunity for a hearing on the record before the Secretary in accordance with sections 554 and 556 of title 5, United States Code. The amount of such civil penalty shall be assessed by the Secretary by written order, taking into account the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses; and may be reviewed only as provided in subsection (b).

"(b) An order assessing a civil penalty under subsection (a) shall be final and conclusive unless the person files, within thirty days from the effective date of the order, an application for judicial review in the Court of Appeals of the United States for the circuit in which such person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in such Court and by simultaneously sending a copy of such notice by certified mail to the Secretary. The Secretary shall promptly file in such Court a certified copy of the record upon which such violation was found and such penalty assessed. The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

"(c) If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute a civil action to recover the amount assessed in an appropriate district court of the United States. In such collection action, the validity and appropriateness of the Secretary's order imposing the civil penalty shall not be subject to review.

"(d) All penalties collected under authority of this section shall be paid into the Treasury of the United States.

"(e) If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary, the Secretary may refuse to provide inspection to, or suspend inspection from, any such person, firm, or corporation until the assessed civil penalty is paid or until otherwise ordered by the Secretary.

"(f) Nothing in this Act shall be construed as requiring the Secretary to report for prosecution or for the institution of libel or injunction proceedings, violations of this Act, whenever the Secretary believes that the public interest will be adequately served by assessment of civil penalties.

"(g) The remedies provided in this section shall be in addition to and not exclusive of other remedies that may be available.".

Draft 8/28/97; 9 am

SECTION-BY-SECTION-ANALYSIS
FOOD SAFETY ENFORCEMENT ENHANCEMENT ACT OF 1997

Section 1. Section 1 would provide that the Act may be cited as "The Food Safety Enforcement Enhancement Act of 1997".

Section 2. Section 2 would amend the Federal Meat Inspection Act (FMIA) by redesignating the current section 411 as section 414 and adding three new enforcement provisions related to notification and recall of products, the refusal and withdrawal of inspection, and the assessment of civil penalties.

Section 411, Notification and Recall, would require persons, firms, or corporations to notify the Secretary of the identity and location of adulterated and misbranded products. Further, section 411 would provide the Secretary with authority to issue orders to cease distribution of and to recall adulterated and misbranded products if there is a reasonable probability of a threat to public health. Section 411 would provide a mechanism to prevent such articles from reaching consumers.

Section 411(a) would require any person, firm, or corporation which has a reasonable basis for believing that any carcasses, parts of carcasses, meat, or meat food products are adulterated or misbranded to immediately notify the Secretary of the identity and location of such articles. The immediate notification of the identity and location of articles believed to be adulterated or misbranded is necessary to provide the Secretary with the opportunity to limit the distribution of such articles, and possibly avoid human illness. The Secretary would prescribe by regulation the means and manner that notification is to be provided.

Section 411(b) would provide that if the Secretary finds, through notification or otherwise, that (1) any carcasses, parts of carcasses, meat, or meat food products are adulterated or misbranded and (2) there is a reasonable probability that human consumption of such articles presents a threat to public health, the Secretary would provide the persons, firms, or corporations with an opportunity to (1) voluntarily cease distribution of such articles; (2) notify all persons, firms, and corporations transporting, storing, or distributing such articles or to which such articles were transported or sold, to immediately cease distribution of such articles; (3) to recall the articles; and (4) to provide, in consultation with the Secretary, notice to consumers to whom such articles were, or may have been, distributed.

If the person, firm, or corporation refuses to or does not voluntarily cease distribution, make notification, recall the articles, and notify the public, within the time and in the manner prescribed by the Secretary, the Secretary would issue an order requiring such person, firm, or corporation immediately (1) to cease distribution of the articles and (2) to notify all persons, firms, and corporations transporting or distributing the articles, or to which the articles were transported or sold, to immediately cease distribution. The Secretary shall, as he deems necessary, provide for notice to consumers to whom such articles were, or may have been, distributed.

Section 411(c) would provide for an opportunity for an informal hearing, to be held as soon as possible but not later than 48 hours after the issuance of the order, to allow the affected person, firm, or corporation the opportunity to contest the order. Further, the informal hearing would allow the affected person, firm or corporation an opportunity to present evidence as to why the articles should not be recalled.

Section 411(d) would give the Secretary authority to require recall of the articles if, after opportunity for a hearing under subsection (c), the Secretary continues to find that there is a reasonable probability of a threat to public health. Upon this determination, the Secretary would, as he deems necessary, amend the order to require a recall. The order would specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide for notice to consumers, to whom such articles were or may have been distributed. If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary would be required to vacate the order.

Section 411(e) would provide that the remedies provided in section 411 are in addition to all other available remedies.

Section 411 would enable the Secretary to better protect the public from receiving products that present a reasonable probability that human consumption of the product presents a threat to public health. Authorized representatives of the Secretary currently have authority to detain products for 20 days that are found outside an official establishment and not in compliance with the FMIA (see section 402 of the FMIA). Under present authority, FSIS must institute an action in the appropriate U.S. District Court in order to get a judicial seizure and condemnation order. The present authority is resource intensive and lengthy. FSIS frequently relies on voluntary recalls by official establishments. This new authority to require recall of certain adulterated or misbranded articles would allow FSIS to protect consumers more effectively and efficiently.

Section 412, Refusal or Withdrawal of Inspection, would provide the Secretary with additional grounds upon which to refuse or withdraw inspection. Section 401 of the FMIA currently authorizes the Secretary, after opportunity for a hearing, to refuse to provide or to withdraw inspection based upon a determination that the applicant or recipient of inspection is unfit to engage in any business requiring inspection under the FMIA because the applicant, recipient, or anyone responsibly connected with the applicant or recipient, has been convicted in Federal or State court of certain violations of law.

Section 412(a) would provide that the Secretary may refuse to provide or withdraw inspection from an applicant or recipient when it has been determined, after an opportunity for hearing, that the applicant or recipient or any person responsibly connected with the applicant or recipient (as defined in section 401) has committed any willful violation of the requirements of the Act or the regulations promulgated under the Act (one willful violation may result in this section being applied) or repeated violations of the requirements of the Act or the regulations promulgated under the Act. This provision does not require a determination of unfitness, nor is a prior criminal conviction or civil or administrative order or determination required.

Section 412(b) would authorize the Secretary to deny or suspend inspection, pending an opportunity for an expedited hearing, with respect to an action under section 412(a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or suspension in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under the Act. The Secretary would have the authority to take immediate action against a violator if such action is deemed in the public health or to assure the safe and effective performance of official duties under the Act. The denial or suspension would be effective upon service of the complaint or other such notice.

Section 412(c) would provide that the determination and order of the Secretary is final and conclusive unless the affected person, firm, or corporation files for judicial review within thirty days after the effective date of the order. Unless the Secretary directs otherwise, inspection would be refused or withdrawn as of the effective date of the order, pending judicial review of the order. The United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business and the United States Court of Appeals for the District of Columbia Circuit would have jurisdiction. Judicial review would be on the record upon which the determination and order are based.

Section 412(d) would provide that the remedies provided in section 412 are in addition to all other available remedies.

Section 413, Civil Penalties, would authorize the Secretary to assess civil monetary penalties for violations of any provision of the Act, the regulations promulgated under the Act, or any order issued under new section 411 of the Act.

Section 413(a) would authorize the Secretary to impose civil penalties of not more than $100,000 for each violation against any person, firm or corporation which violates any provision of the Act, the regulations under the Act, or any order issued under the Act. Each violation and each day would be a separate offense subject to civil penalties. These penalties would be assessed after the person, firm, or corporation has received notice and an opportunity for a hearing on the record in accordance with 5 U.S.C. 554 and 556. The sanction would be based upon the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses.

Criminal sanctions are vital in ensuring the enforcement of the FMIA, but are not enough. Criminal prosecution can be a lengthy and cumbersome process in an overburdened judicial system. Civil monetary penalties, on the other hand, can be imposed administratively, ensuring a timely and effective resolution. Moreover, a monetary penalty is more tangible than a distant and lengthy legal process that may or may not be instituted and may or may not lead to a conviction. The proposed civil penalty amount is reasonable and will deter potential violators. Civil penalties would therefore be an effective enforcement tool.

Section 413(b) would provide that orders of the Secretary assessing a civil penalty may be reviewed in the U.S. Court of Appeals for the circuit in which the party resides or has its principal place of business or in the U.S. Court of Appeals for the District of Columbia Circuit by filing a notice of appeal within thirty days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The findings of the Secretary would be set aside only if found to be unsupported by substantial evidence on the record as a whole.

Section 413(c) would provide that failure to pay the civil penalty after the order assessing the penalty has become final and unappealable or after the appropriate Court of Appeals has entered final judgement in favor of the Secretary shall result in the Secretary referring the matter to the Attorney General who shall institute a civil action to recover the assessed penalty. The validity of the Secretary's order would not be reviewable in such a collection action.

Section 413(d) would require that the civil penalties collected under section 413 be paid into the U.S. Treasury.

Section 413(e) would provide that the Secretary may refuse to provide inspection to, or suspend inspection from any person, firm, or corporation that fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary.

Section 413(f) would provide that nothing in the Act shall require the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings violations of the Act when the Secretary believes that the public interest will be adequately served by the assessment of civil penalties.

Section 413(g) would provide that the remedies provided in section 413 are in addition to all other available remedies.

Section 3. Section 3 would amend section 5(c) the Poultry Products Inspection Act (PPIA) by substituting sections 12-22, and 31-33 of this Act for the reference to sections 12-22. Section 5(c) of the PPIA requires that the Secretary designate any State whose poultry products inspection requirements with respect to transactions wholly within such State are not at least equal to those of sections 1-4, 6-10, and 12-22 of the PPIA. This section would provide that sections 1-4, 6-10, 12-22, and 31-33 would apply to such intrastate transactions and no poultry or poultry products could be sold unless inspected for wholesomeness and passed by inspectors of the Food Safety and Inspection Service (FSIS).

Section 3 of the bill would add at the end of the PPIA three new enforcement provisions related to notification and recall of products, the refusal and withdrawal of inspection, and the assessment of civil penalties.

Section 31, Notification and Recall, would require persons (as defined in Section 4(j)) to notify the Secretary of the identity and location of adulterated and misbranded products. Further, section 31 would provide the Secretary with authority to issue orders to cease distribution of and orders to recall adulterated and misbranded products if there is a reasonable probability of a threat to public health. Section 31 would provide a mechanism to prevent such articles from reaching consumers.

Section 31(a) would require any person which has a reasonable basis for believing that any adulterated or misbranded, immediately to notify the Secretary of the identity and location of such articles. The immediate notification of the identity and location of articles believed to be adulterated or misbranded is necessary to provide the Secretary with the opportunity to limit the distribution of such articles, and possibly avoid human illness. The Secretary would prescribe by regulation the means and manner that notification is to be provided.

<u>Section 31(b)</u> would provide that if the Secretary finds, through notification or otherwise, that (1) any poultry or poultry products are adulterated or misbranded, and (2) there is a reasonable probability that human consumption of such poultry or poultry products presents a threat to public health, the Secretary would provide the appropriate person with an opportunity to (1) voluntarily cease distribution of such poultry or poultry products; (2) notify all persons transporting, storing, or distributing such poultry or poultry products or to which such poultry or poultry products were transported or sold to immediately cease distribution of such articles; (3) to recall the poultry or poultry products; and (4) to provide, in consultation with the Secretary notice, to consumers to whom such articles were, or may have been, distributed.

If the person refuses to or does not voluntarily cease distribution, make notification, recall the articles, and notify the public, within the time and in the manner prescribed by the Secretary, the Secretary would issue an order requiring the person immediately (1) to cease distribution of the poultry or poultry products and (2) to notify all persons transporting or distributing the poultry or poultry products, or to which the poultry or poultry products were transported or sold, to immediately cease distribution. The Secretary shall, as he deems necessary, provide for notice to consumers to whom such articles were, or may have been, distributed.

<u>Section 31(c)</u> would provide for opportunity for an informal hearing, to be held as soon as possible but not later than 48 hours after the issuance of the order, to allow the affected person the opportunity to contest the order. Further, the informal hearing would allow the affected person an opportunity to present evidence as to why the articles should not be recalled.

<u>Section 31(d)</u> would give the Secretary authority to require recall of the articles if, after opportunity for a hearing under subsection (c), the Secretary continues to find that there is a reasonable probability of a threat to public health. Upon this determination, the Secretary would, as he deems necessary, amend the order to require a recall. The order would specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide for notice to consumers, to whom such articles were or may have been distributed. If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary would be required to vacate the order.

<u>Section 31(e)</u> would provide that the remedies provided in section 31 are in addition to all other available remedies.

Section 31 would enable the Secretary to better protect the public from receiving products that present a reasonable probability that human consumption of the products presents a threat to public health. Authorized representatives of the Secretary currently have authority to detain products for 20 days that are found outside an official establishment and not in compliance with the PPIA (see section 19 of the PPIA). Under present authority, FSIS must institute an action in the appropriate U.S. District Court in order to get a judicial seizure and condemnation order. The present authority is resource intensive and lengthy. FSIS frequently relies on voluntary recalls by official establishments. This new authority to require recall of certain adulterated or misbranded articles would allow FSIS to protect consumers more effectively and efficiently.

Section 32, Refusal or Withdrawal of Inspection, would provide the Secretary with additional grounds upon which to refuse or withdraw inspection. Section 18 of the PPIA currently authorizes the Secretary, among other things, to refuse to provide or to withdraw inspection, after opportunity for a hearing, based upon a determination that the applicant or recipient of inspection is unfit to engage in any business requiring inspection under the PPIA because the applicant or recipient (or anyone responsibly connected with the applicant or recipient) has been convicted in a Federal or State court of certain violations of law.

Section 32(a) would provide that the Secretary may refuse to provide or withdraw inspection from an applicant or recipient when it has been determined, after an opportunity for hearing, that the applicant or recipient or any person responsibly connected with the applicant or recipient (as defined in section 18(a)) has had committed any willful violation of the requirements of Act or the regulations promulgated under the Act (one willful violation may result in this section being applied) or repeated violations of the requirements the Act or the regulations promulgated under the Act. This provision does not require a determination of unfitness, nor is a prior criminal conviction or civil or administrative order or determination required.

Section 32(b) would authorize the Secretary to deny or suspend inspection, pending an opportunity for an expedited hearing, with respect to an action under section 32(a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or suspension in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under the Act. The Secretary would have the authority to take immediate action against a violator if such action is deemed necessary to protect the public health or to assure the safe and effective performance of official duties under the Act. The denial or suspension would be effective upon service of the complaint or other such notice.

Section 32(c) would provide that the determination and order of the Secretary is final and conclusive unless the affected person files for judicial review within thirty days after the effective date of the order. Unless the Secretary directs otherwise, inspection would be refused or withdrawn as of the effective date of the order, pending judicial review of the order. The United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business and the United States Court of Appeals for the District of Columbia Circuit would have jurisdiction. Judicial review would be on the record upon which the determination and order are based.

Section 32(d) would provide that the remedies provided in section 31 are in addition to all other available remedies.

Section 33 Civil Penalties, would authorize the Secretary to assess civil monetary penalties for violations of any provision of the Act, the regulations promulgated under the Act, or any order issued under new section 31 of the Act.

Section 33(a) would authorize the Secretary to impose civil penalties of not more than $100,000 for each violation against any person who violates any provision of the Act, regulations under the Act, or any order issued under the Act. Each violation and each day would be a separate offense subject to civil penalties. These penalties shall be assessed after the person has received notice and an opportunity for a hearing on the record in accordance with 5 U.S.C. 554 and 556. The sanction would be based upon the gravity of the violation, degree of culpability, size and type of business of the person, and any history of prior offenses.

Criminal sanctions are vital in ensuring the enforcement of the PPIA, but are not enough. Criminal prosecution can be a lengthy and cumbersome process in an overburdened judicial system. Civil monetary penalties, on the other hand, can be imposed administratively, ensuring a timely and effective resolution. Moreover, a monetary penalty is more tangible than a distant and lengthy legal process that may or may not be instituted and may or may not lead to a conviction. The proposed civil penalty amount is reasonable and will deter potential violators. Civil penalties could therefore be an effective enforcement tool.

Section 33(b) would provide that orders of the Secretary assessing a civil penalty may be reviewed in the U.S. Court of Appeals for the circuit in which the person resides or has its principal place of business or in the U.S. Court of Appeals for the District of Columbia Circuit by filing a notice of appeal within thirty days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The findings of the Secretary would be set aside only if found to be unsupported by substantial evidence on the record as a whole.

Section 33(c) would provide that failure to pay the civil penalty after the order assessing the penalty has become final and unappealable or after the appropriate Court of Appeals has entered final judgement in favor of the Secretary shall result in the Secretary referring the matter to the Attorney General who shall institute a civil action to recover the assessed penalty. The validity of the Secretary's order would not be reviewable in such a collection action.

Section 33(d) would require that the civil penalties collected under section 33 shall be paid into the U.S. Treasury.

Section 33(e) would provide that the Secretary may refuse to provide inspection to, or suspend inspection from any person that fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary.

Section 33(f) would provide that nothing in the Act shall require the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings violations of the Act when the Secretary believes that the public interest will be adequately served by the assessment of civil penalties.

Section 33(g) would provide that the remedies provided in section 33 are in addition to all other available remedies.

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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

Food Safety - Reg reform

FAX COVER SHEET

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- ☐ GREG FRAZIER, CHIEF OF STAFF
  - ☐ KOFI DEGRAFT-JOHNSON, EXECUTIVE ASSISTANT
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- ☐ ANNE KENNEDY, SPECIAL ASSISTANT FOR POLICY
- ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: More Reg Reform + Food Safety

Tom and Mary --

Here's a letter with all of the groups that oppose S. 981 and some of the press materials on food safety. You'll notice it is basically all the major public interest groups plus the unions. I don't see AARP on the letter, but they have become involved on the food safety issues here.

Daschle's office suggested to me that the Administration send a letter outlining a set of maybe 6 concerns that need to be addressed, before the markup. Daschle's office also told me that Levin wants a meeting with Bowles to discuss this issue. That might be how the concerns get expressed.

The problem is, I have no idea what the process is over there for determining the Administration's position and strategy. The agencies would certainly want to review such a letter.

The public interest community wants the Administration to affirm their reading of the bill. But it is possible that if we make too strong criticism of it, it could make Lott more likely to want to move the bill.

The other idea I have been playing with is using this bill, if it starts moving, as a vehicle for other items, like our Food Safety Enforcement legislation. This is worth considering as an approach, should a meeting occur-- the Administration wants these changes plus these other items. We need to do a little work on this approach, but it very well may be feasible.

Please let me know if you hear anything. Thanks.

Eric

Also, NY Times is working on a story on the bill as it relates to pesticides. The peer review etc. provisions that cause delays does not apply to putting new products on the market, but the provisions do apply to taking a product off the market.

CITIZENS FOR SENSIBLE SAFEGUARDS

February 24, 1998

Dear Senator:

As a broad-based coalition of organizations representing working men and women, the environment, consumer concerns, public health, human needs, education, civil rights and other public interest issues, we write to urge you to oppose S. 981, the "Regulatory Improvement Act," and the proposed substitute vehicle for that legislation, released by Senator Thompson on February 4, 1998.

As you may know, many citizens as well as health, safety, and environmental organizations have vigorously objected to S. 981 because it would make it much harder for government agencies to protect the public. While the bill's sponsors assert the new substitute corrects the major flaws in the bill, we do not agree. Indeed, in a number of specific respects discussed in the attached analysis, the substitute bill increases the difficulties that agencies would face in attempting to safeguard the public. The bill, if enacted, would severely damage the government's ability to protect us all from serious harm to our health, safety, and the environment. For these reasons we urge you to oppose its passage.

The substitute would hamstring health, safety, and environmental agencies and threaten the public in five major ways. The bill would:

- Delay agency decision-making with new red tape that creates a thicket of complex procedures for adopting new protective rules;
- Create major new opportunities for regulated interests to attack protective rules in the courts;
- Establish a sweeping, time-consuming program allowing industry scientists to suppress new protections in a secret "peer review" process;
- Hamper agency efforts to address current threats by diverting scarce resources to unnecessary mandatory reviews of thousands of existing safeguards, without regard to the need for such review (a newly added provision that did not appear in the bill as introduced); and
- Place a priority on reducing compliance costs for regulated industries rather than achieving needed protections.

These provisions of the substitute bill, separately and in combination, would harm the public's interest in safe food, safe water, safe workplaces and a healthy environment. They would create tests that emphasize costs rather than safety, procedures that delay action, new tools for industry lawyers to attack rules in court, unfair review panels, and impossible demands to review existing rules that have been critical to progress we have made in improving the quality of life over the last 25 years. We therefore respectfully urge you to oppose this legislation.

Sincerely,

1742 Connecticut Ave., NW Washington, D.C. 20009
Phone: (202) 234-8494 Fax: (202) 234-8584
E-mail Address: regs@rtk.net

Action On Smoking and Health
AFSCME
AFL-CIO
Alliance to End Childhood Lead Poisoning
Alaska Clean Air Coalition
Alaska Center for the Environment
Alaska Conservation Voice
Amalgamated Transit Union
American Federation of Government Employees
American Federation of Nurses Local 535, SEIU, AFL-CIO (CA)
American Lung Association
American Lung Association of Metropolitan Chicago
American Lung Association of Michigan
Americans for Democratic Action
Americans for Nonsmokers' Rights
American Nurses Association
American Oceans Campaign
American Public Health Association
Amigos Bravos (NM)
Arizona Toxics Information
Arkansas Fairness Council
Atlantic States Legal Foundation
Boulder-White Clouds Council (ID)
Buckingham Citizens Action League (VA)
CALPIRG
Center for Advancement of Public Policy
Center for Science in the Public Interest
Chesapeake Bay Foundation
Citizens Aware & United for a Safe Environment (TX)
Citizens Commission for Clean Air in the Lake Michigan Basin
Citizens for a Better Environment (WI)
Clean Water Action
Coalition of Washington Communities
Communications Workers of America
Community & Environmental Defense Services (MD)
Community Nutrition Institute
CONNPIRG
COPIRG
Conservation Council of NC
Consumer Federation of America
Consumers Union
Cook Inlet Keeper (AK)
Defenders of Wildlife
Downwinders At Risk (TX)
Earth Island Institute
Earth Justice Legal Defense Fund
Earthlaw

Environmental Advocates
Environmental Defense Fund
Environmental League of Massachusetts
Environmental Working Group
Florida Consumer Action Network
FLORIDA PIRG
Forest Guardians
Friends of the Earth
Galveston-Houston Association for Smog Prevention
Georgia Wildlife Federation
Government Purchasing Project
Greater Boston Physicians for Social Responsibility
Great Lakes United
Greenpeace
Green Valleys Association
Gulf Restoration Network
Hudson River Sloop — Clearwater
Illinois Paddling Council
ILLINOIS PIRG
INPIRG
International Association of Firefighters
International Association of Machinists and Aerospace
International Brotherhood of Teamsters
Iowa Environmental Council
Kansas Sierra Club
Kentucky Resources Council, Inc.
Kentucky Waterways Alliance
Laborer's International Union of North America
League of Conservation Voters
League of Women Voters of the U.S.
Lone Star Chapter of the Sierra Club
MARYPIRG
MASSPIRG
Michigan Environmental Council
Michigan United Conservation Clubs
Migrant Legal Action Program
Military Toxics 20 Project
Mineral Policy Center
Mining Impact Coalition of Wisconsin, Inc.
Mississippi Corridor Neighborhood Coalition
Montana Environmental Information Center
Montana River Action Network
MOPIRG
MPIRG (MN)
Mothers Organized to Stop Environmental Sins (TX)
National Association for Visually Handicapped
National Consumers League

National Education Association
National Environmental Trust
National Environmental Trust of Michigan
National Parks & Conservation Association
National Organization of Women
National Wildlife Federation
National Citizens' Coalition for Nursing Home Reform
Natural Resources Defense Council
NETWORK: A Catholic Social Justice Lobby
New Hampshire Sierra Club
New Jersey Chapter Sierra Club
New Jersey Environmental Lobby
New Transportation Alliance (WI)
New York City Environmental Justice Alliance
NMPIRG
NJPIRG
North Santiam Watershed Council of Salem, Oregon
NO WASTE of Michigan
Ohio Environmental Council
Ohio PIRG
OMB Watch
OSPIRG (tOR)
Oregon Clearing House for Pollution Reduction
Oregon League of Conservation Voters
Oregon Trout
Ozark Watch League
PENNPIRG
People Against Contaminated Environments (TX)
Physicians for Social Responsibility
PIRGM (MI)
Planning and Conservation League
Potomac Headwaters Resource Alliance (WV)
Protect All Children's Environment (NC)
Public Citizen
Regional Environmental Action League (MN)
REP AMERICA (Republicans for Environmental Protection)
Rocky Mountain Chapter of the Sierra Club
Safe Tables Our Priority
Safe Schools (LA)
Salem Audubon Society (OR)
San Diego County Chapter of the Surfrider Foundation
Save Endangered Wilderness
Save the Dunes Conservation Fund (IN)
Save The River, Inc. (NY)
Sierra Club
Sierra Club, John Muir Chapter, Wisconsin
Siskiyou Regional Education Project (OR)

Society for Animal Protection Legislation
Southern Ecumenical Council
Southern Environmental Law Center
Stakeholder Alliance
St. John's Church (Elizabeth, NJ)
Surface Transportation Policy Project
Sustain-The Environmental Information Group
Tennessee Environmental Council
Tennessee Valley Energy Reform Coalition
The Arc of America
Tip of the Mitt Watershed Council (MI)
Transportation Trades Dept., AFL-CIO
UAW
UNITE
United Mine Workers of America
United Steelworkers of America
United Church of Christ, Office for Church in Society
United Church of Christ Network for Environmental and Economic Responsibility
United Food and Commercial Workers International Union
U.S. PIRG
Utah Chapter of the Sierra Club
VPIRG
WASHPIRG
Western Organization of Resource Councils
Western NY Council on Occupational Safety and Health
West Virginia River Coalition
Wildlands Center for Preventing Roads (MT)
Wisconsin's Environmental Decade
WISPIRG
World Institute on Disability
Wyoming Outdoor Council

Consumers Union

Publisher of Consumer Reports

STATEMENT OF CONSUMERS UNION IN OPPOSITION TO S.981

Consumers Union, the non-profit publisher of *Consumer Reports* magazine, is opposed to S.981 because we believe that it would impose new and unnecessary hurdles to the establishment of needed new public health and safety standards. This legislation would require agencies to expend considerable additional resources to establish and maintain health and safety standards and would give industry lawyers new opportunities to complicate the standards-setting process.

As reported in *Consumer Reports'* March issue, now on the newsstands, 63 percent of chicken sold at retail contains campylobacter, a dangerous pathogen that kills about 500 people in the U.S. annually, makes millions more sick with fever and bloody diarrhea, and in some cases causes meningitis, arthritis and Guillain-Barre syndrome, which can result in paralysis. There is no USDA standard for campylobacter on chicken.

USDA has acknowledged the need to develop a campylobacter standard. It is engaged in research that it says could lead to one. Consumers Union is deeply concerned that the enactment of a bill such as S.981 would make it more difficult to establish and implement a campylobacter standard.

For further information contact:

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Natural Resources Defense Council

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How the New Regulatory Reform S. 981 Would Undermine Efforts to Assure Safer Poultry and Meat

News reports from around the nation continually remind us of the illness and death that can result from improperly handled meat. A new study by Consumers Report found that more 60 percent of the poultry they tested to be contaminated by the dangerous pathogen campylobacter. Last summer many Americans were hospitalized in Colorado from eating hamburger contaminated with the E. coli bacteria. Hudson Foods Company recalled 25 million pounds of beef and closed their Columbus, Nebraska processing plant.

Public health advocates are seeking tough new rules to protect against the pervasive campylobacter contamination, and Agriculture Secretary Glickman has announced plans for stronger government controls. Yet, the regulatory reform bill, S. 981, would cripple these ongoing efforts to ensure better food safety, and could even undermine vital recent progress.

As described below, like its predecessor, the new version of S. 981 would divert scarce agency resources and require the USDA, the Food and Drug Administration, and other regulatory agencies to negotiate massive new red tape and litigation before issuing needed safeguards. The bill's result would be to dramatically tilt the regulatory playing field in favor of meat and poultry packers and other special interest able to deploy legions of lawyers and economic consultants to subvert the regulatory process.

- **S. 981 would delay and discourage the sorely needed new campylobacter rule by requiring the Department of Agriculture (USDA) to translate the health benefits of safer poultry into dollars and cents in order to meet new "net benefit" and "cost-effective" tests.** Rather than promoting a focus on greater health protection, this test encourages greater emphasis on costs, by encouraging the selection of the regulatory proposal that economists conclude has the greatest dollars and cents "net benefit." While the bill does not directly force an agency to reject any rule that cannot pass this test, it continues to require the agency to craft and publish alternative versions of its rules that do pass the "net benefits" test. (Section 623(d)). More protective rules will be vulnerable to industry attacks in the courts and Congress because the "net benefits" test was not met.

- **S. 981 would Threaten the Critical New Food Safety Controls Known as HACCP (Hazard Analysis and Critical Control Points).** In July 1996, USDA took significant steps to modernize sanitation in meat and poultry plants. The HACCP regulations put in place a comprehensive, science-based system to prevent food safety hazards. But now this progress is at risk. The latest draft of S.981 includes a sweeping new requirement directing agencies to review every regulatory safeguard claimed to have a "significant economic impact" on small businesses within 5 to 7 years, and make decisions on whether to preserve the rule, eliminate it or revise it. (Section 644(b)). The HACCP rule would have to be reviewed under this broad test, along with virtually every other important health, safety or environmental safeguard now in place.

- **Scarce agency resources would be diverted away from health protection.** Like other Agencies, the USDA would be required to waste its limited resources on a review of important existing programs like the new HACCP rule, rather than using them to provide the public with desperately needed new safeguards. Under the amendments passed by the anti-environmental 104^{th} Congress, industries would be able to sue the USDA over its review schedule or its failure to meet the bill's ambitious deadlines.

- **New provisions in the bill would require massive new red tape for each of the many required risk assessments that would be required before a new poultry safety rule.** Extensive risk assessments are expressly mandated before issuance of a campylobacter food safety rule or any other effort to provide the public with better protection from unsafe foods, or other public health risks. One new provision (Section 624(d)) would dramatically slow the issuance of safeguards by requiring agencies seeking to protect the public to produce unwieldy new federal register announcements and public comment procedures before conducting each and every risk assessment. Another new provision (Section 624(c)(2)) would establish an impossible requirement for agencies to constantly revise risk assessment assumptions to reflect new data. Equally troubling, meat packers, polluters and others would be authorized to sue over the difficult question of whether the highly technical assumptions used in the required risk assessments reflect the latest data.

- **New one-sided peer review requirements introduce bias and conflicts of interest into the regulatory process.** S. 981 now would bar participation of qualified University researchers if their university received a grant on an unrelated topic from an unrelated division of a large federal agency. Yet, the bill fails to directly bar the participation of researchers with a direct conflict of interest, including for example those employed by meat packers or other regulated interests, simply leaving this matter up to the agencies. Surprisingly, the directive requiring that peer review panels be "balanced" has been dropped from the bill.

- **Another objectionable new provision exempts the bill's peer review panels from the "sunshine in government" provisions of the Federal Advisory Committee Act.** (Section 625(d)). The result could be secret proceedings by panels dominated by industry employees which could kill needed efforts to protect the public.

- **USDA Needs More Authority, Not Less, to Ensure Meat Safety.** The USDA was unable to order a recall of the contaminated Hudson Foods meat, but instead had to rely on the company's voluntary decision to withdraw their product. Agriculture Secretary Glickman has proposed legislation to give him critical recall authority. Congress should act on this legislation rather than moving forward with legislation to further tie the agency's hands.

For More Information Please Contact: David Hawkins, Greg Wetstone, or Sharon Buccino at (289-2868).

February 17, 1998

CRS Report for Congress

Congressional Research Service • The Library of Congress

Compensating Farmers for the Tobacco Settlement

tobacco farmers - SW

Jasper Womach
Specialist in Agriculture Policy
Environment and Natural Resources Policy Division

Summary

Proposals to implement a tobacco settlement are likely to have negative economic consequences for tobacco growers and tobacco-dependent communities. This is because the settlement is designed to reduce cigarette consumption by Americans, particularly young Americans, and thereby decrease domestic demand for U.S.-grown leaf tobacco. This, in turn, likely will affect the value of tobacco marketing quotas held by farmers, and thereby the value of their land and holdings and their ability to obtain credit or contribute to local economies. For these reasons, there appears to be growing support for some kind of compensation to farmers as part of the settlement package legislation. On the other hand, a consistent downward trend in domestic cigarette consumption, which some contend is likely to continue even without the tobacco settlement, argues against compensation.

Compensation is not just an economic issue. Settlement proponents undoubtedly would like the support of Members of Congress from tobacco states and communities. Therefore, how much, if any, of the revenue derived from the tobacco settlement should go for compensation to growers is a political issue, as well. One obvious approach would be to estimate the likely losses to farmers under the various provisions and provide compensation on that basis. But, it is difficult to precisely estimate the potential economic consequences of the tobacco settlement for growers.

Higher Prices, Consumption, and Farm Impact

The tobacco settlement bills contain several measures designed to decrease consumption of tobacco products in the United States. Among the most prominent of these are proposals for substantial increases in the price of tobacco products (either through manufacturer payments or higher excise taxes), which are designed to finance other anti-smoking efforts and health care provisions in the proposal. Price increases have a direct impact on consumption, and consequently, can be used to estimate changes in the domestic demand for U.S.-grown tobacco, its production, and farm income. Other increase, would amount to nearly 70 million pounds. A 11.4% decline, due to a $1.50 price increase, would amount to nearly 175 million pounds.

Production cutbacks of this magnitude, while sizable, are not outside the range of recent experiences. From 1981, a recent peak production year, to 1997, farm output of tobacco declined about 20%. For 1998, the basic marketing quotas stipulated under the federal tobacco support program have been reduced by 16.5% for flue-cured tobacco and 9% for burley tobacco. A tobacco marketing quota is the quantity of tobacco a farm is allowed to market each year. Through marketing quotas, U.S. production is constrained and prices are thereby held higher than would be the case if farmers were free to harvest and sell as much as they wanted.

Calculating Farmer Compensation

Tobacco prices have been supported and stabilized by the federal government's commodity support program since the 1930s. The tobacco program operates through a combination of marketing quotas, which limit supplies, and no-net-cost tobacco loans, which help to balance marketings with demand.[3] The high stable prices created by the tobacco program raise farm incomes above what they would be otherwise. As it might be expected, the economic benefits of the tobacco price support program have been capitalized into land values and marketing quota rents. The holders of the 336,000 quotas likely will realize a loss in net worth under a tobacco settlement. A rough estimate is that 63% of the quotas are held by absentee landlords whose rental income could decline. Likewise, under the assumptions made here, all of the roughly 124,000 tobacco farm operators (owners and lessees) would be expected to suffer a decline in sales revenues.

How much of a decrease in net worth or rent would likely result from a $0.60 or $1.50 per pack cigarette price increase? In Kentucky, a sizable proportion of the tobacco quotas are leased and transferred to another farm for a production season. Survey data indicate an average lease-and-transfer price of $.42 per pound for burley marketing quota over the past 5 years.[4] One way to estimate the loss to farm owners from declining quota

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[3]A more complete explanation of the federal tobacco support program is available in CRS Report 95-129 ENR, *Tobacco Price Support: An Overview of the Program*. Tobacco marketing quotas are assigned to farms that have a history of tobacco production. The owners of these farms are characterized as holders of quota in this report.

[4]This average is calculated from survey data collected and published annually by William Snell, Department of Agricultural Economics, University of Kentucky. Data are not available on quota sales prices in North Carolina, but experts in North Carolina and the U.S. Department of Agriculture agree that $1.87 may not be far off. The holders of burley tobacco marketing quota are allowed to lease the quota to other tobacco growers, who then transfer the quota and produce on their own land. Consequently, there is an active lease-and-transfer market for burley quotas. Unlike burley, flue-cured marketing quotas cannot be leased and transferred. Rather, farms with flue-cured quota are leased and the program participation records reconstituted so that production can be located anywhere on the combined properties. While there is an active tobacco farm-lease market in North Carolina, lease rate data are not collected. However, experts believe that the $0.42 per pound average for burley in Kentucky is a reasonable estimate for average flue-cured lease rates in North Carolina. Two simultaneous but opposing circumstances are pushing sale prices

(continued...)

Community Impacts

Certainly, tobacco farming is an important part of the agricultural economy of the regions where production is concentrated, as the following USDA data show. Flue-cured tobacco production is centered in North Carolina. Burley production is centered in Kentucky. These two states account for 65% of total tobacco production. The surrounding states of Tennessee, Virginia, South Carolina, and Georgia produce 26%. In 1997, some 124,000 tobacco farms harvested 795,000 acres, with a yield averaging 2,069 pounds per acre. This total crop of 1.65 billion pounds could have a farm value of about $3 billion once the seasons marketing receipts are tabulated. In North Carolina, tobacco cash receipts account for nearly 32% of total crop receipts and nearly 14% of total crop and livestock receipts. In Kentucky, tobacco receipts account for nearly 42% of crop receipts and nearly 22% of total crop and livestock receipts.

The significance of tobacco to local economies is summarized in a USDA report titled Tobacco Dollars and Jobs.[5] On the national level, if there were no domestic tobacco consumption, total employment would actually increase because the money now spent on tobacco products would be spent on more labor-dependent items. But direct employment in tobacco farming would decline by 79,000 jobs. The areas most adversely impacted by reduced tobacco production would be the isolated rural communities throughout Kentucky, the Virginia-Tennessee, and Virginia-North Carolina borders, the coastal plain of the Carolinas, Georgia, and northern Florida. In 1992, 311 counties had tobacco sales of more than $1 million. In 43 of these counties, tobacco receipts exceeded 10% of local earnings (with 8 counties in the 20-30% range, and 1 county reaching 55%).

Tobacco quota holders and farm lessees are obviously identifiable as economic losers if their rental incomes and sales revenues decline. But the impact may spread to the entire community if farm and personal consumption expenditures decline. Local property tax revenues might decline due to declining property values. This could then impact on community services. It is beyond the scope of this report to quantify the magnitude of potential community impacts because the outcome depends largely upon how dependent the local economy is on tobacco and what substitute economic activities are possible. Additionally, tobacco leaf and cigarette exports could increase in the future and offset some of the decline in domestic consumption.

Legislative Proposals for Farmer Compensation and Community Assistance

Several bills have been introduced in the 105th Congress that propose to compensate tobacco quota holders, to make transition payments to farm operators who do not own, but are quota lessees, and to provide economic development assistance to tobacco dependent communities. As will be seen by examining the bills, the compensation rates vary but appear to be on the generous side.

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[5]Fred Gale, Tobacco Dollars and Jobs, *Tobacco Situation and Outlook Report*, Economic Research Service, U.S. Department of Agriculture, September 1997. pp37-43.

Are you doing this?

Food Safety
- E coli
- EW

request for assistance from the Kenya Ministry of Health and in collaboration with WHO and the DoD, CDC dispatched a six-member team.

Tom - Can we get into this in some way? How is it being funded? What's the timetable of further experiments, etc.? Elena cc: Bruce

- **E. coli Vaccine:** On February 9, scientists at the National Institute of Child Health and Human Development announced that they have developed an experimental vaccine against E. coli O157, the pathogenic bacterium that causes severe food poisoning. The results of this clinical trial are reported in the February issue of the *Journal of Infectious Diseases*. Although further clinical trials are required before the vaccine is declared protective in humans, scientists are considering another strategy to eradicate E. coli O157 -- mass vaccination of cattle -- which would eliminate the pathogen at its source.

- **Hospital Fraud and Abuse:** On February 11, the Office of Inspector General (OIG) released its voluntary compliance program for hospitals. The guidance is intended to combat fraud and abuse in the hospital industry.

- **Tobacco and Children:** On February 13, the FDA expects to sign a contract with NC to enforce FDA regulations prohibiting retailers from selling cigarettes and smokeless tobacco products to children under 18. This is the first such contract of 1998. In 1997, FDA contracted with ten states to enforce the tobacco regulation: FL, WA, IL, TX, MA, CA, MN, AR, PA, and CO. Under the contract, a state conducts unannounced retail compliance checks. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to adolescents and seeks a fine of $250 for the second violation and greater fines for subsequent violations.

- **Guatemalan Berries:** On February 9, FDA issued a letter to the Guatemalan Embassy stating that since fresh blackberries and frozen blackberries and raspberries from Guatemala had not been implicated in the 1996 and 1997 outbreaks of cyclosporiasis in the U.S., FDA will not object to the importation of these products, subject to normal FDA import and sampling procedures. Last summer, the Guatemalan authorities were informed that importation of Guatemala's 1998 Spring crop of <u>fresh</u> raspberries would not be allowed unless information on the cause and prevention of cyclosporiasis from Guatemalan raspberries was available or if alternative processing methods become available which would ensure the destruction of *Cyclospora*.

- **Depression and Smoking:** In the February issue of the AMA's *Archives of General Psychiatry*, researchers supported by the National Institute of Mental Health report on a study which found that a history of major depression was associated with progression of smoking and that a history of daily smoking was associated with increased risk for major depression. According to the researchers, their study is the first report on the influence of major depression on the progression of smoking among people who have ever smoked.

O157:H7 Vaccines

There are at least 3 groups working on vaccines against *Escherichia coli* O157:H7 in humans or animals. This new publication by NIH researchers describes an O157 vaccine in a very preliminary stage of development. It is not clear who would be in the human target population for vaccination, e.g. all children between 2 and 5 years or between 1 and 16 years, etc. The better target for an O157 vaccine may be cattle (destined to become food), since these animals appear to be the major reservoir for O157 in the U.S. However, neither the natural infection nor several vaccine trials in cattle have proved effective against subsequent infection/colonization.

A brief summary of relevant research projects:

1) John Robbins, National Institutes of Health

Vaccine Trial - In a recent clinical trial, the vaccine against *E. coli* O157 caused adult volunteers to produce enough serum antibody to kill the bacteria in laboratory experiments, and volunteers suffered no serious side effects (a few of the vaccinees had a mild skin reaction at the injection site). The power of the vaccinees' serum to kill the bacteria persisted throughout the clinical trial, which lasted for 6 months. The results of this clinical trial are reported in an article in the February issue of the *Journal of Infectious Diseases*. The NIH scientists propose that this vaccine-induced bactericidal activity is a correlate of immunity.

Cattle - The NIH vaccine is now being tested in cattle in cooperation with the Calgene Corporation. Preliminary results show that the cattle produce antibody, but whether the antibodies will clear O157 from the cattle gut has yet to be determined. Once these data are evaluated, a determination will be made as to whether the vaccine is sufficiently immunogenic to continue research. If continued research is warranted, USDA (APHIS) will become involved since challenge studies of cattle with O157 will require USDA protocol approval. The purpose of these studies would be to determine if infection in cattle could be prevented by the vaccine when cattle are challenged by feeding them *E. coli* O157:H7.

Proposed Trial in Children - A phase 2 clinical trial in children is being proposed and is in the initial planning phase. No details are currently available.

2) Agricultural Research Service

ARS experience with the immune response and vaccine against *E coli* O157:H7 in cattle has not been encouraging because:

a. Oral infection with O157:H7 in cattle caused an anti-O157 LPS serum immune response. The immune response did not correlate with reduced fecal shedding or with protection against re-infection.

b. A preliminary live-oral O157:H7 vaccine was tried in cattle. The vaccine strain does not express Shiga toxin, which is believed to be a critical virulence factor. However, the vaccine did not prevent subsequent infection or shedding despite a significant immune response (serum antibody) against O157 LPS.

c. ARS also developed a vaccine which inhibits the effects of the Shiga-like toxin important in edema of pigs. A similar toxoid based vaccine for humans would produce broader protection than the NIH human vaccine because of similarities of the Shiga-like toxin produced by several bacterial species. The toxoid vaccine was shown to protect pigs and was effective in vivo. The NIH vaccine in humans has not yet been demonstrated to protect against disease.

3) Alison O'Brien-Uniformed Services University of the Health Sciences
With ARS and University of North Carolina

Dr. O'Brien's research group is working to develop a broad spectrum vaccine that will hopefully be effective against all enterohemorrhagic *E. coli*. This group includes *E. coli* O157:H7. This work is very preliminary. The group is currently trying to combine different shiga toxins with the attachment factor of O157:H7 to produce an effective immunizing antigen. If successful, this work will result in a broad spectrum vaccine that will be effective against O157:H7 and other serotypes compared to the NIH vaccine which may be specific to only O157:H7.

This group received a USDA grant "Intimin: candidate for an *E. coli* O157:H7 anti-transmission vaccine." Intimin is required for enterohemorraghic *E. coli* (EHEC) O157:H7 infection and disease in neonatal calves and piglets. Objectives of this grant are to determine if antibodies against intimin passively protect neonatal pigs and cattle from O157:H7 infection and disease and to determine if intimin plays a role in colonization of older cattle. A piglet model will be used first for proof of concept, then a calf model to confirm applicability to calves.

Food safety Mandatory Recall - SW

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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

Food Safety - Mandatory Recall SW

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- ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: Food Safety Report Being Released Tomorrow Am

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THE CENTER FOR PUBLIC INTEGRITY

Press Advisory

News Conference
9:30 a.m.
Thursday, February 26, 1998
National Press Club
Zenger Room

The Center for Public Integrity releases an important investigative study about how Congress has responded to the growing threat of food contamination. Few issues today are more directly relevant to the American people than food safety. Cases of food poisoning have increased exponentially in recent years, so much so that federal officials characterize the thousands of deaths and millions of illnesses annually from microscopic, food-borne pathogens as being of epidemic proportions. Not surprisingly, according to public opinion surveys, over the past decade most Americans have consistently believed that the federal government should do more to safeguard the public health.

The Center's findings will be released at a news conference on Thursday, February 26, at 9:30 a.m., in the Zenger Room of the National Press Club.

"There's been much talk about food safety recently, but very little discussion of how exactly Congress has reacted to this perceived crisis," Charles Lewis, the executive director of the Center for Public Integrity, said. "We found surprises all over Washington on this life-and-death subject."

The Center for Public Integrity is a nonprofit, nonpartisan research organization that has issued 28 investigative reports since 1990. This is the first of four "Congress and the People" studies to be issued by the Center in 1998. More than a dozen researchers, writers, and editors conducted scores of interviews and reviewed tens of thousands of pages of campaign-finance data, U.S. Department of Agriculture records, House and Senate lobbying and financial disclosure reports, and congressional hearing transcripts. Among other things, the Center analyzed ten years of witness testimony, hearings, proposed legislation and legislative outcomes, and compared them with campaign contributions over the same period.

For more information, please call (202) 783-3900.

Summary

Thousands of Americans die each year—and millions more become sick—from the food they eat, and the number of disease-producing agents in the nation's food supply is growing. Cases of poisoning from the E. coli 0157:H7 bacterium alone have increased dramatically in the past decade, from virtually zero to approximately 20,000 a year. Government officials at the U.S. Department of Agriculture and the Centers for Disease Control and Prevention have described the current food-safety situation as an epidemic.

Not surprisingly, the American people are more concerned today about the safety of their food than at any other time in recent memory—and public-opinion polls reflect their clear sense that the federal government is not doing enough to protect their health. Yet, amid the heightened public discourse about the purity of our food, very little has been said specifically about the conduct, accountability, and responsiveness of Congress to this perceived crisis.

The Center for Public Integrity has never done a study about food contamination. As a nonprofit, nonpartisan organization that publishes investigative studies about public-service and ethics-related issues, the Center does not take formal positions on legislative matters, and we certainly have no "agenda" when it comes to food-safety public-policy alternatives. As with nearly all of our past 28 reports released since 1990, our interest is very simple: examining the decision-making process of government and whether or not it has been distorted in any way.

This major Center investigation involved scores of interviews and reviewing thousands of pages of data from the Federal Election Commission and the Center for Responsive Politics, U.S. Department of Agriculture records, House and Senate lobbying and financial disclosure reports, and congressional hearing transcripts, in addition to thousands of secondary sources. We found that Congress has consistently ignored the growing threat to the public health

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Top staff - T. hd - A. me

posed by the slaughter and meatpacking industry, the producers who raise the animals, and the distributors, wholesalers, and retailers who sell the products to the public.

Among the Center's major findings:

- The federal program designed to protect Americans from contaminated meat has been a dismal failure, internal Agriculture Department records show. Only 43 percent of all meat products recalled by their manufacturers from 1990 to 1997 was actually recovered, leaving the rest—more than 17 million pounds of contaminated meat—to be eaten by unsuspecting consumers. Meanwhile, in 1994, 1995, and 1997, Congress and the meatpacking industry opposed granting the Secretary of Agriculture the regulatory authority to issue mandatory recalls of contaminated meat. Currently, recalls are voluntary.

- Over the past decade, the food industry poured more than $41 million into the campaign treasuries of Capitol Hill lawmakers. More than a third of the industry's contributions went to members of the Senate and House agriculture committees. Among the leading recipients of money from food processors are the current Agriculture Secretary, Dan Glickman; the Majority and Minority Leaders of the Senate, Trent Lott and Tom Daschle; the Speaker of the House and the House Minority Leader, Newt Gingrich and Richard Gephardt; and six past and present chairmen or ranking minority members of the Senate and House agriculture committees.

- During the escalating public-health crisis of the past decade, the food industry has managed to kill *every* bill that has promised meaningful reform. The few congressional hearings on food-safety regulations in the 1990s have been stacked with industry witnesses, and as a policy option, tougher government regulation simply never made it out of the Senate and House agriculture committees.

- The meat industry has created one of Washington's most effective influence machines, partly by recruiting federal lawmakers and congressional aides for its lobbying juggernaut. Of the 124 lobbyists whom the Center identified as working for the meat industry in 1997, at least 28 previously worked on Capitol Hill.

SUMMARY

- In early 1997, the Clinton Administration proposed having food processors foot some of the bill for government inspections of their meat, poultry, and egg products. The plan was immediately denounced by many Members of Congress, including Republican Bob Smith of Oregon, the chairman of the House Agriculture Committee, who branded it "unwise and unnecessary." The Center found that Smith and members of his staff took more than forty trips underwritten by food-industry interests in 1996 and the first half of 1997.

The extent of influence held by the meat industry over Congress extends far beyond the life-or-death safety of the food Americans eat. The Center found that meatpacking continues to be the most dangerous profession in the United States. And just four meatpacking companies control 82 percent of the beef, lamb, and pork slaughter market, the highest level of concentration in the industry's history. From the enforcement of workplace safety regulations to antitrust statutes, the meat business today appears to be in little danger of being "tenderized" by suddenly aggressive congressional oversight or new reform legislation.

On the subject of promulgating public policies to help ensure food safety, the agenda in Congress today is substantially set by the industry. From filling lawmakers' campaign coffers to plying them with all-expenses-paid trips and dangling the possibility of lucrative post-employment opportunities, the meat interests have overwhelmed the supposedly objective decision-making process in Washington.

And despite the growing disquiet that the food on any plate might very possibly be unsafe, Congress continues to protect the food industry instead of the public health, steadfastly opposing more stringent government food inspection and safety standards.

CHAPTER 6

R&R: Recall and Recovery

On August 12, 1997, the Department of Agriculture announced that Hudson Foods Company, a meat-processing firm based in Rogers, Arkansas, had voluntarily recalled 20,000 pounds of frozen hamburger patties made at its Columbus, Nebraska, plant because the ground beef might have been contaminated with the E. coli 0157:H7 bacterium. The Agriculture Department had been alerted to the problem by the Colorado Department of Public Health and Environment, which had received reports of illness from several consumers who had eaten the company's hamburgers the previous month.

Two days later, the USDA announced that Hudson Foods was recalling another 20,000 pounds of frozen hamburger patties that had been shipped to fast-food and other restaurants. And the next day, the USDA announced that the size of the recall was much greater than originally estimated—more than 1.2 million pounds in all.

Fueling the escalating recalls was an industry practice known as "rework," in which one day's leftover hamburger is ground in with the next day's output. By the time the USDA was through with its recommendations, Hudson Foods had agreed to recall 25 million pounds of meat, the largest recall in U.S. history.

Or at least that's what everyone thought.

The USDA actually decided to recall meat from one month further back than was publicly announced, increasing the total recall to as much as 35 million pounds.[1] Of that amount, only 8 million to 10 million pounds was actually recovered.

Shockingly, the Hudson Foods case is par for the course: Under the USDA's system of protecting Americans from consuming contaminated food, less than half of recalled meat is ever recovered—which means that the majority of the tainted product is eaten by the public.

According to the Center for Public Integrity's analysis of USDA recalls, among all domestic closed cases from 1990 to 1997, manufacturers recalled more than 32.5 million pounds of meat and poultry but recovered only 14.6 million pounds, or 45 percent. Including outstanding or open cases, such as the massive Hudson Foods recall, they recalled more than 60 million pounds of domestic and foreign meat and poultry during the same period.

"Sometimes when we learn of a problem, we can bat close to 75 to 85—even sometimes 90—percent, but when you have product that is produced in the hundreds of thousands of pounds that has been shipped all over, some of that does get consumed," Jesse Majkowski, the director of the Food Safety and Inspection Service's Emergency Response Division—which is in charge of recalls and recovery—told the Center.

In August 1997, Agriculture Secretary Dan Glickman asked Congress to grant him the authority to order meatpacking companies to recall contaminated meat. Currently, recalls are voluntary and the USDA must negotiate the procedure with companies, sometimes resulting in delays during which the meat in question is consumed. Because the USDA has the bargaining chip of being able to withdraw its inspectors from plants, thereby shutting down operations, companies tend to comply with recalls.

"I do not have the authority to order a [mandatory] recall," Glickman told a reporter. "Most folks would be shocked to know that." He called this limit on his powers "one of the biggest loopholes out there."[2]

The loophole isn't likely to be closed anytime soon. Congress failed to act on two similar proposals in 1994 and 1995. And the industry is against increased regulatory authority.

"The statutory authority sought by the USDA is not necessary and would be contrary to sound public policy," Gary Jay Kushner, a partner at Hogan & Hartson, told the Senate Agriculture Committee in October 1997. Kushner was representing the American Meat Institute, the Grocery Manufacturers of America, the National Broiler Council, the National Food Processors Association, and the National Turkey Federation. "Frankly, to take away a company's limited right to discuss with the agency the scope and depth of its recall would likely lead to less co-ordination and more litigation—both to the consumer's detriment."

At the same hearing, the National Food Processors Association, the trade association of the $430 billion food-processing industry, characterized the USDA's proposal as an attempt "to fix something that is not broken."[3]

One of the reasons the USDA is seeking mandatory recall powers is to reduce delays between the issuing of a voluntary recall and a company's ability to negotiate or respond to it. Citing the Hudson Foods example, the Food Safety and Inspection Service's administrator, Thomas Billy, told the Senate committee, "It is not usual for three separate [voluntary] recall notices to be issued over a nine-day period, ultimately involving up to 25 million pounds of product. I think with the information we had available, we could have mandated a recall earlier."

Kushner, on the other hand, testified that voluntary-recall negotiations typically take only hours, not days. But Carol Tucker Foreman, the director of the Safe Food Coalition and a former Assistant Secretary of Agriculture for food and consumer services in the Carter Administration, disagreed in her testimony. "I can tell you that during my four years at USDA, there were at least two occasions where the department was stiffed for a matter of days," she said. "The companies did finally go and get [the contaminated food] back, but it was not an easy thing to get done, and during that period of time, the product stayed on the market, it got bought, it got taken home."[4]

Industry found support at the hearing from Senator Richard Lugar, a Republican from Indiana and the chairman of the committee, and Senator Robert Kerrey, a Democrat from Nebraska. Lugar suggested that irradiating red meat may be more effective than increased government authority in responding to food-related sickness. As for public squeamishness about irradiation, Lugar said blithely, "They had better get over it."[5] Yet while irradiation will kill deadly pathogens, it doesn't address the fact that the same meat was most likely contaminated with feces.

Glickman and the Clinton Administration are seeking $573 million in meat-inspection fees to be paid for by the meatpackers. "We view this as a food-safety issue," he said.[6]

The proposal faces hostile opposition from Senate Appropriations Agriculture Subcommittee Chairman Thad Cochran, a Republican from Mississippi; Senator Dale Bumpers of Arkansas, the ranking Democrat on the panel; and Republican Bob Smith of Oregon, who chairs the House Agriculture Committee. Bumpers blasted Glickman for his continued insistence on the fees. "This may be the sixth consecutive year that the department has asked for the user fees," Bumpers said. "And I think it will be the sixth consecutive year they will not be granted."[7]

"I did not expect an embrace of this proposal from up here," Glickman responded, referring to the Senate Appropriations Committee. "But the fact of the matter is that there are limited funds within our budget, and if we don't fund our food-safety program, we're going to have to get the money from somewhere else."

Even if Congress required the industry to shoulder some of the regulatory costs, or granted the USDA mandatory-recall authority to allow quicker recalls, the problem of actually recovering tainted products would remain.

One thing that makes recovering product harder is grocery stores' and restaurants' practice of regrinding one company's lot, or "chub," of meat with those from other companies, thus making trace-back harder. "Some will just regrind this coarse ground product into a finer grind, put it into their own packaging, and send it out on the shelves," Jesse Majkowski of FSIS told the Center. "Others will buy from same company in different varieties of coarse grounds and different fat levels and blend that. Some retail corporations or chains will have a practice of grinding their day-old steaks. Some, if they're cutting steaks or meat in the supermarkets, will use the trimmings in the ground beef. Every retail store is different." The USDA has no regulations to ensure that each player in the food chain keeps consistent records of where meat came from and what was blended with what.

According to Jesse Privett, a federal meat inspector in Texas, some grocery stores add fat to their hamburger to increase its weight. "The sad thing about it is they'll buy 80/20 lean/fat and add fat to it, but on their case they'll say 80/20," Privett told the Center. "Once it comes out of that chub, there is no way to track it, because these large grocery-store chains will have products from three or four major packinghouses in their warehouses."

Not only does the USDA generally recover less than half of recalled meat products, but it also does a poorer job of recovering the most hazardous meat. It's less successful recovering meat with bacteria contamination, which makes people sick or kills them, than it is recovering meat with minor health violations.

A breakdown by class of violations, recalls, and recoveries for all domestic and foreign closed cases of contaminated meat from 1990 to 1997 shows that the USDA recalled more than 13.7 million pounds of Class I violations—the most serious category—and recovered more than 6.1 million pounds, or 44 percent. But the agency did much better for Class III—covering such things as labeling violations and extraneous materials in food—recovering 49 percent of all meat recalled.

Over the same seven years, the agency recalled more than 2.4 million pounds of ground beef. Of this amount, more than 1.9 million pounds was recalled for bacteria contamination, of which 43 percent was recovered. That means that more than 850,000 pounds of bacteria-contaminated ground beef was consumed by the American public. (Hamburger is particularly susceptible to making people sick from a food-borne pathogen like E. coli 0157:H7, because the microbe can get mixed throughout the patty and is killed only by thorough cooking.) It took the agency, on average, 143 days—or almost five months—to close these cases.

Majkowski said that FSIS doesn't know if the unrecovered meat was consumed, but he admitted that it was possible; if it was eaten, it may have been properly cooked and the bacterium killed. "Part of the product is consumed—no doubt about that," he said. "But we've only had a couple of recalls with illnesses associated."

There's no way to know for certain if people get sick from a recall because many sufferers never see a doctor to report it. Even a visit to the doctor doesn't guarantee that the illness is recorded as having originated from a food-borne pathogen.

In June 1997, the USDA recalled 14,000 pounds of grilled chicken from a Tyson Foods plant in Pine Bluff, Arkansas, for bacteria contamination. At the same time, the FDA, the Environmental Protection Agency, and the USDA were investigating elevated levels of dioxin, a suspected carcinogen, in two birds at Tyson processing plants in Pine Bluff.[8] The investigators found three to four parts per trillion in edible chicken meat. The federal government said that the levels weren't high enough to pose a threat to consumers, but it nevertheless issued a directive in July for the poultry plants to prove that their processed chicken contained less than one part per trillion of dioxin. The directive also affected a Cargill plant and a ConAgra plant. The source of the dioxin was found in chicken feed.

The USDA has permitted hundreds of plants to operate while inspectors file tens of thousands of citations for unsanitary conditions and food contamination, according to a January 1998 report by Cox News Service.[9] USDA Process Deficiency Reports for 1996 reveal 138,593 critical packing-plant violations that would make consumers ill if the product involved were eaten, according to USDA records. Although the vast majority of the nation's 6,000 packing plants had just a few violations, 299 plants were cited every week.[10]

Arkansas led the nation in critical violations, amassing 15,269 in 1996. A violation is deemed critical if it is certain to cause contamination of food, reach consumers, and have a detrimental effect on them.

A Tyson Foods-operated plant in Waldron, Arkansas, accumulated 1,753 critical violations in 1996, the highest of any plant in the country, but never missed a day of production as a result of federal enforcement of violations, according to the Cox Newspapers report. After a Cox reporter visited the plant, Agriculture Department officials closed the operations for repeated violations. There were seven plants that had 1,000 critical violations in 1996, the last year for which there are complete records.

The federal government's sorry record in keeping contaminated meat products from being consumed by an unsuspecting public is at sharp odds with the all-is-well pronouncements of industry representatives. "The government and industry have an outstanding and historic record of co-operation on food-safety issues," the National Food Processors Association said in a statement to members of the Senate Agriculture Committee in October 1997. "The current system of co-operative recalls has proven successful in protecting consumers from adulturated or misbranded products."[11]

As the USDA's own data make clear, however, the current recall system is nothing short of a colossal failure.

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